

9

Regulating food safety in the European Union

*Stephan Marette**, *Jean-Christophe Bureau*, *Bénédicte Coestier* and *Estelle Gozlan*

Introduction

Recent and highly publicized incidents in the European Union have urged policy makers to consider changes in the food-safety regulations affecting domestic and imported food products. The Bovine Spongiform Encephalopathy (BSE) crisis, followed by a series of more anecdotal food-contamination cases, has triggered a major change by placing food safety on the top of the agenda of most EU governments.

The BSE crisis has had dramatic economic consequences, in addition to a significant number of deaths (most of them in the United Kingdom). After the finding of a possible link between BSE and a new strain of human disease, demand for beef fell and export bans hurt the entire sector throughout the European Union, costing billions of euros. The poor management of this crisis by British and other national and European authorities has also led to less visible, but very large impacts in terms of citizens' emotion. At a smaller scale, the 1999 contamination of feed in Belgium also had serious trade impacts. When it became public that some fat used in animal feed was inadvertently contaminated with cancer-inducing dioxin, some animal imports from several European countries were banned in a number of regions, including the United States. This resulted in a decline in meat production in Belgium, hitting particularly the swine and poultry sectors. Again, a major effect was the loss of consumer confidence, which at some point led to imaginary risks. The withdrawal of Belgian soda (Coca Cola) from the market in 1999, in spite of any scientific evidence, can be seen as an indirect consequence of the dioxin crisis. The frequent food scares that have followed the release of information about pathogens such as *Listeria* found in some prepared meat and some soft cheese during the years 2000 in France, can also be attributed to a general mistrust of consumers (statistics show that the number of food-borne diseases due to *Listeria* has actually been falling and that fatal casualties are very exceptional). Such food scares seem to be mainly due to the release of information, which did not occur in the past.

A particular situation in the EU is also the growing mistrust in science over the last decade. France is a typical example where the government has minimized the effect of major accidents, which have fueled suspicion and eroded public confidence. (The importance of asbestos-related cancers has been largely hidden under the pressure of the industry, and, when disclosed, past responsibility of mandated doctors in spreading wrong information has had a very negative effect on public opinion.) Involvement of scientists in hiding information from the public in the nuclear sector

* UMR Economie Publique INRA, 16 rue Claude Bernard, 75005 Paris, France

has had a similar effect. (Scientists from government agencies claimed that the Chernobyl radioactive cloud has stopped exactly at the French border, something that nobody has actually believed.) So has the continuous denying of the involvement of public agencies in spreading HIV-contaminated blood, until journalists disclosed evidence. Poor management of information and assurances from government-appointed scientists made the mistrust of science a very sensitive issue in the food sector. New production methods driven by technology have added to consumer unease. Consumer concern about genetically modified organisms and growth activators cannot be understood without taking this background into account. Indeed, European consumers have a peculiar position regarding biotech food. While GMOs seem to have been tacitly accepted in the US, they have caused large protests in Europe. However, environmental protection organizations and US consumers play a dynamic role in the Starlink case (see Taylor and Tick (Taylor and Tick 2001)). In France, GMO experiments have led to numerous acts of destruction (and to penalties for the activists), up to a point where experimental research is practically impossible on the territory. While the reluctance of consumers to purchase processed food containing GM ingredients is perhaps overestimated, the obligation of labeling has led processors to avoid using GM material whenever they could.

The BSE, dioxin and other food crises have increased the demand for more regulation and stricter enforcement of existing rules across EU countries. While these incidents acted as catalysts, the background was already a demand for more priority given to food safety on the policy agenda of the EU. As incomes rise, consumers become more demanding and are more prepared to pay for a regulatory regime that provides higher standards and minimizes risks.

Regulations are also evolving because of the international environment. International agreements have urged the EU to implement new instruments and new regulatory procedures. The Uruguay Round, which resulted in a constraining legal framework, with the creation of the Dispute-settlement body of the World Trade Organization (WTO), shapes the regulatory framework in the food-safety area. Disputes falling under the Sanitary and Phytosanitary (SPS) agreement have led the EU to implement measures that were previously unfamiliar, including systematic risk analysis, in the sense defined under the *Codex Alimentarius* measures (see Box 1). It is noteworthy, for example, that the 1997 arbitration of the WTO dispute on hormone-treated beef had taken place while EU governments were relatively unprepared to justify their measures by such analysis, which subsequently became routine procedure.

More generally, the Uruguay Round agreements have changed dramatically the way countries regulate food safety. Since 1995 (enforcement of the Marrakech Agreement), all WTO members have had to comply with the TBT Agreement, and a country may not reject panel conclusions simply because they are unfavorable. Many examples may be given of countries that have changed their restrictive practices and the very large number of notifications and discussions on potential flashpoints have made it possible to solve problems without embarking on the dispute-settlement procedure under the WTO.

The economic consequences of adopting certain standards, in particular in the *Codex Alimentarius*, have become very important, since these standards can now provide a basis for justifying or challenging an import ban. A 1997 WTO panel concluded to the non-conformity of the EU ban on hormone-treated beef, because most of the hormones incriminated had been tested within the *Codex*, which had set maximum residue limits.

Box 1: The international framework for food-safety regulations

Various publications from US and EU government agencies show that domestic regulations impede imports in almost all countries. Regulatory barriers in the European Union are often pointed out by US agencies (Bureau, Gozlan and Marette 1999). The EU ban on hormone-treated meat is one of the most quoted examples. In the EU Commission's market-access database, the pages relative to Japan are particularly impressive. Even Australia, a country known for low tariffs, has technical standards, which often preclude imports. The US conditions of sanitary inspection, with long and unpredictable delays, open lists for insects, which make import authorizations unpredictable, and complex quarantine rules, are also accused of making it unnecessarily difficult to export food products to the United States.

As a result of multilateral negotiations, rules have been introduced which aimed at minimizing the negative effects of sanitary, phytosanitary and technical regulations on international trade. Before 1995, GATT panel decisions have established the general principle that international rules do not permit WTO members to restrict the imports of products on the basis of how they are produced. The Uruguay Round provides a framework for solving disputes, through the WTO's Dispute Settlement Body. It tackles the problem of non-tariff trade barriers through the Sanitary and Phytosanitary (SPS) agreement and a strengthened Technical Barriers to Trade (TBT) agreement. And it gives greater importance to international bodies, especially Codex Alimentarius, an international code of standards for human-health protection under the auspice of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The SPS Agreement covers health risks (food safety) arising from additives, contaminants, toxins and pathogens contained in food products. Members' measures that are based on international standards are deemed to be in accordance with the SPS Agreement. (When a regulation complies with an international standard, there is no need to notify the WTO or to justify it against a challenge from another State.) Members may introduce or maintain SPS measures that result in a higher level of protection than that achieved by the relevant international standards, if there is scientific justification or if it is a consequence of a level of SPS protection deemed appropriate by the Member based on an appropriate assessment of risks. The agreement asserts the right of signatory countries to take the measures they deem necessary to protect human, animal or plant life or health, provided that such measures are based on scientific principles, are not maintained without sufficient scientific evidence, and are not applied in an arbitrary or unjustifiable way. The agreement states that sanitary measures may not be used for protectionist purposes. The SPS agreement encourages the harmonization of SPS measures based on internationally accepted standards, guidelines or recommendations. It also encourages the signatories to conclude bilateral and multilateral agreements on the recognition of equivalent sanitary and phytosanitary measures of other WTO members.

The scope of the 1979 Technical Barriers to Trade (TBT) agreement was also extended during the Uruguay Round. Compliance with relevant international standards is encouraged. The TBT agreement is wide-ranging and covers all technical regulations and standards except those falling under the SPS agreement, including those relating to packaging and labeling.

The Uruguay Round also resulted in the introduction of a notification procedure, which acts as an early-warning system when national TBT or SPS regulations would be liable to restrict trade. If the disagreement persists, the WTO may, at the request of the parties involved, set up a panel to examine the problem. Final arbitration can lead to compensation measures authorized by the WTO, as the ones taken by the United States against the European Union, which refused to amend its legislation after being recognized as violating the SPS agreement with its import ban on hormone-treated beef.

The outcome of the panel, even though it was partially changed by the Appellate body in 1998, has changed completely the status of the international standards in the EU regulatory process. Because these standards are now at the core of economic disputes, "scientific" discussions have been difficult within the *Codex*. Up to now, the adoption of controversial standards with large economic consequences has been delayed (case

of maximum limits on residues of rBGH or somatotropin, case of GMOs), or has been adopted with an ambiguous wording (standards on pasteurization of dairy products). However, in very complex and controversial cases such as GMOs, for example, either the adoption of precise standards, or the clarification of the status of GMOs by a WTO panel or appellate body in the international framework might be necessary in the future. They are likely to act as major constraints for the EU domestic regulation.

Changing the EU regulation on food safety

Among the many emerging public concerns, agro-food is one of the most visible sectors, and pressures for government intervention are high. The combination of public concern, the media coverage of the various crises, and the international framework, has led to considerable institutional changes in the EU. In Germany and the United Kingdom, the ministry of agriculture has now become a more general ministry, whose name indicates that farmers come second to consumer protection. France and the UK have established a new food agency with a broad mandate for health, safety and inspection responsibilities. The European Commission issued a White Paper after a wide debate on food policy and food law in January 2000 in order to restore consumer confidence (*White paper on food safety* 2000). It underlines the need for the establishment of the European Food Authority, whose creation was subsequently decided but whose localization still needs to be defined. These EU changes have also put food safety on the top of the agenda for accessing countries. Candidate countries have drawn “food-safety strategies” that outline the transposition and implementation of existing EU legislation. They are also supposed to draw on the White Paper in order to prepare some initiatives in this area (the implementation of the EU legislation in some candidate countries has already received approval from the Commission).

The White Paper proposes a wide range of measures to improve the corpus of legislation covering all aspects of food products as well as a new legal framework that covers the whole of the food chain. The objective is to establish a high level of consumer health protection and to attribute primary responsibility for safe food to the industry, producers and suppliers.

In particular, the White Paper stresses two areas of public regulation. The first one is the food-safety control, with control procedures at both national and European level. The paper acknowledges the need to create a coherent and transparent set of food-safety rules, and to recast the different control requirements, making all parts of the food production chain subject to official controls. The proposal is to improve, and to make more coherent, the system of national inspection services and controls. Controls at the borders of the EU would also be extended. The ability to trace products through the whole food chain is a key issue.

The second area of intervention is consumer information. The incentive is set on risk communication, and on providing consumers with essential and accurate information so that they can make informed choices. The European Food Agency will play a major role in the operations of risk assessment and management, but also in communication. The White Paper mentions binding labeling rules, through the codification of a labeling directive, including on novel food and on supplements, and involving more general rules on advertising messages. For instance, a Labeling Directive is proposed that would remove the current possibility not to indicate the components of compound ingredients that form less than 25% of the final product. The labeling provisions of the Directives on GMOs also show that a large role is left

for “informational” instruments (see Box 2). One of the objectives is to ensure proper and consistent compliance and enforcement and to “avoid unnecessary administrative procedures”.

Box 2: Regulation of GMOs in Europe

The body of regulation relative to GMOs relies on EU directives that have been adopted over the last ten years. The EU directive 90/220/CEE relative to the dissemination of GMOs is oriented towards the regulation of the protection of the environment. The main purpose of this directive is to regulate and harmonize the administrative procedures and the evaluations of GMOs for dissemination. This regulation has recently been amended by Directive 2001/18/CE in the spirit of the precautionary principle. The revised directive specifies the conditions that have to be fulfilled – assessment of the risks to the environment, a plan for monitoring in order to identify effects of GMOs on human health or the environment, among others – for the release of GMOs to proceed. The same conditions apply for GMOs or products containing GMOs that are placed on the market with additional proposals for labeling and packaging.

With respect to the issue of liability, the revised directive does not include any liability regime that would oblige marketers of GM food to give financial compensation for sanitary or environmental damage. However, article 32 states that the Commission should make a legislative proposal for implementing the Cartagena Protocol on biosafety; and article 27 of the Protocol states that the parties must adopt rules and procedures appropriate to responsibility and compensation for possible damage resulting from cross-border transport of live modified organisms.

The food-safety aspects of GMOs are regulated by the Novel Foods regulation CE 258/97. This regulation states that the safety of the products must be assessed when the new product contains a GMO or, resulting from genetic engineering, is substantially different from a traditional ingredient. In such cases labeling is required. The procedures to evaluate innocuousness of novel foods are described. Notice that the most worldwide used GMOs, Monsanto Roundup Ready soybean and Novartis Bt corn, were marketed before the regulation. A regulation that states that food containing these ingredients must be labeled was adopted in 1998 (1139/98). The regulation 49/2000 sets the threshold for mandatory labeling at 1% GMO, in order to account for accidental contamination. And the regulation 50/2000 provides for specific additional labeling requirements for food and food ingredients containing additives and/or flavorings that have been genetically modified or have been produced from genetically modified organisms.

The EU regulation raises concern regarding compatibility with international rules. The US-Canadian approach for evaluating GMOs (based on risk assessment) differs from the EU conception, which is more based on a precautionary approach to risk assessment and management. Up to now, the diverging conceptions have not led to an official dispute brought to the WTO. (Note that there has been a formal WTO notification of a dispute of Egypt challenging imports of tuna in GM soybean oil from Thailand (WT/DS205/1, WTO).) The odds that such a dispute may occur in the future are high. (Sheldon (Sheldon 2002) provides an analysis of the reasons for such a dispute along with a discussion of whether such a dispute can be resolved through existing WTO procedures.) The IATRC (*Agriculture in the WTO: the role of product attributes in the agricultural negotiations* 2001) has examined the issue; the outcome is uncertain. Given the various GATT agreements, the EU mandatory labeling could be challenged under either the SPS or the TBT agreement. The Article III of the GATT states that countries cannot discriminate between like goods on the basis of origin, raising the issue of the equivalence of GM and non-GM goods. The SPS-agreement approach of precaution (Article 5.7) is more restricted than the one underlying the EU regulation. The GATT provisions for ethical concerns (article XX) are unlikely to legitimate a ban. The EU could argue that there is a difference between the concept of equivalence and the concept of substantial equivalence mentioned in the agreements, and that GM crops are not equivalent to their GM counterparts and should therefore be labeled.

Liability or, more generally, self-enforcing procedures, have received less attention from the EU authorities than mandatory regulations and information-based procedures for ensuring food safety. The clarification of responsibilities of producers in the animal-feed sector can perhaps fall in the “liability” category, if we consider the various economic instruments. However, it also involves many mandatory regulation aspects (e.g. the revision of the legislation on animal-feed processing). More recently, in the discussions in the EU parliament on the regulation of GMOs, the proposals of the Commission for more liability of producers have been largely turned down by members of the European Parliament, a decision that environmentalists and consumer organizations have found difficult to accept.

The food crises that are mentioned in the White Paper in order to justify the need for a new approach of food safety, have not only generated a demand from citizens for more precaution, but also for more responsibility. In particular, the BSE crisis, as well as the foot-and-mouth disease (FMD) outbreak in 2000 has raised many questions about who should bear the costs of past mistakes. Up to now, it is mainly governments that have covered the costs, at least those costs that have been covered, given that many stakeholders have borne uninsured costs (including offal retailers, for example in the case of BSE, or the British rural tourism industry in the case of FMD). According to PricewaterhouseCoopers, the losses expected in the tourism industry from FMD crisis range from £1 billion (twice the loss of the agricultural sector) to £3.4 billion (The Economist, March 31st 2001)). Because of these food crises, beyond the claims of consumers for more safety, taxpayers are also demanding that producers, and possibly regulators, are more liable for possible contamination or mismanagement. This adds to the importance of more investigation on liability rules as a food-safety instrument.

Transatlantic difference about the role of liability

The role given to liability in the White Paper raises the issue of one of the most striking differences between the EU and US approaches. Punitive damages in product-liability action are very different in the United States and in European countries. In the United States, *ex post* liability clearly plays an important role in deterring firms from marketing unsafe products. Because of the potential outcome of tort law, firms often set up standards that exceed those required for passing the government approval process. Antle (Antle 1995) shows that this reduces the need for a “command and control” type of government intervention. In some EU countries, economic sanctions are very limited in the case of food-safety problems: when an unsafe product is marketed, resulting in the death of consumers, this rather results in penal sanctions for the manager than in large economic sanctions for the firm. Fundamental differences in the legal systems for protecting consumers from health hazards provide some justification for diverging conceptions on the role of government in setting standards. More generally, differences in the legal environment, such as *ex ante* regulation versus *ex post* litigation as a basis for legislation, contribute to explaining differences in governmental standards between countries.

If liability procedures are not seen as a central instrument in the White Paper, this does not mean that they are absent from the EU legislation on food safety. The Directive concerning liability for defective products (85/374/EEC, amended by Directive 99/34/EC) has required all member states to issue conforming “strict liability” laws on producers of defective products that cause personal injury or property damage (see Box 3).

Box 3: Liability for food products in practice : the case of France

The EU directive on the responsibility for defective products (85-374), has been translated into French law (98-389). This law introduces a large responsibility for producers, importers and sellers.

Traditionally, the French law, based on the Napoleonic code, emphasizes penal law. The French Penal Code specifies penal sanctions for endangering deliberately other people's life and health. In the Civil Code, though, the concept of civil responsibility applies for products one would legitimately expect to be safe. Absolute safety is not required but is an objective. The plaintiff must prove the damage, default and the causality between the default and damage. The producer can be responsible for the defect even though the product was made in respect of legal standards and good practices, unless the producer shows that he had not put the product in circulation, or that the defect did not exist when the product was put on the market.

The producer is not responsible if the state of knowledge or techniques do not make it possible to detect a default. However, there is an obligation for the producer to anticipate damages if there is suspicion, and to gather scientific information. That is, the "development risk" is not a complete exoneration of responsibility. However, lawyers acknowledge that the practical consequences of this 1998 law create many problems, since it opens the door for endless responsibility. The fact that appeal courts sometimes go back to the EU Directive in the interpretation of the law has also increased the scope for potential responsibility of producers even in the presence of development risk. The industry sees these changes in the legal system as a drift towards "compassionate law" that aims mainly at compensating a victim, even though the responsibility of the producer is questionable, and an obstacle to innovation.

A recent application of the law which has generated jurisprudence is that a butcher (retailer) was found responsible for selling meat infested with trichinellosis (horsemeat, CA Toulouse 112632, December 2000). It is noteworthy that the scandal of tainted blood in the 1990s, as well as the BSE crisis, has raised the issue of the responsibility of the government for not taking timely measures that would have prevented distribution of contaminated material.

One major question is the possible use of the French law 98-389 as an instrument for ensuring liability of producers and sellers of GMOs in the case of possible negative effects on consumers' health or the environment. While lawyers are still divided on that, it seems that GMO crops and genetically modified animals qualify as a "product" covered by the law, given the French interpretation of the EU directive, and the inclusion in the French law of agricultural goods. While this is still subject to controversy, jurisprudence suggests that a possible "defective" character of a GMO could also be taken into account, even though it has been approved by the various commissions involved in the EU and French process of approval. This would particularly be the case if labeling had been improperly done (labeling is codified by a French law that has translated the 1139/98 regulation). However, there are difficulties that raise questions on the practical role of this law. Possible accidental contamination of non-GM food by GMOs can occur. There is still disagreement on the definition of equivalent and non-equivalent products. The status of the development risk, which is a case of liability exclusion in the Directive, is still unclear in practice. The multiplicity of interventions in the food chain makes it difficult to assess who is responsible and which clauses of limitation of responsibility can be invoked. Perhaps more important, a liability action might be difficult for a victim of GMOs because of the burden of proof that is borne by the plaintiff. Scientific evidence might make it difficult to determine the cause of a possible damage. The ten-year limitation of the directive might also appear short in the case of GMOs. In brief, the legal issue of producers' liability in the case of GMOs, even when national laws provide more precision than the EU directive, is still very controversial and unclear. (Readers will find more details on this complex issue in Cassin (Cassin 1999)).

The directive aspires to protect victims in addition to promote improved food safety. It covers any defective product manufactured in or imported into the EU. The concept of strict liability (without fault) is introduced, the burden of proof is set on the injured party. However, the producer will not be liable if it is proven that at the time the product was placed on the market the defect which caused the damage did not exist, or if the state of scientific knowledge was not such as to enable the defect to be discovered. Since the 1999 amendment, producers of non-processed agricultural products are also liable without fault for damage to the health of individuals caused by defective products.

The BSE and dioxin crises have pressed the Commission to consider reforming some aspects of the Directive 85/374/EEC. This is the reason why the Commission has recently adopted a Green Paper on producer liability that reflects a consultation of all sectors. The aims of the paper are to collect information on the application of the Directive and to gauge reactions to possible revisions. The latter include aspects such as the goods and damage covered, the burden of proof, the existence of financial limits, the ten-year deadline for responsibility, suppliers' liability, and the lack of any obligation on producers to obtain insurance that characterizes the Directive.

Food safety from the economic side

Governments can use several policy instruments to protect consumers and alleviate market inefficiencies. Economists often distinguish mandatory regulations (e.g. minimum safety standards (MSS), including input standards, process standards or product-performance standards), information regulation (e.g. labeling) and liability enforcement. These different instruments are seen as means to circumvent some market inefficiencies such as informational inefficiencies (e.g. imperfect consumer information on the safety of products, or non-revelation of producer information) and insufficient safety efforts by producers.

Economic theory suggests that a system of market, regulatory and legal components can provide incentives to firms to produce safe food (Antle 1995). Economists often favor market-forces-based instruments. They rely on incentives for firms not to lose business reputation, market shares or sales revenues if consumers become concerned about safety problems with a firm's product.

When human health is at stake, public intervention often favors command and control instruments such as MSS. However, such instruments are sometimes costly and do not always pass cost-benefit analysis (Arrow et al. 1996). In some cases, instruments relying on consumers' information are preferable. When risk is deemed to be small and/or non-lethal, giving consumers the choice between different levels of risk at different prices may be economically efficient (Beales, Craswell and Salop 1981).

The economic theory develops some recommendations about liability, one of America's favorite instruments, that European regulators seem to be less fond of. Is there scope for changes in the EU food-safety regulation towards more responsibility-based instruments? In Europe, the Directive 85/374 is extended to defective agricultural products. However, only five countries among the fifteen Member States transposed the liability for defective agricultural products in their domestic law (see Annex 1 page 34 in the Green Paper (*Green paper on liability for defective products* 1999)). Very few Eastern-European countries looking towards membership in the EU transposed the legislation on this point.

Legal liability for damages generally has two goals: providing compensation to victims and limiting risks by creating incentives for lowering the probability and/or the severity of accidents. Two types of liability rules are usually distinguished by economists: the strict liability for compensating victims whatever the efforts made for limiting risks, and the negligence rule for punishing injurers only if the regulation was not respected (Shavell 1980). Liability appears to be a flexible tool, since each firm has some freedom for managing the risk. Under negligence rule, the regulator (and indirectly taxpayers) may be overexposed to liability if the regulation was deemed *ex post* insufficient or was not implemented. This is the issue that is raised by the many criticisms underlining the absence of regulatory reactions for the BSE outbreaks in Europe. (As it is impossible to identify the origin of the BSE contamination, the regulator in France appears to be the only “person” responsible for the victims’ families (see Libération, “Inerties et entraves au Ministère de l’Agriculture”, 26 Mars 2002). Pressure from lobbies for limiting stringent regulation in the nineties could suggest extension of liability to the animal feeding industry or to farmers’ unions. For instance, the head of the French Agency against fraudulent products (DGCCRF) was regretting some resistances by the French Ministry of Agriculture for implementing policies: “*Nous nous sommes heurtés dans tous les cas à une profonde réticence du ministère de l’Agriculture. Ce dernier semble soucieux de privilégier des intérêts particuliers sans prendre suffisamment en compte la protection de la santé du consommateur*”, Comment for the Ministry of Finance, by Christian Babusiaux, DGCCRF, 24 Mai 1995.)

The threat of sanctions for regulator failures by independent Courts could force the regulator to put the regulation into effect. For instance, in 2001, the regulator’s liability regarding water pollution was established by a Court due to its absence of real control regarding the pig facilities in French Brittany (Tribunal administratif de Rennes, 2 Mai 2001, n°97182).

Two conditions are necessary for reaching an efficient level of food safety via liability: (1) sufficient information for consumers for proving harm *ex post*, (2) sufficient funds from the injurer’s side for a complete indemnification in case of a damage in order to avoid “judgment-proof” problems. Both “failures” are acute in the food system (Antle 2001).

Regarding imperfect information about harms, the origins of contamination with microbial contaminants or pesticide are often impossible to prove for isolated consumers. Indeed, the precise liability is difficult to establish in a vertical supply chain including numerous farmers, processors and retailers. Moreover, consumers eat many different types of products. Moreover, how to determine a product liability while the food has disappeared once it was eaten? Consumers may be careless regarding food freezing or cooking. Eventually, incubation is sometimes very long as for the Creutzfeldt-Jacob disease (BSE) or cancer linked to chemicals (dioxin). Consumers need to have credence in goods of which they cannot judge the safety at the time of purchasing. For all those goods, preserving brand reputation is not sufficient for entailing a firm’s effort. For producers of processed food or for retailers, the preservation of a brand reputation may influence the level of prevention. All these reasons suggest that liability is limited due to imperfect information. However, the mandatory traceability or certification could be a way to develop an efficient liability process, since it becomes possible to detect fraudulent sellers or tainted food. For instance, traceability is already used for food recall systems (such as those implemented by the French Institut de Veille Sanitaire) in case of contamination

incidents. As to liability, product recall may be costly to firms in terms of reputation (e.g. on firms' market valuation, see Salin and Hooker (Salin and Hooker 2001)).

A food recall is a voluntary action carried out by industry in cooperation with federal and state agencies. It may be initiated either by the firm or at the request of the regulating agencies. The purpose of a recall is to remove products from markets when there is evidence that the product is contaminated, adulterated or misbranded. To this regard, they constitute information on product harmfulness that could be used by plaintiffs.

The link between liability and traceability raises the issues of (i) the way to finance certification taking into account the liability (Crespi and Marette 2001), (ii) new contractual relationship between suppliers and clients including scientific tests and monitoring, (iii) new technologies and investments for traceability that could influence market concentration and/or vertical integration in the agro-food chain. Public labeling for GMOs may imply false messages and cheating on products, requiring sanctions (McCluskey, 2001). The labeling "GMO-free" seems very fragile according to the imperfect testing procedures.

With respect to imperfect compensation, legal liability faces the issue of the "judgment-proof" injurer, that is an injurer unable to pay some portion of the losses to victims. The fact that a potential liability of an injurer is bounded by its wealth and the limited liability, by reinforcing risk, has implications on the prevention activity (Shavell 1986). Many prevention efforts require better equipment. For instance, prevention efforts by industrial firms or farmers for improving safety or reducing pollution are very difficult to implement, even in developed countries, mainly because of the prohibitive costs. Firms invest in prevention if their expected profits are high enough. In the meat sector, Antle (Antle 2001) and MacDonald and Crutchfield (MacDonald and Crutchfield 1996) showed that small processing plants suffered from implementing safety regulations and/or HACCP plans due to a resulting high fixed cost. Prevention costs and the degree of competition among firms are also a key issue in determining producers' solvency. Box 4 shows that insolvency may be strategically chosen by firms according to the market structure (i.e., the number of firms).

Concentration in the industry influences the profit of firms, and indirectly the wealth of firms and their probability of being "judgment-proof". The agro-food sector is characterized by the coexistence of multinational companies wielding oligopolistic/oligopsonistic power and able to cover damages and farmers with a very limited ability for indemnifying third parties or consumers. The concentration ratio is high for many food industries in Europe and in the US (Cotterill 1999) allowing the use of liability. However, the limited farmers' size suggests that liability could be extended to their upstream suppliers (as the agrochemicals firms) or the downstream processors. On the other hand, liability as a regulatory instrument might play a significant role in the concentration of the industry. An interesting illustration, with transnational consequences, is the case of the company Aventis, which recently sold its share of Aventis CropScience to Bayer, partly due to pending liability payments because of the new StarLink maize, a genetically modified organism (GMO). Traces of the GMO were found in processed foods, the costs of which may force Aventis CropScience to compensate farmers and manufacturers up to US\$ 200 million in the USA (see Taylor and Tick (Taylor and Tick 2001) for details). Aventis faced too many financial difficulties after the resulting withdrawal of the StarLink maize. This litigation in the USA had a major effect on the world market structure for the agrochemicals with the recent merger between two European firms, Aventis and Bayer. Despite the regulation harmonization among countries, the foreign regulation

may have direct effects on a domestic market. Four recent mergers have led to a rapid increase in the three-firm ratio (CR3, namely the sum of the market share of the three largest firms) with a shift from 34% in 1998 to 60% in 2000 concerning the worldwide trade for agrochemicals. Among the main reasons for those recent mergers are: (i) new environmental standards and pesticide-residue regulation entailing high expenditures on R&D, (ii) increasing risk of liability suits due to food safety or the environment, (iii) consumer reluctance toward innovations such as GMOs, which deters some farmers from adopting these products. Harhoff, Régibeau and Rockett (Harhoff, Régibeau and Rockett 2001) underline the dilemma for this industry between a stringent regulatory approval process and the risk of increasing market concentration. This dilemma also exists for the liability tool due to the risk of insolvency that depends on the market concentration (see Box 4).

Box 4: Liability, product information, and solvability

Coestier, Gozlan and Marette (Coestier, Gozlan and Marette 2002a; Coestier, Gozlan and Marette 2002b) provide theoretical models designed for the analysis of limited liability. Under a judgment-proof scenario, victims are not fully compensated due to the limited wealth of a firm. The costly prevention activity may dramatically reduce the available funds for indemnification in case of a damage. Victims compensation can also be limited due to the small size of involved producers. The delegation of risky activities from big firms to small and medium firms with a pronounced limited liability weakens the effectiveness of any legal liability regime.

An analysis of the incentives of firms to invest in prevention under alternative public regulations is proposed, in the case of consumers unaware about the safety risk. An efficient regulation needs carefully consider the following aspects. First, the prevention activity affects the profit of firms: a higher effort reduces both the probability of an accident and the profits that are available to pay damages; thus, higher effort increases the probability of being judgment-proof. Second, the profits of firms are affected by the market structure: the more concentrated the market, the higher the profits and the higher the assets available for compensation; higher profits reduce the probability of being judgment-proof. A unified framework for studying the impact of legal liability on prevention is provided, making it possible to emphasize the strategic use of insolvency by firms.

It is shown that whatever the market structure, under alternative liability rules, the private optimal level of effort depends on the perspective of profits and more precisely on the maximum willingness to pay for consumers with respect to the magnitude of damages. For certain parameter values, incentives to invest in prevention are diluted: under strict liability where the injurer is liable regardless of his effort, firms either underinvest or overinvest in prevention. The overinvestment in prevention appears as a pernicious effect of liability under potential insolvency: it is the result of the strategic use of the limited wealth and limited liability by firms. It can be corrected with the negligence rule under which the injurer is liable only if the level of “due care” was not implemented (Coestier, Gozlan and Marette 2002a). When the magnitude of damages is large, the negligence rule as strict liability leads to underinvestment in prevention.

In a second paper, the strict liability is compared with a policy that provides information about the product risk to the consumers (Coestier, Gozlan and Marette 2002b). Providing information avoids the judgment-proof problem. Indeed, the risk is internalized in the demand by consumers. When the potential damage is too large, consumers prefer to avoid purchasing, while being “judgment-proof” would emerge under strict liability. However, it is shown that providing information can be dominated by alternative policies such as strict liability, as an over investment in safety results in a higher welfare than a market closure.

The empirical study by Buzby and Frenzen (Buzby and Frenzen 1999) underscores the very limited use of liability in the USA and UK for food

contamination. In particular, they mention the ambiguity about the nature of microbial contamination (“natural and to be expected”, or “adulterant that should be controlled”), which is a key issue in litigation, and previous cases at the federal level in the United States have not provided a “consistent interpretation of liability”. For example a 1974 case ruled *Salmonella* in chicken as a natural contaminant, while a 1994 decision made *E. coli* O157:H7 in beef an adulterant, due to the fact that pathogens would be eliminated by “proper cooking” in the first situation, but not in the case of beef, which is often “lightly cooked”. Second, legal costs, time and difficulties concerning the burden of proof discourage in practice most individual people to seek legal redress for food-borne illness. Legal incentives may work better in outbreak situations than in individual cases, since the “causality relation” is then easier to infer for health authorities. Third, the US legal system “provides lawyers with incentives to choose their cases selectively and to strive for high settlement awards”, resulting in frivolous suits and excessive or fraudulent consumer claims. The limited use of liability for food contamination is confirmed for France by Collart Dutilleul (Collart Dutilleul 1997; Collart Dutilleul 1998).

Along with reasons (1) and (2), the existence of the public indemnification (as for instance for the “mad-cow” disease outbreaks in the UK and France) and the existence of social security tend toward a diminished role for tort liability (Viscusi 1989). The evaluation of the damage for some contaminations (like *Salmonella* or *Listeria*) may vary a lot. (For instance, some ERS estimations of the economic loss linked to *Salmonella* in the US in 1995 range from \$0.9 billion to \$12.2 billion.) At the farm level, some prevention efforts are sometimes difficult to implement due to the absence of knowledge, as for pesticide application or soil pollution.

Finding the right policy instrument is a titanic task as is illustrated in Box 5. Even though the case described deals with a very stylized case, in particular with a very simple competition structure, the optimal instrument between mandatory standards, labels and liability depends on several factors. It shows, in particular, that reputation-based instruments can be efficient if consumers find out rapidly that a product was unsafe after consumption. If a hazard appears in the long run, there is generally the need for more command and control policy instruments (Shavell 1987).

Box 5: Information and optimal regulation

One of the major problems that economists face when analysing the efficiency of the various forms of regulation in the product-safety area, is the structure of information. Optimal instruments are likely to be different if consumers are informed on the safety of the products (perfect information), if they can find out that a product is tainted after some research or investment in time (search good), if they can find out immediately after consumption (experience good), or if they never find out, or with a very long delay, or if they can never be sure that a particular good caused the disease (credence good). What makes the issue more complicated is that the optimal regulation for a given information structure can also depend on the structure of competition of the industry. Competitive industry will face price pressures that interfere with the reputation signals that they can deliver to consumers, which also has price effects (a quality signal can take the form of a low introductory price, of a high and non-imitable price, or of investment in publicity, etc.).

In order to illustrate the optimal regulation to provide food safety under various information structures, Marette, Bureau and Gozlan (Marette, Bureau and Gozlan 2000) have assumed that a firm faced no other price constraint than the willingness to pay of its customers (that is, it acts as a monopoly and sets its price unilaterally). In their model, trade takes place over two periods. A common discount factor $\delta \geq 0$ is used for valuing the second-period gains relative to the first-period ones. The marginal cost of production c is constant, regardless of the safety of the product. A product is either harmful or harmless, and a higher

level of safety effort made by the seller increases the probability of it to be harmless. By selecting a level of effort $\lambda \in [0,1]$, the seller incurs a fixed cost equal to $f \lambda^2/2$ in the first period. This framework accounts for both a moral-hazard effect and an adverse selection effect when consumers are imperfectly informed. Indeed, the level of safety depends on the seller's effort, which refers to moral hazard. However, when $\lambda < 1$, the seller cannot totally control the final safety of the product, which refers to adverse selection. Consumers purchase either one or zero unit of the good. Acquiring harmful products results in a zero utility for consumers. Heterogeneous willingness to pay for safe goods is represented by a parameter $\theta \in [0,1]$ distributed over the population of consumers. In the first period, if prior to purchase a consumer detects that the good is harmful, he/she does not acquire any product, resulting in a zero utility. The consumer will acquire a good in the second period only if he/she acquired a harmless product in the first period.

Solving the optimal program of the producer leads to the conclusion that: (i) when the cost of the safety effort f is large the safety effort is systematically lower than the socially optimal level (under perfect information as well as with experience goods); (ii) despite experience by consumers, imperfect information is likely to lead to a lower safety effort than under perfect information; (iii) with experience goods, the seller chooses not to signal the safety of its product. Nevertheless, the prospect of sales in the second period is an incentive for providing a significant safety effort, while, with credence goods, market forces result in an absence of effort and a market failure.

Regarding the optimal policy instruments, they show that a minimum safety standard (MSS) can be a useful tool for correcting a sub-optimal level of safety under both perfect and imperfect information. With experience goods, an MSS leads to shifting from a separating to a pooling equilibrium. This results in a higher safety effort, but may increase the welfare losses due to the pricing strategy of the seller. With credence goods, an MSS is a necessary and efficient tool when the cost of the safety effort is low. However, for large values of f an MSS does not make it possible to avoid market closure.

A label is potentially a useful instrument for reducing market inefficiencies in the case of credence goods, provided that the regulator or a third party mandated by consumers, has the ability to verify the safety effort. This may require specific means for monitoring the production process.

Under *perfect information*, liability enforcement is irrelevant since consumers are aware of the characteristics of the products by assumption, and dangerous products are not purchased. Enforcement of liability policy in the case of *credence* goods runs into the lack of conclusive evidence that a particular disease results from a well-identified source. If the regulator verifies the production process, punitive damage for misrepresentation with a credence good has effects similar to those of an MSS.

In the case of *experience* goods, the regulator may implement a punitive damage so that it prevents the seller from selecting the pooling equilibrium with harmful products. The punitive damage must therefore be larger than the profit under pooling equilibrium without any effort. In such a case, liability enforcement may be a policy instrument that dominates the MSS in terms of welfare. Indeed, it makes it possible to benefit from the safety-revelation mechanism, while avoiding possible prohibitive compliance and enforcement cost of the MSS. The combination of liability enforcement and MSS may show some form of social optimality. The setting of an appropriate MSS could result in a socially optimal level of effort. Simultaneously, liability enforcement deters the sale of harmful products. This policy mix therefore leads to a market equilibrium, which is similar to the one under perfect information, even in the presence of experience goods.

Conclusion

Recent food crises, together with the development of new production techniques and the international pressures provided by the WTO Uruguay Round agreements dealing with product quality and safety, have urged the European Union to reform

safety regulations. The White Paper is a fundamental step in that direction. It has led to the implementation of a centralized authority, and is likely to lead to future directives and national regulations.

It is noteworthy that command and control as well as informational instruments are more central in the White Paper, and more generally in the EU food-safety regulation, than incentive-based instruments, such as product-liability laws. The recent arbitration of the EU parliament for minimizing the liability of GMO producers suggests that the liability instrument is not as favored by regulators as it might be in other countries. Economists, however, tend to consider that if a firm that circulated products making people ill has to pay financial compensation as well as punitive damage, courts and legal fees, it will have more incentives to invest in food safety than if its managers are only liable in front of a penal court. However, in order to be efficient, product-liability laws must specify the exact circumstances under which firms are held liable. The present EU legislation on liability, and the ongoing thought that has led to a Green Paper on liability suggest that there are still many gray areas as to whether or not food safety issues could fall under liability laws (*Green paper on liability for defective products* 1999). The uncertainty surrounding the liability of producers in the case of a possible problem with GMOs that have been approved by the EU regulator illustrates the ambiguities of the present legislative framework in the case of a development risk. The development of traceability in the food supply chain may reinforce the effective role of liability.

Potential liability is part of the expected costs of the firm that would not take enough precautions regarding product safety. A firm will invest in safety up to the point where the marginal cost of safety equals the marginal expected benefits of reducing the risk of financial compensation and possible punitive damage. Therefore, the legal system could provide optimal deterrence if the firm correctly anticipates the compensation. Despite the limitations to the efficiency of liability as a regulatory instrument, we believe that there is a need for more investigation on the scope for which liability can be an efficient instrument, and that this issue is perhaps overlooked in the case of food safety. Instruments like incentive-based mechanisms have limitations, but they are also very powerful instruments that could minimize the administrative and regulatory burden. If liability is not always the right solution, the costs of command and control instruments for the society as a whole should not be underestimated.

In the various EU initiatives, government regulation is not the only approach deserving consideration, with measures ranging from voluntary practices to codes of good conduct, private standards, labeling and economic incentives. Still, the issues are complex and the required policy response unclear. The appropriate response is especially difficult to ascertain in cases where there are strong consumer concerns and insufficient or uncertain scientific evidence of health risk, as for GMOs.

References

- Agriculture in the WTO: the role of product attributes in the agricultural negotiations*, 2001. International Agricultural Trade Research Consortium, University of Minnesota, St. Paul, MA. IATRC Commissioned Papers no. 17.
- Antle, J. M., 1995. *Choice and efficiency in food safety policy*. AEI Press, Washington, DC.

- Antle, J. M., 2001. Economic analysis of food safety. *In: Gardner, B. L. and Rausser, G. C. eds. Handbook of agricultural economics, volume 1.* Elsevier, Amsterdam. Handbooks in Economics no. 18.
- Arrow, K. J., Cropper, M. L., Eads, G. C., et al., 1996. Is there a role for benefit-cost analysis in environmental, health and safety regulation? *Science*, 272, 221-222.
- Beales, H., Craswell, R. and Salop, S., 1981. The efficient regulation of consumer information. *Journal of Law and Economics*, 24, 491-544.
- Bureau, J. C., Gozlan, E. and Marette, S., 1999. *Food safety and quality issues: trade considerations.* Organisation for Economic Co-operation and Development, Paris.
- Buzby, J. C. and Frenzen, P. D., 1999. Food safety and product liability. *Food Policy*, 24 (6), 637-651.
- Cassin, I., 1999. Les organismes génétiquement modifiés et le nouveau régime de la responsabilité du fait de produits défectueux. *Gazette du Palais*, 22-23 (1), 99.
- Coestier, B., Gozlan, E. and Marette, S., 2002a. Prevention limited liability and market structure. *In: Papers of the 5th INRA-IDEI conference on: industrial organization and the food processing industry, Toulouse, France, June, 14-15, 2002.* UMR Economie Publique, INRA, Paris.
- Coestier, B., Gozlan, E. and Marette, S., 2002b. Product safety: liability rule versus information regulation. *In: Papers of the 5th INRA-IDEI conference on: industrial organization and the food processing industry, Toulouse, France, June, 14-15, 2002.* UMR Economie Publique, INRA, Paris.
- Collart Dutilleul, F., 1997. Regards sur les actions en responsabilité civile à la lumière de l'affaire de la vache folle. *Revue de Droit Rural*, 252, 227-233.
- Collart Dutilleul, F., 1998. Les analyses en agroalimentaire et le droit de la responsabilité civile. *Revue de Droit Rural*, 266, 450-455.
- Cotterill, R. W., 1999. *Continuing concentration in food industries globally : strategic challenges to an unstable status quo.* Dept. of Agricultural and Resource Economics, University of Connecticut, Storrs. Research Report University of Connecticut, Food Marketing Policy Center no. 49.
- Crespi, J. M. and Marette, S., 2001. How should food safety certification be financed. *American Journal of Agricultural Economics*, 83 (4), 852-861.
- Green paper on liability for defective products*, 1999. Available: [http://europa.eu.int/comm/internal_market/en/update/consumer/greenen.pdf] (6 Mar 2003).
- Harhoff, D., Régibeau, P. and Rockett, K., 2001. Some simple economics of GM food. *Economic Journal*, 111, 265-291.
- MacDonald, J. M. and Crutchfield, S., 1996. Modeling the costs of food safety regulation. *American Journal of Agricultural Economics*, 78 (5), 1285-1290.
- Marette, S., Bureau, J. C. and Gozlan, E., 2000. Product safety provision and consumers' information. *Australian Economic Papers*, 39 (4), 426-441.
- Salin, V. and Hooker, N. H., 2001. Stock market reaction to food recalls. *Review of Agricultural Economics*, 23 (1), 33-46.
- Shavell, S., 1980. Strict liability versus negligence. *Journal of Legal Studies*, 9, 1-25.
- Shavell, S., 1986. The judgment proof problem. *International Review of Law and Economics*, 6, 45-58.
- Shavell, S., 1987. *Economic analysis of accident law.* Harvard University Press, London.

- Sheldon, I. M., 2002. Regulation of biotechnology: will we ever 'freely' trade GMOs? *European Review of Agricultural Economics*, 29 (1), 155-176.
- Taylor, R. and Tick, J., 2001. *The StarLink Case: issues for the future*. Resources for the Future, Washington, DC.
- Viscusi, W., 1989. Toward a diminished role for tort liability: social insurance, government regulation, and contemporary risks to health and safety. *Yale Journal on Regulation*, 6, 65-107.
- White paper on food safety, 2000. Available: [http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf] (6 Mar 2003).