

THE EUROPEAN FOOD IMPORT SAFETY REGIME UNDER A ‘STRESS TEST’: THE MELAMINE CONTAMINATION OF THE GLOBAL FOOD SUPPLY CHAIN

*Alberto Alemanno**

Abstract

Ensuring that European food imports are safe presents special challenges, as production takes place in third countries outside the direct control of the member states. Yet, contrary to conventional wisdom, besides a few exceptions regarding high-risk products (such as animals and animal products), the regulation of food import safety in the European Union (EU) is not the focus of direct legislative attention. As a result, the safety of food imports in Europe is pursued not through the application of special conditions governing the import of third-country products, which would impose systematic and Herculean checks at the external borders, but rather through the decentralised enforcement by member states’ market surveillance authorities of a harmonised set of product safety regulations: the European food safety acquis. This article provides a critical analysis of this regime by choosing as a case study the recent melamine dairy scandal. Although representing one of the most challenging food contaminations the world has ever faced, the melamine dairy scandal did not produce any tangible negative health effects on the European population. By examining in detail the main features and mechanisms of the EU food safety regime, with a particular focus on the rapid alert system (RASFF), this article assesses to what extent this outcome can be ascribed to the European regulatory framework or to other factors.

1 Introduction

The European Union (EU) is the largest food importer in the world. Yet, contrary to conventional wisdom, besides a few exceptions regarding high-risk products (such as animals and animal products), the regulation of food import safety in the European Union is not the focus of direct legislative attention. As a result, the vast majority of the €1.5 trillion worth of third-country goods imported into the EU¹ is not subject to systematic controls at border inspection posts.² Thus, once they have satisfied customs formalities, third-country imports circulate freely within the territory of the EU internal market regardless of their origin.³ Hence, most of the import safety problems in Europe are not detected at the point of entry on the EU external border (where it would be a Herculean task to systematically check all incoming shipments) but tend to arise once the products are already within the territory of the European internal market, where they are subject to member states’ controls. Under this model, consumers throughout the EU are therefore entitled to expect that their interests will be protected and taken into account not simply by their own state but by all member states, regardless of the origin (domestic or international) of the products placed on the European market.

To ensure this outcome, it was necessary to elaborate a regulatory safety framework that, while capable of being applied to all products in free circulation within the EU, remained homogeneous enough to be consistently enforceable throughout Europe. This was crucial, since non-uniform national policies in relation to imports could have

* Associate Professor of Law, HEC Paris, and Editor of the *European Journal of Risk Regulation*. The author wishes to thank two anonymous referees for their valuable inputs. Comments are welcome at: <alemanno@hec.fr>.

¹ A wide range of trade statistics can be accessed on the DG Trade’s website at: <<http://ec.europa.eu/trade/statistics>>.

² As illustrated below, only some high-risk products are subject to systematic controls at border inspections posts, such as live animals and animal products (see, e.g., Commission Decision 2007/275/EC).

³ This is a direct consequence of the EU being a customs union. See Willem Molle, *The Economics of European integration: Theory, Practice and Policy* (2001, 4th ed.) at 12.

important safety implications and could also lead to serious distortions of trade. Moreover, the design of a regulatory safety framework by any World Trade Organisation (WTO) member (which includes the EU) must conform to its multilateral trade obligations.⁴

However, there is a significant dose of historical fortuity within the evolution of EU policy towards product safety. Indeed, although not originally foreseen, the EU has resorted to countless regulatory instruments that have encompassed the control of all kinds of risk to public health and safety: not only product safety regulation in pharmaceutical law, food law, chemicals and medical devices, but also in wider areas such as safety at work and environmental protection.⁵ As illustrated below, the constitutional basis of the EU legislation that regulates product safety is founded on trade considerations; safety is merely a subsidiary consideration. Perhaps this is not entirely surprising from a US perspective to the extent that, as has been said regarding food safety, ‘regulators in both jurisdictions ultimately derive their legal authority to define and control food safety risks from their constitutional power over the free or interstate movement of goods and both share some aspects of that authority with their constituent states’.⁶

In the absence of a dedicated import safety regime in Europe, it is crucial, in order to understand how Europe addresses the growing concerns about import safety and security, to examine the European product safety framework as it applies to both domestic and imported products as well as the existing import control mechanisms. Such an examination will be the focus of the first part of this article, which then proceeds to identify the main features of the European regime and analyses its partial reform following the 2007 ‘summer of recalls’, when over 18 million toys were recalled globally because of magnetic parts that posed a choking hazard. The recent melamine dairy scandal will be presented as an interesting case study illustrating the European approach to import safety by exemplifying its reactive rather than proactive nature.

2 The Emergence of the European Product Safety Acquis

Although it might be surprising to any person outside the grip of European law, the foundation on which the EU enjoys competence to legislate in relation to product regulation is based almost exclusively not on a policy of consumer protection but on the facilitation of trade, in particular the free movement of goods, within the context of the creation of the internal European market. The EU’s gradual involvement with product safety issues is indeed nothing more than a rather accidental spill-over effect of the realisation of the common market.⁷ When implementing the prohibition laid down in Article 34 of the Treaty on the Functioning of the European Union (TFEU) on ‘quantitative restriction and measures having an equivalent effect’, the Commission, helped by the European Court of Justice, derived the right to review the contents of laws as yet not harmonised at EU level.⁸ In particular, because product safety concerns might have become a possible source of hindrance to intra-EU trade, the EU had to step in. This process shows why, and also how, the EU was forced to address an import safety issue emerging among its own members well before tackling ‘external’ import safety.

How did the EU tackle ‘internal’ import safety issues? As is well known, the EU enjoys both negative (Article 34 TFEU) and positive integration powers (Articles 114-115 TFEU) to attain the treaty-sanctioned imperative of free movement of goods. However, before the 1986 shift to qualified majority voting (QMV), EU harmonisation required, under Article 115, a unanimous vote in the European Council.⁹ Against this

⁴ Alberto Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (2007).

⁵ Alberto Alemanno, ‘The Shaping of Risk Regulation by EU Courts’, Jean Monnet Working Paper 18/2008 (New York University 2008).

⁶ Marsha Echols, ‘Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws’ (1998) 4 *Columbia Journal of European Law* 525 at 530.

⁷ Ellen Vos, *Institutional Frameworks of the EU Health and Safety Regulation. Committees, Agencies and Private Bodies* (1999) at 9.

⁸ Alemanno, *Trade in Food*, above n. 4, at 34.

⁹ Alberto Alemanno, ‘Food Safety and the Single European Market’ in Christopher Ansell and David Vogel (eds.), *What’s the Beef? The Contested Governance of European Food Safety* (2006) 237-258.

thorny institutional backdrop, which had led to a sort of regulatory impasse over EU harmonisation, the ECJ developed, in its legendary Cassis de Dijon judgment,¹⁰ the principle of mutual recognition. This original principle implies the substitution of 'home state control' for 'host state control' in the handling of obstacles stemming from interstate regulatory diversity, consisting inter alia in different safety standards. According to this principle, once a product has been lawfully marketed in one member state, it should be admitted into any other state without restriction.¹¹ However, the host country may challenge the presumed equivalent level of protection pursued by the home country's legislation by invoking the exceptions listed in Article 36 TFEU or the judicially identified mandatory requirements.¹² Home state control prevails in the absence of a sufficiently compelling basis for host state control. The principle of mutual recognition, while preserving local, regional and national traditions, allowed the EU to realise an internal market without having to adopt hundreds of 'vertical' directives.¹³ However, even among European member states, which are relatively similar in terms of regulatory approach, national regulations cannot always ensure equivalent levels of protection. This stems from the different approaches to regulation adopted in each member state, reflecting differences in culture, the specific functioning of their political institutions and also their different perceptions and attitudes towards the management of risk. As a consequence of the resulting differences in regulation, the goals of free movement could not have been achieved without some form of 'positive integration' that came about through agreement on common rules to overcome the obstacles that could not have been tackled solely by the mutual recognition principle.¹⁴

Thus, the Commission's response in the post-1986 period was to introduce legislation to harmonise the laws of the member states on health and safety, thereby removing these obstacles to trade. However, to avoid the excessive 'Euro-uniformity' of the traditional approach to harmonisation, which implied slow negotiations on technical specifications among member states, a 'new approach' to harmonisation was developed.¹⁵ Under this new approach, legislative harmonisation, 'a common rule for a common market', was restricted to laying down 'essential health and safety requirements', and the formulation of technical specifications (so-called European Norms) to meet these conditions was delegated to private standardisation bodies, such as the European Committee for Standardisation (CEN) and the European Committee for Technical Standardisation (CENELEC).¹⁶ Although these specifications are not binding as such (unlike the essential requirements), member states are obliged to presume that products manufactured in accordance with them comply with the 'essential requirements' laid down in the directives (and which are therefore legally binding). As a result, these

¹⁰ In Case 120/78, *Rewe-Zentrale AG v. Bundesmonopolverwaltung für Branntwein* [1979] ECR 649, involving the review of a German rule prescribing minimum alcohol content for fruit liqueurs, the European Court of Justice stated that where a product 'suitably and satisfactorily' fulfils the legitimate objective of a member state's own rules (public safety and protection of the consumer or the environment), the importing country cannot justify prohibiting its sale in its territory by claiming that the way it fulfils the objective is different from that imposed on domestic products.

¹¹ This formulation was developed for the first time in the Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in case 120/78 ('Cassis de Dijon').

¹² This concept was introduced by the ECJ to soften its expansive interpretation of Article 28 of the EC Treaty and is used by the same court as a flexible tool to balance the sometimes competing interests of market integration and market regulation.

¹³ This new approach to harmonisation was launched by the European Commission in its White Paper on the Completion of the Internal Market, COM (85) 603, 7, published in June 1985. It eventually became the cornerstone of the 1992 Programme. See Alfonso Mattered, *Le marché unique européen* (1992) at 80.

¹⁴ Paul Craig, 'The Evolution of the Single Market' in Catherine Barnard and Joanne Scott (eds.), *The Law of the Single European Market: Unpacking the Premises* (2002) at 12.

¹⁵ Under the new approach, the EU institutions, apart from legislating only on 'essential requirements', have also delegated the determination of more detailed standards to quasi-public European standards organisations and then coordinated quasi-public national bodies in charge of assessing the conformity of products produced in any one member state for sale throughout the EU market.

¹⁶ Concerns have been expressed that business interests predominated in the standardisation bodies. See Stephan Whetherill, 'The Evolution of the Single Market: Harmonisation or Liberalisation?' (1990) 53 *Common Market Law Review* 578.

products can be marked CE (conformité européenne) by their suppliers.¹⁷ This new approach, by allowing a manufacturer to show that its products complied with essential safety requirements, even if they did not comply with the EU standards, shifted towards minimum, rather than total, harmonisation. As stated, ‘the EC legislation would set a floor, and the Treaty a ceiling, with member states being free to pursue their own policies within these boundaries’.¹⁸

Although the free movement of goods within the internal market is still the primary policy consideration for product safety legislation at the EU level, various provisions of the treaty have been amended in the meantime to specify the need for a ‘high level of protection’ in matters of safety, health, public health, and consumer protection (Articles 114(3), 168(1), 168(4), 169, 191(2) TFEU). As a result, when called on to regulate risks regardless of their origin, the EU legislature is caught between two competing treaty-sanctioned goals and must strike a balance between attaining a high level of protection of human health and consumers’ interests and ensuring the effective functioning of the internal market.

2.1 The Product Safety Law Acquis

In parallel with the ‘new approach’ directives, which, combined with the mutual recognition principle, aimed at ensuring the internal free movement of goods within the EU, the European legislature also developed two separate frameworks for product safety law – one for non-food consumer products and another for food products – which together make up the product safety law acquis and apply to both domestic and imported products.¹⁹

To reinforce the overall level of consumer protection within the EU, a General Product Safety Directive (GPSD) laying down performance standards was first introduced.²⁰ This directive establishes a general obligation for manufacturers to place only safe products on the market and establishes conformity assessment criteria and procedures based on manufacturers’ self-declaration of compliance (known as the CE marking).²¹ Since this obligation covers only manufacturers of non-food consumer products, the subsequent General Food Regulation (GFR) introduced a similar requirement for food business operators as well.²² Both instruments complement the EU liability regime for defective products, as laid down by Directive 85/374/EEC,²³ which sets out the principle that ‘the producer shall be liable for damage caused by a defect in his product’ (strict liability regime).²⁴ Under this legislation, a producer includes not just the manufacturer but,

¹⁷ Stephan Farr, *Harmonization of Technical Standards in the EC* (1996) at 5.

¹⁸ Craig, above n. 14, at 24.

¹⁹ This distinction is increasingly questioned today and has recently been defined as a ‘disadvantageous dichotomy’. Both regimes indeed pursue common objectives: to protect consumer health and safety and to ensure the proper functioning of the internal market. See Anthony Brack, ‘A Disadvantageous Dichotomy in Product Safety Law: Some Reflections on Sense and Nonsense of the Distinction Food-Nonfood in European Product Safety Law’ (2009) 20 *European Business Law Review* 173-198.

²⁰ Originally, it was Directive 92/59/EEC, then replaced by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ 2002 L 11/4. This directive covers fully those consumer products that are not subject to sector-specific legislation (e.g. child-care products, furniture and lighters) and complements sector-specific legislation by applying to products covered by sectoral legislation (e.g. toys, chemicals, pharmaceuticals, cosmetics, machinery and electrical products) for those safety risks not addressed in that legislation.

²¹ See GPSD (2001): Art. 17. See also Dave Lohbeck, *CE Marking Handbook: A Critical Approach to Global Safety Certification* (1998) at xi.

²² Regulation (EC) No. 178/2002 of 28 January 2002, OJ 2002 L 31, sets forth the general principles and requirements of food law, establishes the European Food Safety Authority and articulates procedures in matters of food safety.

²³ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations, and administrative provisions of the member states concerning liability for defective products, OJ 1985 L 210/29, as amended by Directive 1999/34/EC, OJ 1999 L 141/20.

²⁴ Article 1 of this directive provides for absolute liability for damage caused by any defect (subject to a number of exceptions that are not relevant here).

under certain circumstances, every link in the supply chain.²⁵ While the GPSD and GFR promote safety by acting ex ante, the liability regime ensures compensation for damages, which may stem from both food and non-food products.²⁶ Although compensatory in nature, the liability directive is also expected to produce a preventive effect in the end.²⁷ Under the GPSD, the safety of non-food products is presumed if production took place according to standardised norms. The same cannot be said of the GFR, where it is explicitly stated that 'food shall be deemed to be unsafe if it is considered to be injurious to health and/or unfit for human consumption'.²⁸

Even when a product is in conformity with relevant standards, the authorities are not barred from taking appropriate measures, such as organising appropriate checks, introducing warnings, stopping sales, withdrawing products from the market and recalling them from consumers.²⁹ Under both regimes, member states are entrusted with ensuring compliance by producers and distributors in such a way that food or consumer products placed on the market are safe, regardless of their origin (imported or domestic). As a result, they are obliged to establish market surveillance authorities to ensure that the general safety requirements are complied with. These authorities may adopt interim protective measures and enjoy mandatory recall power.³⁰

2.2 Rapid Alert Systems

These national, post-market enforcement mechanisms, based on national market surveillance, have been strengthened since the 1980s by the creation of two rapid alert systems: the Rapid Alert System for Non-Food Consumer Products (RAPEX)³¹ and the Rapid Alert System for Food and Feed (RASFF).³² Both systems have been put in place to provide (national) control authorities with a tool to exchange information about measures taken in response to serious risks detected in non-food and food products.³³ This coordination adds value to surveillance and enforcement action at the national level to increase the safety of European citizens.

²⁵ Michel Cannarsa, *La responsabilité du fait des produits défectueux: Étude comparative* (2005).

²⁶ An amendment to the directive has clarified that this product liability legislation includes all food as well as non-food products. This change in the scope of this directive reflects the outbreaks of diseases and food safety concerns that occurred in the 1990s.

²⁷ See, e.g., Guido Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (1970).

²⁸ GFR (2004): Art. 14(2).

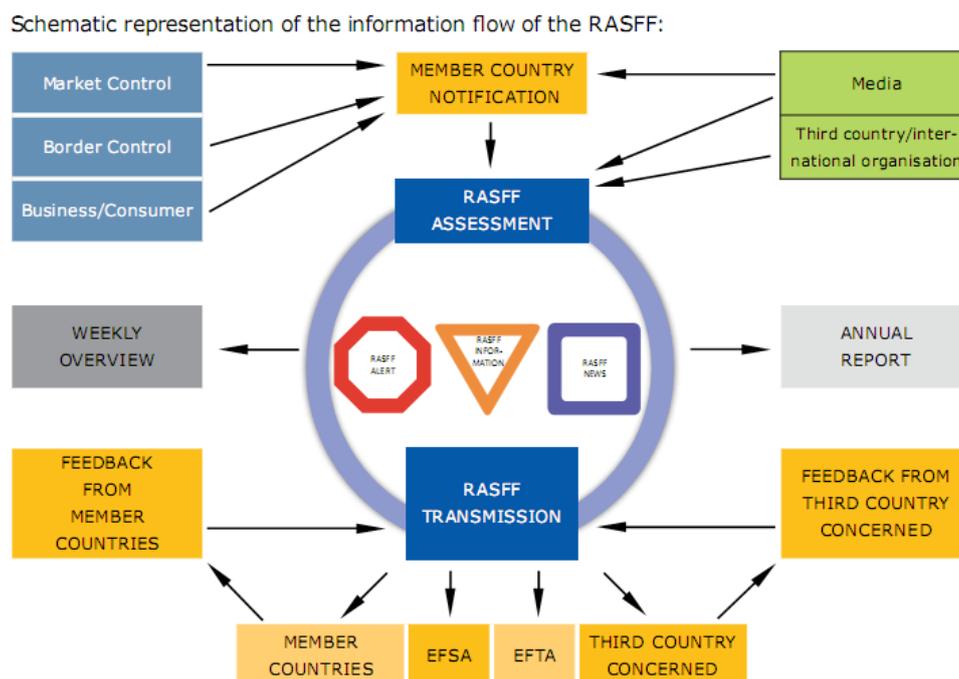
²⁹ GPSD (2001): Art. 5; GFR (2002): Art. 19.

³⁰ GPSD (2001): Art. 8; GFR (2002): Art. 54.

³¹ GPSD (2001): Art. 12.

³² GFR 2004: Arts. 35 Art. 50.

³³ For an original and insightful overview on EU rapid alert systems, see Sanna Zanden Kjellen, 'Rapid Alerts for Crises at the EU level' in Stefan Olsson (ed.), *Crisis Management in the European Union* (2009) at 61.

Figure 1:

Under both rapid alert systems, the European Commission must be notified of all measures taken to prevent or restrict the marketing of a product adopted by the national authorities or the producer/distributor in relation to a dangerous product. If the examination of the notification conducted by the Commission leads to validation, the relevant information is circulated to the RAPEX/RASFF members in all member states. Notifications are published on a weekly basis on the websites of the Commission.

If we break down the total number of RASFF notifications received in 2007 according to the type of control, it appears that most of them concern official controls on the internal market, whereas the second largest group concerns controls at border posts when the consignment was not accepted for import. Almost 60 per cent of notifications to the RAPEX system in 2007 and 2008 concerned third-country products, and more than 50 per cent of these notifications concerned products imported from China. Under RAPEX, China was indicated as the country of origin of the notified product in more than half of all cases in 2007 and 2008 (52 per cent for China including Hong Kong).³⁴

Both the RAPEX and RASFF systems may be open to applicant countries, third countries or international organisations on the basis of reciprocity. In any event, to avoid the recurrence of the problem detected, RAPEX and RASFF inform third countries of origin in a systematic way. As the recent melamine dairy scandal has shown (see below), the rapid alert systems represent the internal market's safety net vis-à-vis unsafe products.

2.3 EU Action in the Case of 'Serious Risk'

Under both the GPSD and GFR, the Commission may adopt temporary (emergency) EU measures in the case of a serious risk to human health, animal health, the environment or consumer safety. They trigger the same market surveillance and restrictive measures in all member states with respect to the specified product.³⁵ Generally, EU action may occur where the risk cannot be contained satisfactorily by means of measures taken by the member states individually. These measures are normally introduced in full consultation

³⁴ *RAPEX Annual Report (2007)* at 24; *RAPEX Annual Report (2008)* at 17.

³⁵ GPSD (2001): Art. 13; GFR (2002): Art. 53.

with the member states and on the basis of comitology decisions.³⁶ They may result, depending on the origin of the product, in the suspension of the placing on the market or of the import of the food or consumer product in question.³⁷ In the latter case, which involves commercial policy that falls within the sphere of exclusive EU competence, only the Commission may act to limit imports of third-country products into the EU. To date, five such measures have been adopted at the EU level. Three concerned consumer products (in particular a ban on phthalates in children's toys,³⁸ a ban on novelty cigarette lighters³⁹ and a warning on toys containing or made from magnets⁴⁰), whereas the other two related to food items, namely aflatoxins⁴¹ and melamine in dairy products.⁴²

2.4 Controls on Imports from Third Countries

Although lacking a dedicated import safety regime providing for systematic controls at the border, the EU has adopted a set of control mechanisms on imports of certain specific products. As a result, these controls are not uniform across sectors but are instead a function of the level of risk: the higher the risk the greater the control. The most significant dedicated import control system covers products of animal origin (POAO) and live animals. POAO and live animals are subject to especially stringent import controls, which are carried out at the EU borders, before their physical entry into the EU.⁴³ These checks are carried out at 297 approved border inspection posts (BIPs), located at road, rail, airport or port entry points into the EU.⁴⁴ These controls are a key element in the system for the protection of human health and the prevention of introduction of serious animal diseases. A considerable body of Community legislation has been developed to regulate and support these controls.⁴⁵ Yet, ex post controls are not the only form of regulatory action to address import safety issues. Third countries are required to receive formal approval before they are eligible to export high-risk products, and the Food Veterinary Office (FVO) routinely carries out a mission to verify on-the-spot compliance with the relevant EU requirements.⁴⁶ Similar pre-export listing requirements may be established if necessary by the Commission, assisted by the Standing Committee on the Food Chain and Animal Health, for any specific food, including food products of non-animal origin.

³⁶ Comitology in the European Union refers to the committee system that oversees the delegated acts implemented by the European Commission.

³⁷ GPSD (2001): Arts. 8(1)(b)-(f) and 13; GFR (2002): Art. 53(1)(a)(b).

³⁸ Commission Decision 1999/815/EC of 7 December 1999 adopting measures prohibiting the distribution of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC-containing phthalates.

³⁹ Commission Decision 2006/502/EC of 11 May 2006 requiring member states to take measures to ensure that only lighters that are child-resistant are allowed to be sold and to prohibit the sale of novelty lighters.

⁴⁰ Commission Decision 2008/329/EC of 21 April 2008 requiring member states to ensure that magnetic toys placed or made available on the market display a warning about the health and safety risks they pose.

⁴¹ Commission Decision 2006/504/EC of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins. Aflatoxins are highly toxic and carcinogenic secondary fungal metabolites and have been detected in various food commodities including pistachio nuts.

⁴² Commission Decision 2008/757/EC of 26 September 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China.

⁴³ Consignments of live animals and animal products that are introduced into the EU are subject to veterinary checks carried out by official inspection services of the member states.

⁴⁴ BIPs are defined in Council Directives 97/78/EC and 91/496/EEC.

⁴⁵ Legislation in this area is extensive to the point that it is almost impossible to fully cover it. In addition, various EU Commission decisions are subject to frequent updating, e.g. lists of approved establishments, lists of approved BIPs, etc.

⁴⁶ The FVO also inspects all proposed new BIPs before their approval and subsequent listing in the *Official Journal*, as well as those already approved and for which the Member States request additional approval categories.

3 The European Approach to Import Safety and Security Concerns

Following several high-profile, worldwide alerts involving key consumer products, the European Commission carried out a thorough review of the product safety law acquis in the latter half of 2007. This review focused on existing legislation, enforcement capacity of member states, obligations of economic operators and cooperation with third countries. The European Commission's analysis suggested that the problems relating to unsafe products were limited (mainly involving non-food products) and that possible solutions should concentrate on those areas where there were problems, as opposed to developing an overall new system. As a result, a new legislative framework for goods has been developed in response to identified weaknesses in the acquis. This new framework builds on and complements the existing system for (non-food) consumer products under the GPSD so as to substantially realign it with the most recent and effective safety framework for food products (GFR). At the same time, some of these reforms also extend to the food sector.

3.1 Customs Authorities: From a Reactive Role to a (More) Proactive Approach

Recognising the increasing threat to public health and safety posed by imported dangerous products, the EC legislature expressed the need to reform the role played by customs authorities at the points of entry. Data from the member states showed that in the first half of 2007 an average of 9 per cent of incoming consignments were checked. Although this percentage is significantly higher than the 3 per cent recommended by the World Customs Organisation, it seems inadequate in the light of the new developments, including enlargement and globalisation and the role of organised crime.⁴⁷ Indeed, under the previous legislative framework,⁴⁸ there was no obligation for the customs authorities to initiate specific control checks for unsafe products beyond the standard customs control procedures involving a mere documentary check. Therefore, the role of custom authorities was substantially reactive once an unsafe product had been identified in the course of customs controls. No proactive obligations existed for the customs authorities to carry out controls for unsafe products at EU borders on their own initiative. In the future, following the entry into force of Regulation (EC) No. 765/2008 in January 2010, customs authorities 'shall carry out appropriate checks on the characteristics of the products on an adequate scale ... before these products are released in free circulation'.⁴⁹ While the exact scope of this obligation to perform checks on consumer products is likely to become a matter of interpretation, customs authorities maintain the power to suspend the release of a product for free circulation on the EU market.⁵⁰ However, their decision is temporary (its validity does not last more than three days) and may be confirmed only by the market surveillance authorities when the product presents 'a serious risk' or does not comply with EU authorisation.⁵¹ In the former case, national authorities may even destroy or otherwise render inoperable the relevant products.⁵²

⁴⁷ See Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – An Industrial Property Rights Strategy for Europe COM (2008) 465 final.

⁴⁸ Council Regulation (EEC) No. 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries.

⁴⁹ Regulation (EC) No. 765/2008: Art. 27(1)).

⁵⁰ Regulation (EC) No. 765/2008: Art. 27(3).

⁵¹ Regulation (EC) No. 765/2008: Art. 29.

⁵² Regulation (EC) No. 765/2008: Art. 29(4).

3.2 Traceability for Non-Food Consumer Products

To increase product safety, the EC legislature has introduced traceability as a mechanism that can provide a continuous flow of information and allow for the retrieval of the history and the origin of a product at any point in the supply chain. Although traceability does not in itself make a product safe, it is a risk-management tool to be used to assist in containing a product safety problem.

Its primary aim is therefore to ensure product safety and to assist in enabling an unsafe product to be removed from the market, notably by making the recall of a product easier. The system of traceability for non-food consumer products is based on Article R7 of Decision 2008/768/EC, which requires economic operators to be able to identify any economic operator who has supplied them with a product and any economic operator to whom their products have been supplied. This approach, which is largely inspired by the traceability system introduced in the food sector, may be defined as a one-step-backward, one-step-forward approach, requiring each operator to know the step before him or her in the food chain as well as the step after.⁵³ Everyone involved in the supply chain has to be put in the position of being able to identify any person responsible for the supply of an unsafe food product. This goal is translated into an operational duty imposed on manufacturers, who must ensure that their products bear mandatory information concerning not only the product (type, batch, serial number, etc.) but also their own information (name, registered trade name or trademark and address).⁵⁴

It is believed that the introduction of such product information will help to make market surveillance simpler and more efficient by ensuring the traceability of a product throughout the whole supply chain. Indeed, an efficient traceability system assists market surveillance authorities in the job of tracing economic operators who have made non-compliant products available on the market.

3.3 Obligations of Importers and Distributors with a View to Ensuring Traceability

The new legislative framework for the marketing of products has also introduced, for the first time, a specific set of obligations on importers (performance standards).⁵⁵ Importers are obliged to place only compliant products on the EU market and, for this purpose, before placing a product on the market, they shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer and that the product bears the required conformity marking and mandatory information of the product (type, batch, serial number, etc.) and of the manufacturer (name, registered trade name or trademark and address). Similar obligations have been imposed on distributors, the idea being that both importers and distributors, because they are close to the marketplace, should be involved in market surveillance tasks carried out by national authorities and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned.

In addition, the new legislative framework aims to clarify the conformity assessment procedures and to reinforce the quality and use of accreditation to ensure that certification bodies are truly competent to work in support of the application of the EU harmonisation legislation.

3.4 Increased Cooperation Between Customs and Market Surveillance Authorities

Another important part of the reform aims at improving cooperation between customs (which rely on the Risk Information System (RIS) in the customs area) and market

⁵³ GFR (2002): Art. 18.

⁵⁴ Annex I of Commission Decision 2008/798/EC: Art. R2(5) and (6).

⁵⁵ Annex I of Commission Decision 2008/798/EC: Art. R4.

surveillance authorities (which rely on the rapid alert systems). All customs officials' decisions to block or reject goods at the EU borders for safety reasons must immediately be sent to the domestic market surveillance authority concerned, which in turn will immediately transmit the information to the other member states' customs and market surveillance authorities through the RAPEX⁵⁶ and RASFF systems. At the same time, the rapid alert systems' contact points should also inform their customs authorities of the measures and actions taken by market surveillance authorities relating to imported products that pose a serious risk in order to avoid further imports of the same product into the EU market. Thus, customs authorities, by becoming recipients of all information exchanged through the rapid alert systems, may better target control actions related to a certain type of goods (e.g. toys originating from a certain third country). In the meantime, the customs authorities have introduced Commonly Agreed Priority Control Areas (CAPCA), enabling the EU to carry out targeted control actions relating to a specific type of goods.

Besides this reform, the Commission has put forward a proposal to improve toy safety in Europe by replacing and modernising the 20-year-old toys directive.⁵⁷ This directive introduced various safety-enhancing provisions, such as prohibiting the use of carcinogenic chemicals in toys, reducing the use of substances such as lead or mercury and obliging operators to issue appropriate warnings to prevent accidents.⁵⁸

4 Europe and the 2008 Melamine Dairy Scandal

The manner in which Europe handled the 2008 melamine dairy scandal provides an overview of the actual practice and functioning of import control mechanisms and procedures in urgent situations.

When the European Commission was made aware that high levels of melamine had been found in infant milk and other milk products in China during the summer of 2008,⁵⁹ it initially chose not to act, as imports of milk and milk products originating from China were not allowed into the EU. However, several notifications through the RASFF confirmed the presence of melamine in composite products containing milk ingredients as well as the illegal import of milk and milk products from China. Therefore, after some reflection, the Commission realised that certain composite products (i.e. products that simultaneously contain a processed product of animal origin and a product of non-animal origin) containing processed milk might have reached the EU market, and decided to enact emergency measures on the basis of Article 53(2) GFR. In a record 24 hours, the Commission adopted, after consulting the Standing Committee on the Food Chain and Animal Health (SCFCAH), a decision prohibiting the import into the EU of all composite products from China intended for the nutrition of infants or young children.⁶⁰ However, by relying on the advice of the European Food Safety Authority (EFSA),⁶¹ the Commission in 2008 required member states to systematically check all composite products containing at least 15 per cent milk products originating from China.⁶² Indeed, according to EFSA's worst-case scenario, children with a high daily

⁵⁶ Regulation (EC) No. 765/2008: Art. 27(5).

⁵⁷ Proposal for a Directive of the European Parliament and the Council on the safety of toys, COM (2008) 9 final.

⁵⁸ Directive 2009/48/EC of the European Parliament and the Council of 18 June 2009 on the safety of toys, OJ 2009 L 170/1.

⁵⁹ Melamine is a chemical intermediate used in the manufacture of amino resins and plastics and is used as a monomer and as an additive for plastics. High levels of melamine in food can result in very severe health effects.

⁶⁰ Article 2 of Commission Decision 2008/757/EC imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China.

⁶¹ EFSA received a request on 19 September 2008 from the European Commission's Health and Consumers Directorate requesting urgent scientific advice on the risks to human health due to the possible presence of melamine in composite food products imported from China into the EU.

⁶² Commission Decision 2008/757/EC of 26 September 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China, OJ 2008 L 259/10.

consumption of such products might exceed the tolerable daily intake of melamine (0.5 mg/kg body weight). Within the same decision, the Commission, by clearly rejecting a zero-risk approach, established – taking into account the available occurrence data – the level of 2.5 mg/kg as the appropriate one to distinguish between unavoidable background presence of melamine and unacceptable adulteration. It therefore required member states to destroy all products containing higher levels of melamine.

Given that member states are expected to report any unfavourable results of laboratory analyses through the RASFF, the Commission has been regularly reassessing its decision in the light of the results of the controls carried out by the EC member states' authorities.

One month later, in October 2008, member states reported, via the RASFF system, significant difficulties in establishing the exact milk or milk product content of composite products. This led the Commission to realise that the value of 15 per cent was largely irrelevant in deciding whether a consignment is subject to control requirements prior to import. As a result, in order to streamline and simplify import control procedures, the Commission amended the second part of its previous decision and established the requirement of controls irrespective of the exact amount of milk or milk products in the composite products (Commission Decision 798/2008/EC).⁶³ Building on member states' notifications, moreover, the Commission decided to introduce, within the amended decision, random checks prior to importing other feed and food products with a high protein content originating from China.⁶⁴

In the meantime, according to information made available by the member states through the RASFF, high levels of melamine were also found in products containing soya or soya products imported from China, as well as in ammonium bicarbonate, which is used in the food industry as a raising agent. The Commission therefore considered it appropriate to extend the measures laid down in Commission Decision 2008/798/EC to these products by prohibiting, in particular, the import of products containing soya and soya products intended for use by infants and young children originating in or consigned from China. It also introduced 100 per cent testing of feed and food containing soya and soya products originating in or consigned from China and food products containing additive ammonium bicarbonate imported from China. This final decision, Commission Decision 2008/921/EC, has not only amended the previous October 2008 decision but, being confirmative of EU action, is no longer subject to continuous reassessment and is currently in force.⁶⁵

5 Exporting the European Approach to Import Safety

Ensuring that imports are safe presents special challenges, as production takes place in third countries outside the direct control of the member states. However, besides a few exceptions regarding high-risk products (such as animals and animal products), the regulation of import safety in the EU is not the focus of direct legislative attention. As a result, import safety in Europe is pursued not through the application of special conditions governing the import of third-country products, which would impose systematic checks at the external borders, but rather through the decentralised enforcement by member states' market surveillance authorities of a harmonised set of product safety regulations: the European product safety acquis. This multi-level and multi-actor regulatory framework, which is applicable to all products that seek to gain access to the EU market and then circulate within it, applies to both domestic and imported products.

While its enforcement is decentralised at the member state level,⁶⁶ any action taken by national market surveillance authorities and customs officials within the EU

⁶³ Article 2(2) of Commission Decision 2008/798/EC of 14 October 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China, OJ 2008 L 273/18.

⁶⁴ *Id.*

⁶⁵ GFR (2002): Art. 53(1).

⁶⁶ Member states are responsible for carrying out checks of their conformity and, when doing so, are subject to common rules to avoid any distortion that might adversely affect safety and health.

framework must be communicated to the European Commission, which, in accordance with the existing rapid alert systems (RAPEX and RASFF), centralises this information before transmitting it to all national authorities. Following the recent reform, national authorities' activities and findings will also be communicated to the customs authorities, which, by becoming recipients of all information exchanged through the rapid alert systems, will be better able to target control actions related to a certain type of goods (e.g. toys originating from a third country). This exchange of information facilitates authorities' tasks of ensuring product safety within the European market and enables the European Commission, whenever national intervention is not adequate to achieve a declared safety goal, to act for the entire EU. This shared allocation of responsibility, which is made possible by the rapid alert systems, is one of the distinguishing features of the European approach to import safety.

By not providing systematic checks at the external border, the European regulatory approach to import safety is substantially reactive: it is only once an unsafe product has been identified in the course of random customs controls or internal market surveillance that either the relevant member state or the Commission will act. Indeed, no proactive obligation exists for the customs authorities to carry out controls on unsafe products at the EU border on their own initiative. Instead, they confine themselves to a documentary check, which might be supported by a certification scheme. However, as illustrated by the recent handling of the melamine scandal, the European framework, although substantially reactive, is capable, once triggered, of becoming preventive and even precautionary, allowing EC action even in a situation of scientific uncertainty.

While it is true that Commission action was not in *casu* triggered by alarming findings of its own inspection authorities but rather by media reports, it moved swiftly and effectively to coordinate customs' and market surveillance authorities' reactions vis-à-vis those products. The introduction of an obligation on customs authorities to perform controls 'on an adequate scale' before imported products can be released in free circulation might reasonably be interpreted as a sign suggesting that the European regime has shifted towards more prevention at the external borders. However, notwithstanding this apparent willingness of the EU to strengthen checks of non-food products at the external border, the essence of the EU approach towards import safety is not expected to change. The EU, aware that systematic controls at the border are not a realistic option, seems likely to shift its regulatory focus to where the source of possible safety issue is located, namely the country of origin. Indeed, the EU is currently focusing its efforts on extending its reactive 'safety-net' regulatory model beyond its borders, thus inevitably giving rise to an interesting legal export of its own approach to import safety. In particular, it recently developed the RAPEX-China system, which establishes a regular and rapid transmission of data between the EU's and China's product safety administrations. Under this newly created rapid alert system, the Commission provides the Chinese authorities with information on consumer products originating from China that have been identified as dangerous and consequently banned or withdrawn from the EU market. Under the terms of the agreement, China is expected to investigate all the notifications it receives and, where necessary, to adopt measures limiting further exports of the notified dangerous products to the EU. To date, after the first three years of operation, 1,110 RAPEX notifications have been investigated by China (out of 4,766 stored in the database) and in 617 investigated cases appropriate preventive measures were adopted either by the Chinese government or voluntarily by the Chinese manufacturer or exporter. In most of the other investigated cases (44 per cent), no measures were taken – mainly because China could not find the company responsible for manufacturing and/or exporting the dangerous products to the EU.⁶⁷ The most recent (twelfth) report presents a further decrease (from 26 per cent to 17 per cent) in the number of cases where a Chinese manufacturer and/or an exporter could not be found. EU and Chinese authorities are currently cooperating to extend the EU RASFF system to China in order to cover food products as well.

⁶⁷ Further improvement can be expected as a result of recently adopted EU requirements that the name and the address of the manufacturer and the importer must be provided. However, continued efforts are still needed to ensure effective international traceability.

The immediate gain from including China in the EU rapid alert systems is to prevent further imports into the EU of dangerous products without crossing jurisdictional lines. Once more, this confirms the reactive nature of the EU approach to import safety, while simultaneously showing that it has the aptitude to quickly adopt preventive measures in an emergency. However, the major success of extending these alert systems to China has been to familiarise the local authorities with an original cooperation mechanism that they did not hesitate to choose as a blueprint for the creation of their own rapid alert systems. RAPEX and RASFF are both likely to be instrumental in establishing the foundations of market surveillance culture in China and beyond.

6 Conclusion

Although representing one of the most challenging cases of food contamination the world has faced, the melamine dairy scandal did not have any tangible negative health effects on the European population. Even though this encouraging result cannot be entirely ascribed to the European product safety *acquis* per se, the European regime, by showing its flexible and reactive nature, certainly contributed to this favourable outcome. On the one hand, the emergency powers entrusted to the Commission have indeed permitted the rapid adoption of an initial import ban coupled with targeted checks. On the other, the feedback received, via RASFF, by the national authorities in charge of the implementation of these emergency measures, has enabled the EU to update its decision by targeting the right products and fine-tuning its precise reach. The EU reaction substantially contained the damage by preventing recurrences. Notwithstanding the high risk of over-reaction facing the authorities in this model scenario of the social amplification of risk, the EU, by relying on its multi-actor and multi-faceted mechanisms of control, seems to have managed to adopt an approach proportionate to the risk at stake. The Commission, by rejecting a zero-risk policy, struck a fair balance between reaction and over-reaction. Yet, it should not be forgotten that the pre-existing EU ban on Chinese dairy products facilitated the containment of the scandal. Therefore, the extent to which this felicitous outcome can be ascribed to the EU import safety model is not easy to determine. Would the EU reaction have been sufficiently preventive to contain the severe mortality risks that have occurred in China if the ban on Chinese dairy products had not been in place? What would have happened if Chinese dairy products could have been marketed in the EU before and during the melamine crisis? Would the system have showed a similar level of efficacy in the presence of a higher number of contaminated products? These are legitimate, though hypothetical, questions that have not been addressed directly in my analysis. Although presenting itself as a 'stress test' for the EU import safety regime, the melamine crisis did not wholly challenge this system. As more import safety challenges are likely to occur in today's globalised markets, the jury is still out on the ability of the EU import safety regime to address a full-scale crisis.