

A Disadvantageous Dichotomy in Product Safety Law – Some Reflections on Sense and Nonsense of the Distinction Food-Nonfood in European Product Safety Law

ANTONI BRACK¹

Abstract

This paper researches a number of similarities and differences between European legal regimens with regard to food and non-food product safety, based on the assumption that these regimens may have overly diverged. A tentative conclusion is that there are enough similarities to justify an effort to reconcile the two regimens. The point of departure for this research (Section 1) is an overview of sources of law laid down in the EC Treaty for drawing up legislation in the area of product safety (food and non-food). In Section 2, the Product Safety Law *acquis* is presented; this is the cumulative body of European law implemented so far, based on these sources. EC-Treaty articles constitute the legal basis for the Product Safety Law *acquis*, which in turn forms the legal basis for policies. Therefore, Section 3 deals with the Commission's current policy intentions: indications of what can be expected in this area in years to come.

A core characteristic of the Product Safety Law *acquis* is the precautionary principle (Section 4), which refers to safety risk management, intended to prevent the marketing of defective products. Should preventive risk management measures fail, the producer's ability to trace already marketed hazardous products is crucial in order to limit liability, as explained in Section 5. Section 6 highlights an important legal presumption in non-food safety law. The safety of non-food products is presumed if production took place according to standardised norms. A long term European law-reform programme is introduced in Section 7. This so-called Better Regulation programme is a perfect opportunity to adjust the Product Safety Law *acquis* to new insights. Section 8 summarizes our observations and findings. Section 9 discusses the utility of the Confident Consumer concept. Because it seems disadvantageous to focus on the differences between food and non-food safety

¹ Chair Regulatory environment of business enterprise (Business Law), School of Management & Governance, University of Twente, The Netherlands. A preliminary version of this paper has been presented in Vienna, Austria (25 Jun 2006) at the first Conference of "Eurosafes", the European Association for Injury Prevention and Safety Promotion, <<http://www.eurosafes.eu.com/csi/eurosafes2006.nsf/>>. Many thanks to those who attended the paper session and took part in the discussion. Special thanks to Dirk van Aken, Jan Ende, Wim Rogmans and Willem van Weperen; they all delivered useful comments à titre personnel on a draft version of the paper. This does not imply that they are in favour of the ideas presented here.

rules, the possible advantages of a policy and law reform are assessed. Therefore Section 10 concludes to attune both parts of product safety law to the similarities instead of focusing on differences. Maintaining the dichotomy is disadvantageous to progress.

1. Fundamentals of Rule Making Competence

Consumer products can be roughly categorised in food and non-food. However, when discussing safety rules for consumer goods, the term “product safety” usually refers to non-food products exclusively; in the case of food products, the term “food safety” is used. The same applies to the use of product (safety) law and food (safety) law. In this paper, the collective term “product safety law” is used to refer to rules for consumer product safety; to avoid confusion, an explicit distinction will be made between food and non-food. Product categories subject to special regulations, such as pharmaceuticals, pesticides and cosmetics, fall outside the scope of this paper and will therefore not be discussed.

The legislative bodies of the European Community, referred to as the European Union (EU) for brevity, have no self-evident authorisation to introduce or amend legal rules. The European Court of Justice has explicitly stated that the Treaty must provide a specific authorisation for introducing European rules on a particular subject. This case law was a response to unremitting attempts by the Commission to extend its authorisation, by automatically referring to the Treaty’s basis for establishing the internal market.

The question is which particular authorisation forms the basis for drawing up rules for product safety (food and non-food) in the EU. Or in legal terms: what is the legal basis for the *product safety acquis*, or the communal result in this area? Authorisations with (A) the establishment, maintenance and advancement of the internal market as a direct objective belong to a different category than (B) those authorisations with no direct relation to this area.²

- (A) Article 14 defines the internal market as an area with no internal frontiers, within which free movement of, among other things, goods is ensured. Note that expiration of the date mentioned in Article 14–1 (31 December 1992) has no influence on legislative competence dealing with the internal market. Article 95 refers to achieving the objectives laid out in Article 14. According to 95–3, the Commission is held to base proposals aimed at completion of the internal market for the policy domains of health, safety,

² Apart from establishing an internal market, the safety of food and non-food products relates to European policy domains of (public) health, safety, and consumer protection. Relevant sections from the Treaty’s articles mentioned in this paper are summarised in the Annex.

and consumer protection on a high level of protection, in particular taking into account any new development based on scientific facts. These are also the objectives of the European Parliament and the Council, albeit under a lesser degree of constraint.

- (B) Unrelated to the completion of the internal market, the Articles 152 and 153 depict the authorisations with respect to cooperation between the Commission and the member states. Measures in these areas do not supersede national decisions, but constitute a supplement. This applies both to furthering public health and the prevention of human diseases and disabilities (152), as to protecting the health, safety and economic interests of consumers (153). So European consumer protection law can be based on completing the internal market, but can also function independently, supporting and complementing national legislation.³ Finally, it is important to note that the text of the Articles 152 and 153 explicitly state that “a high level of human health protection” and “a high level of consumer protection” must be ensured.

Our conclusion is that unhindered European trade in consumer products must be trade in safe products, based on a high level of protection, taking new developments and scientific facts into account. In cases where product safety cannot be directly linked to completing the internal market, we see that the EU can draw up rules and implement measures in cooperation with and in support of member states, as product safety has bearing on policy domains of both public health and consumer protection. Here too, a high level of protection must be ensured.

So far, we have not observed any distinction between food and non-food consumer products on this primary level.

2. Product Safety Law Acquis

Using the sources of powers of the Treaty, regulations for improving product safety have come into existence. Up until several years ago, these consisted of Directives exclusively; in recent years, we have seen the emergence of a self-executing Regulation. This elaborate regulatory complex consists of a subsystem on a Community general level (infra: a), and another, related subsystem dealing with CE marking on a Community specific product group level (infra: b). The latter is known as the so-called New Approach regulation regarding driving back technical trade barriers. When taken together, these two subsystems comprise an interesting multilevel and multi-actor regulation complex of practical importance.

³ Ellen Vos, *Institutional Frameworks of Community Health and Safety Legislation* (Hart Publishing, Oxford 1999).

(a) General Community level: Public Product Safety & Private Liability

This legal domain predominantly consists of the following components:

1. Directive 85/374/EEC concerning liability for defective products and Directive 1999/34/EC amending Directive 85/374/EEC,⁴
2. Directive 2001/95/EC on general product safety,⁵
3. Regulation 178/2002/EC on general principles of food law.⁶

A useful distinction for structuring this area is the distinction between preventive and repressive effects. All components are geared towards preventing hazardous products: ideally, only safe products, foods included, are brought onto the market. In those cases where prevention has failed and resulted in damage or injury to users of hazardous products, the product liability Directive offers a special option for recourse. However, this compensatory regulation is also expected to have a preventive effect in the end.

Not all components of this domain apply to all products at all times; the regulation from the aforementioned item 3 (self-evidently) only applies to food products. However, the amendment of the product liability Directive turned out explicitly that this directive applies to both food and non-food products. The product safety Directive was drawn up with mostly non-food in mind. After the General Food Law referred to in item 3 came into force, it became clear that the product safety Directive applies to non-food only.

Somewhat in parallel with the distinction between food and non-food is a distinction between a pre-marketing and post-marketing focus of the components of this regulatory complex. Even though preventing the marketing of a defective product is a pre-marketing issue initially, the focus of the non-food-centric General Product Safety Directive (GPSD) is post-marketing surveillance nevertheless.⁷

⁴ See amongst other titles: Geraint Howells, *Comparative Product Liability* (Dartmouth Publishing 1993) and C.J. Miller & R.S. Goldberg, *Product Liability*, 2nd ed (Oxford University Press 2004). See also Stephen Weatherill, *EU Consumer Law and Policy* (Edward Elgar Publishing 2005), Chapter 6, 135.

⁵ See: Chr. Hodges, "A New EC Directive on the Safety of Consumer Products" [2001] EBLR 274–280.

⁶ See *in general*: B.M.J. van der Meulen, *The Right to Adequate Food – Food Law between the Market and Human Rights*, inaugural address, Wageningen University, The Netherlands 2003 (Elsevier Juridisch 2004), and Bernd van der Meulen & Menno van der Velde, *Food Safety Law in the European Union – An Introduction* (Wageningen Academic Publishers, The Netherlands 2004). Debra Holland & Helen Pope, *EU Food Law and Policy* (Kluwer Law International 2004). Raymond O'Rourke, *European Food Law*, 3rd ed (Sweet & Maxwell London 2005). Caoimhín MacMaoláin, *EU Food Law – Protecting Consumers and Health in a Common Market* (Hart Publishing, Oxford – Portland Oregon 2007).

⁷ Hans-W. Micklitz (ed.), *Post Market Control of Consumer Goods* (Nomos Verlagsgesellschaft 1990).

The regulatory complex composed of the directives and the regulation mentioned form the general level of the Product Law domain. In legal literature, it is rarely approached as a single, coherent entity, because it is composed of a private law part and a public law part, and also because Food Law unfortunately has a tendency to be regarded as an independent specialism.⁸ Notwithstanding this, it is an interesting, societally important combination of several levels and different actors. It involves not just the European legislative body, but also legislative organizations of member states, because of the well-known requirement for European directives to be transposed into national legislative bodies. The directly applicable General Food Law Regulation needs no further transposition, although adaptation to their respective national legislative bodies was deemed necessary by many member states. This General Food Law is clearly focused on pre-marketing, and, together with the General Product Safety Directive, belongs to the public administrative law domain. The product liability directive belongs to the domain of private law, and its main focus is post-marketing, at least in a formal legal sense. Its scope is both food and non-food.

The Commission has the obligation to periodically report on the application of these laws in practice. In 2006, a report was published on the application of the Product Liability Directive.⁹ It was considered not to be necessary to submit any proposal for its amendment. In 2007 the GPSD is due to be evaluated.

(b) Community Product Group level: New Approach and CE-Marking

Apart from the previously described (a) general regulatory complex, dozens of product groups have their own specific standards for health and safety. Examples are biocides, cosmetics, tobacco and medicinal products, which are beyond the scope of this paper, but also “new approach products”. These are product groups regulated by special norms created according to the new approach procedure for speeding up the realisation of the internal market (“Europe 1992”). Negative integration, based on the principle of mutual recognition and the requirement of unanimity in decision making, left a large number of technical trade barriers in place. This meant that a product, brought onto the market in accordance with one member state’s regulations, automatically had to be admitted in other member states, barring exceptional circumstances, and thus national regimes were maintained. Positive integration in the form of European product law, based on harmonisation of national product law regimes and a majority rule decision making process, might speed up the realisation of the European internal market. The so-called *new approach* to the clearout of technical barriers to trade is a combination of essential

⁸ For instance because of the unique existence of a source with a worldwide importance, the Codex Alimentarius, see: Alessandra Battaglia, “Food Safety: Between European and Global Administration” (2006) 6 Global Jurist Advances, Article 8 (1–14).

⁹ Brussels 14.9.2006, COM(2006) 496 final.

safety requirements that are legally binding, and detailed technical standards being offered to manufacturers for voluntary use. The well-known *CE-mark* is the icon of this regulatory complex, consisting of three layers:¹⁰

- a) A number of system-supporting primary regulations, among other things consisting of a catalogue of possible regulation types and quality modules,
- b) The by now dozens of independent legal regulations, each of which prescribes fundamental safety requirements for a broadly defined product category: these are the abstract legal standards dealing with safety,
- c) Technical specifications, drawn up in a non-democratic process by conglomerates of manufacturers and other experts, based on an elaboration of the abstract legal safety regulations, on request of the European government, and subsidized with EU funds.

The CE-marking, not seldom viewed by the public as a guarantee for safety, is a declaration of conformity with fundamental safety requirements indicating a high level of protection. It is called simply a regulatory mark, a signal on the packaging of products in order to be a free pass for the entire internal European market. “CE marking acts in effect as the passport that authorizes the product to be placed on the market and to circulate freely within the Community, and must be marked on the product. The CE marking symbolizes conformity to all the obligations incumbent on manufacturers for the product under the Community directives that relate to it.”¹¹ CE is short for *Conformité Européen*.¹²

An essential characteristic of this regulatory complex is that the manufacturer can benefit from the *presumption of conformity rule*: if demonstrably produced according to European standards, these products may circulate freely within the common market. Conformity assessments are executed by certification institutes recognised for their expertise and therefore named “notified bodies”.

This regulatory complex with practical business importance facilitates the free circulation of products and supports public health and safety of consumers. It is characterised by a combination of legislative public law rules, which is implemented in the form of supplemental norms and standards by private law oriented “legislative” bodies.¹³ The more or less democratically organized legislation by the

¹⁰ A. Brack, “The CE-mark and the New European Approach to Product Law: A System of Fundamental Legal Safety Requirements and Technical Specification Standards” (1999) 6 *International Journal for Consumer & Product Safety* 45–59.

¹¹ Christopher Hodges, *European Regulation of Consumer Product Safety* (Oxford University Press, 2005) at 57.

¹² “If you are French, the letters ‘CE’ may stand for ‘Conformité Européen’. If you are not, you might assume they don’t stand for anything. Either way, this symbol is the CE-mark.”, David Hanson, *CE Marking, Product Standards and World Trade* (Edward Elgar Publishing, 2005) at 1.

¹³ Sebastian Farr, *Harmonisation of Technical Standards in the EC*, 2nd ed (John Wiley & Sons, 1996) and recently: (1) Christopher Hodges, *European Regulation of Consumer Product Safety* (Oxford

governmental legislative body limits itself to defining vague, exceedingly abstract “fundamental” safety rules for very extensive product categories (such as gas burning appliances, pressure equipment, etcetera). These legally binding rules are rendered operational in a twilight area between public and private law by standardization institutions, which draw up specifications of an optional nature.¹⁴ This creates the illusion of deregulation: a collection of open and vague standards, supplemented with self-rule by networks of stakeholders; in other words: governance without government as well as governance beyond the state. Also, this means that ensuring a particular public interest, namely public health and safety, is entrusted to and dependent on self regulation by stakeholders.¹⁵

The so-called *safeguard clause* is the final piece of this system: a member state retains the competence to withdraw a proven unsafe product from the market, even if this product bears the CE-mark.¹⁶ In the end, the public interest with regard to product safety can prevail over private interests connected with the free circulation of products.

3. Policy Context: Organisation and Strategy

Product safety policies perfectly match the required high level of protection for the proposals concerning health, safety and consumer protection to establish the internal market (Article 95 EC-Treaty, see this paper’s appendix). Other product safety policies, carried out in support of national policy, can be based on the Treaty’s public health article (152) or the consumer protection article (153).¹⁷ As Article 153 too mentions health protection as a part of consumer protection, product safety spans both articles. The public health of Article 152 is about preventing human illness and diseases by research, information and education: the medical approach. The consumer protection approach of Article 153 is about preventing damages and injuries caused by accidents while using hazardous products. The magic words that supports the overlap are “the prevention of injury and the promotion of safety”.¹⁸ An appropriate illustration of this mixed approach is the Communication from the Commission that formulates its purpose as follows: “This communication focuses on the prevention of accidents and injuries in Europe by public health actions. (...)”

University Press 2005) and (2) Harm Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005).

¹⁴ Damian Chalmers, “Private Power and Public Authority in European Union Law” (2005–6) 8 Cambridge Yearbook of European Law 59, 64.

¹⁵ See Schepel (2005, supra) at 67. The attachment of the CE-mark to products might even be based on self-declaration of safety: see Hodges (2005, supra) at 57.

¹⁶ Hodges (2005, supra) at 58, 171.

¹⁷ C.D. Ehlermann, “The Internal Market Following the Single European Act” (1987) 24 CML Rev 361–409, specially at 387–388.

¹⁸ Proposal for a Council Recommendation, Brussels, 23.06.2006, COM (2006) 329 final.

These actions should be undertaken in the framework of the Community Public Health Programme (2003–2008), the Consumer Policy Strategy (2003–2006) and follow-up initiatives.”¹⁹ Amongst the priority areas mentioned in this Communication are safety of children and of elderly citizens and prevention of interpersonal violence, as well as prevention of injuries caused by *products* and services. It is confusing that only non-food products fall within the scope of this Communication.

In 2005, the Commission expressed a strategy: “Healthier, safer, more confident citizens: a Health and Consumer protection Strategy”.²⁰ This clear and integrated programme was an introduction on a proposal for a Decision of the European Parliament and the Council establishing a Programme of Community action in the field of Health and Consumer protection 2007–2013. This comprised a valuable attempt to integrate policy plans in the areas of health and consumer protection, and bridge the artificial gap between both policy domains. Quite unsurprisingly, product safety was given a prominent role, as expressed on the Commission’s web site: “keep dangerous products off the EU’s internal market”. The policy programme was an attempt to combine the objectives of the Articles 152 and 153 of the Treaty on one common ground: to protect citizens from risks. The health-related part of the programme discussed food safety, while the consumer protection part dealt with the necessity of international regulatory cooperation on product safety.²¹ The proposal would have had organizational consequences, as this Strategy Programme 2007–2013 would entail the formation of a new Executive Agency in the Commission’s bureaucracy, organized in two departments: a Health Department and a so-called Consumer Institute. Policies of food safety and non-food product safety were proposed to be organised apart but still together in one executive agency.

Very unfortunately the proposals in this Communication (COM (2005) 115 final) have not been transposed into official decisions. Instead of this proposed joint programme that came to a standstill in the process of further decision making, the Commission evidently had to separate the health policy plans from the consumer protection strategy proposals. “In order to respond to a demand from stakeholders, the Council and European Parliament”,²² the Commission launched a replacing successor. This EU Consumer Policy Strategy 2007–2013²³ declares to have three main objectives in this period: to empower consumers, to enhance their welfare and to protect them effectively. By 2013, products and services will be safe, a sweeping

¹⁹ Communication from the Commission to the European Parliament and the Council on Actions for a Safer Europe, Brussels, 23.6.2006, COM (2006) 328 final.

²⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Brussels, 6.4.2005, COM (2005) 115 final.

²¹ Obviously understood to mean *non-food* product safety.

²² COM (2007) 99 final, p 3.

²³ Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, Brussels 13.3.2007, COM (2007) 99 final.

statement reads. Several references to product safety can be found in this policy document, probably all of them pointing at the safety of non-food products.

Currently, the Commission's DG Health and Consumer Protection ("SANCO") is supervised by two commissioners and subdivided into three departments with separate programs: Food and Feed Safety, Consumer Affairs, and Public Health.²⁴ On 18 December 2006, the programme of Community action in the field of consumer policy (2007–2013) was determined.²⁵ The recitals of this financial framework refer to "health and safety aspects of services and non-food products (...) as well as consumers' interests in the development of standards for products and services". This is a affirmation of the usual approach towards product safety: the safety of non-food products, including the public-private mixed CE-mark regulatory complex, apparently belongs to the domain of consumer protection. An Annex of this programme lists a summary of actions and instruments. Here too, prominent references to the safety of consumer goods and the safety of products can be found. Given the clear references to product safety standards, the drafting of standardisation mandates and the General Product Safety Directive, it is a logical assumption that in this context, product safety applies to non-food only.

Logically as a result of the separation between programming plans for consumer protection and health policy, a Health Strategy programme (2008–2013)²⁶ has been determined with reference to the influence of food and nutrition on human health.

For the record, mention must be made of an ongoing, somewhat related activity, i.e. the Review of the Consumer Acquis.²⁷ The aim of this operation is revising part of existing European consumer law.²⁸ This operation is part of the "Better Regulation" programme, which is mentioned briefly further on in this paper. It is interesting to note a possible proposal to introduce the EU wide direct producers' liability for non-conformity in cases that consumer goods do not have the quality that contracting consumers are entitled to expect. Certainly, a product's lack of safety performance is a serious case of non-conformity, but the Commission states clearly that the liability for damage caused by the defectiveness of a product should fall outside the scope of the consumer acquis review, and is continued to be regulated by the Product Liability Directive.²⁹

²⁴ See: http://ec.europa.eu/dgs/health_consumer/index_en.htm.

²⁵ Decision No 1926/2006/EC of the European Parliament and of the Council, O.J. 30.12.2006, L 404/39.

²⁶ Decision No 1350/2007/EC of the European Parliament and of the Council, O.J. 20.11.2007, L 301/3.

²⁷ Green Paper on the Review of the Consumer Acquis, Brussels, 08.02.2007, COM (2006) 744 final.

²⁸ Geraint Howells and Thomas Wilhelmsson, "EC Consumer Law: has it come of age?" (2003) 28 ELR 370–388. Hans-W. Micklitz, Norbert Reich and Stephen Weatherill, "EU Treaty Revision and Consumer Protection" (2004) 27 JCP 367–399.

²⁹ "Green Paper" (supra footnote 24) at 30.

4. Precautionary Principle: Provisional Risk Management Measures

The Commission's communication on this principle³⁰ has contributed to its central role in European policy concerning human health and environment. The Regulation General Food Law³¹ defines (in Article 7) the principle.³² Restricted to its most essential characteristics, one could summarise the definition as follows: *In specific circumstances where, (...), the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection (...) may be adopted, pending further scientific information for a more comprehensive risk assessment.* I have underlined the part about risk management for the sake of this paper's further reasoning. Important is the definition's reference to "scientific uncertainty". This is particularly relevant because one of the EC Treaty's requirements for attaining a high level of protection is taking into account any new development based on scientific facts.

Although this principle has many supporters, it is a major subject of controversy in literature. Opinions on this subject matter range from an obvious standpoint of caution, in particular in the case of uncertainty,³³ to the view that the principle is unwieldy, illogical, or even unmanageable.³⁴ In the scope of this paper, a pragmatic approach seems sensible. As absolute safety does not exist, regulating product

³⁰ Communication from the Commission on the Precautionary Principle, Brussels 2.2.2000, COM (2000) 1.

³¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, O.J. 1.2.2002 L 31/1.

³² Article 7 General Food Law reads as follows:

"1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraf 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment."

³³ A study by the Dutch Health Council offers an overview: M. Faure & E. Vos (ed.), *Juridische afbakening van het voorzorgbeginsel: mogelijkheden en grenzen*, (Den Haag, Gezondheidsraad 2003) (publicatie nr A03/03). See also: Joanne Scott & Ellen Vos, "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO" in: Christian Joerges & Renaud Dehousse (eds.), *Good Governance in Europe's Integrated Market* (Oxford University Press, 2002) at 253–286. Ellen Vos, "Risicobeheersing door de EU: Het nieuwe beleid op het gebied van voedselveiligheid" in Ellen Vos & Geert van Calster (eds.) *Risico en voorzorg in de rechtsmaatschappij* (Intersentia, 2004). Marjolein B.A. van Asselt & Ellen Vos, "The Precautionary Principle and the Uncertainty Paradox" (2006) 9 *Journal of Risk Research* 313–336.

³⁴ R. Pieterman, J.C. Hanekamp, L. Bergkamp, "Onzekere voorzorg bedreigt rechtszekerheid" (2006) 1 *Nederlands Juristenblad* 2–8. These authors wrote (in my translation from Dutch): The pre-

safety will necessarily come with a reservation: the parties involved in producing consumer goods have the obligation to pursue products which are *as safe as possible* in the light of current knowledge and state of the art.³⁵ This warrants a precautionary approach: the GFL has placed the principle in the context of the so-called “general principles”. The section of the GFL concerning these general principles of food law have a certain systematic and coherent structure.³⁶ Food law pursues a high level of protection of human life, health and the protection of consumers’ interests. Therefore risks should be assessed and analysed in order to make the management of risks possible. Risk management takes into account the opinions of the European Food Safety Authority and in specific circumstances the precautionary principle may be applied by taking provisional risk management measures.

Several years previously, during the revision of the General Product Safety Directive (GPSD), an elaborate political discussion took place about the inclusion of the precautionary principle into the updated GPSD.³⁷ The European Parliament turned out to be a vocal proponent of inclusion of the principle into the new Directive, referring to the Commission’s communication.³⁸ Industry, member states and the Commission resisted the EP’s view. The compromise finally agreed upon is that the principle is only mentioned in the GPSD, but not defined. The article in this Directive in question shows that the competent authorities are responsible for applying the precautionary principle. When studying the GFL, however, it is not immediately clear whether the general principles of food law, to which the precautionary principle belongs, must be observed by both governmental bodies and producers. As this concerns the general principles of food law, all parties responsible for food safety are involved in the application of the principle. The systematic placement of the precautionary principle within the scope of risk management suggests that risk managers are the ones responsible for its application. Producers must of course observe caution when dealing with scientific uncertainty in the area of food safety, but it is obvious that they may take “provisional risk management measures”, also without any legal provisions. They are even obliged to take those mea-

cautionary principle renders no useful contribution at all to solve problems related to decision making in situations of relative high uncertainty.

³⁵ C Hodges, *Safety and Risk* (2005) Chapter 18: 225–227 points to the definition of “safe product” in article 2 GPSD referring to “the minimum risks compatible with the product’s use considered to be acceptable”. The determination of the acceptable level of risk fits well into the case law of the Community Courts according to Julien Cazala, “Food Safety and the Precautionary Principle: the Legitimate Moderation of Community Courts” (2004) 10 *European Law Journal* 539–554.

³⁶ Bernd van der Meulen & Menno van der Velde, *Food Safety Law in the European Union – An Introduction* (Wageningen Academic Publishers, The Netherlands 2004) at 155–156. Raymond O’Rourke, *European Food Law*, 3rd ed (Sweet and Maxwell 2005) at 23–27.

³⁷ See: Christopher Hodges, “A New EC Directive on the Safety of Consumer Products” [2001] EBLR 274–280.

³⁸ Communication from the Commission on the Precautionary Principle, Brussels 2.2.2000, COM (2000) 1.

asures. The explicit legal mentioning of the precautionary principle instead indicates that enforcement authorities are entitled to take provisional measures whenever necessary. Thus public enforcement officers should be able to apply risk management procedures as well. Article 17 GFL confirms that this is the appropriate division of roles. This article specifies the responsibilities concerned. The primary responsibility for food safety obviously lies with the food producing industry: 17(1) states that food business operators at all stages shall ensure that foods satisfy the requirements of food law, while 17(2) puts member states in charge of enforcing food law and of monitoring, verifying and surveillance of food safety; they should take “activities as appropriate to the circumstances”. These are the same “specific circumstances” that the article about the precautionary principle is referring to.

In this respect, there is no difference in regulating food and non-food, if one keeps the central point, the primary rule of the GPSD, in mind. “The purpose of this Directive is to ensure that products placed on the market are safe” (Article 1(1)). And Article 3(1) of the same Directive reads: “Producers shall be obliged to place only safe products on the market.” If only safe products (non-food) are allowed on the European markets, there should be no room for uncertainties about safety because defective non-food products can be as harmful as unsafe food products and, after all, human health and product safety are basic consumer rights.

Indeed, the precautionary principle should not be excluded from safety considerations concerning non-food: a high level of protection, based on new scientific developments, is equally related to food as well as non-food products.

5. Risk Management, Products Liability and Traceability

The precautionary principle in the European product safety regulation is embedded in the risk management approach;³⁹ applying this principle means the adoption of provisional risk management measures. Within the General Food Law, risk analysis (Article 6), the precautionary principle (Article 7) and protection of consumers’ interests (Article 8) belong to the general principles of food law (section 1: Articles 5–8). These should help to accomplish the general objectives (Article 5). We have seen that the precautionary principle can be applied in cases of non-food products of questionable safety as well. The ultimate purpose of the application of risk management tools is prevention of damage and avoidance of products liability.⁴⁰

³⁹ Howard Abbott & Mark Tyler, *Safer by Design – A Guide to the Management and Law of Designing for Product Safety*, 2nd ed (Gower Publishing 1997) at 8–9, 41. See also Chr. Hodges, *Safety and Risk* (2005), at Chapter 18.

⁴⁰ Amongst many other titles see for instance: C.J. Miller & R.S. Goldberg, *Product Liability*, 2nd ed (Oxford University Press 2004). See also: Geraint Howells, *Comparative Product Liability* (Dartmouth 1993); Duncan Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge University Press 2005); Susan Woodley (ed.), *Liability for Products in a Global Economy, The Comparative Law Yearbook of International Business, Special Issue 2004* (Kluwer Law International 2005).

The basic rule of the Products Liability Directive⁴¹ (Article 1) reads: “The producer shall be liable for damage caused by a defect in his product.” Generally speaking, a producer in the sense of this legislation is not just the manufacturer, but under certain circumstances every link in the supply chain. A product should provide the safety which a person is entitled to expect. By “a person” the Directive means the general public. By damage it means either death or personal injury, and damage to property. An amendment to this Directive⁴² has made absolutely certain that this products liability legislation includes all food as well as non-food products. Article 2 defines “product” as all movables, including electricity. No doubt as a result of pressure exerted by agricultural lobbyists, “primary agricultural products” (meaning unprocessed products of the soil, of stock-farming and of fisheries) “and game” were originally (1985) excluded from the scope of this directive.⁴³ It is important to understand that after having been processed, agricultural foodstuffs have become “products” in the sense of this definition. In 1999, an amending directive cancelled the exception of primary agricultural products and game. So, after the enactment of this amendment, even in cases of *unprocessed* food, producers are liable for damage caused by defective products. This change in the scope of the directive reflects the outbreak of diseases and disasters in agriculture like BSE (mad cow disease),⁴⁴ swine fever, avian influenza and so on.⁴⁵ A recital in the amending directive therefore considers: “Whereas including primary agricultural products (...) would help restore consumer confidence in the safety of agricultural products; whereas such a measure would meet the requirements of a high level of consumer protection”. Although one might call this an understatement in the light of the seriousness of food hazards, apparently every detail was expected to help restore the confidence of the public.

In a sense the legal threat of having the obligation to compensate the damage caused by a defective product stimulates producers to manage safety matters: identify product risks, apply a risk reduction programme including a design review, assess the possibilities of risk transfer and taking risk retention measures. A well-known part of this approach is known as HACCP: Hazard Analysis Critical Con-

⁴¹ Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC), O.J. L 210, 7.8.1985, p 29.

⁴² Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, O.J. L 141, 4.6.1999, p 20.

⁴³ Although each member state was allowed to provide in its legislation that “product” also means primary agricultural products and game.

⁴⁴ Keith Vincent, “Mad Cows’ and Eurocrats – Community Responses to the BSE Crisis” (2004) 10 *European Law Journal* 499–517. In fact, the outbreak in 1996 of the BSE crisis has been considered the “Year Zero” of the EU food regime: Ellen Vos & Frank Wendler, “Food Safety Regulation at the EU level”, Chapter 3 in E. Vos and F. Wendler (eds.) *Food Safety Regulation in Europe – A Comparative Institutional Analysis* (Intersentia, Antwerpen-Oxford 2006) at 70.

⁴⁵ C.J. Miller & R.S. Goldberg, *Product Liability*, 2nd ed (Oxford University Press 2004) at 285–286. Also Hodges, *Safety and Risk* (2005) at 241 (Chapter 18).

trol Point. This deals with anticipating where in the production process causes exist of products becoming dangerously defective, and identifying production steps where those causes can be dealt with: the *critical control points*. This method of analysis was initially developed for the food industry, but there is no reason at all why it cannot be equally applied to the non-food industry: "The principles can also have a wide application outside the food industry."⁴⁶

From this we conclude that just like the precautionary principle, (other) risk management principles are applicable to processes of design and production of food and non-food products alike. Should the management of hazard prevention fail, the producer of defective (food and non-food) products will be held liable for the compensation of damage. Both General Food Law (Article 21) and General Product Safety Directive (Article 17) include a reference to the application of product liability rules: these public law provisions concerning the prevention of unsafe products on the market are without prejudice to the private law principle of liability for defective products. Producers' liability legislation includes defective food as well as defective non-food products.

An essential prerequisite for the prevention of damage and injury caused by defective products is traceability, that is the producer's ability to trace products already put into circulation.

So-called continuous improvement of product quality needs input based upon customer experience and consumer complaint analysis. The GPSD, for instance, recommends the carrying out of sample testing of marketed products and keeping a register of complaints (Article 5). These measures are consistent with modern views of Total Quality Management being a circular sequence of product design, manufacturing, marketing and distribution, and the feedback of information on customer satisfaction and dissatisfaction into the phase of redesign.⁴⁷ Traceability enables the monitoring of the performance of marketed produce in order to enable the withdrawal from the supply chain or the recall from the ultimate buyer if necessary.

Traceability is a legally recognised prerequisite. The General Food Law states: "The traceability of food (...) shall be established at all stages of production, processing and distribution" and demands that food be adequately labelled or identified to facilitate its traceability (Article 18). Likewise, the General Product Safety Directive includes obligations of producers (duty of information and warning, recall, withdrawal from the market) presupposing the monitoring of products put into circulation: post-market control (Article 5). Monitoring, withdrawals and recalls are impossible without actual traceability.

⁴⁶ Howard Abbott & Mark Tyler, *Safer by Design – A Guide to the Management and Law of Designing for Product Safety* 2nd ed (Gower Publishing 1997) at 41.

⁴⁷ Antonio J. Bailetti & Paul F. Litva, "Integrating Customer Requirements into Product Designs" (1995) 12 *Journal of Product Innovation Management* 13–15.

The European network of supranational and national public authorities supports business activities concerning traceability from a public health and consumer protection point of view. Two separated systems of rapid exchange of information with respect to the tracing, withdrawal and recall of dangerous products are in operation. RAPEX is executed on the basis of the GPSD⁴⁸, exclusively for warnings concerning non-food products.⁴⁹ A similar system referred to as RASFF is operated for information on unsafe food (and feed) products and based on the GFL.⁵⁰ Notifications are published on a weekly basis on the web sites of the European Commission.⁵¹ By the way, the difference in the presentation format of these public warning systems is striking: RAPEX is conveniently arranged: clear, detailed and informative with a photograph of the hazardous product; RASFF on the other hand is obscure, cryptic, and mysterious, to put it mildly: not informative at all.

6. Presumption of Conformity with General Safety Requirement

A remarkable flexibility is built into the New Approach part of European product safety law. As pointed out in Section 2 of this paper (product safety law *acquis*), the so-called New Approach is a combination of essential safety requirements that are legally binding on the one hand, and detailed technical standards being offered to manufacturers for voluntary use on the other hand. Having followed certain conformity to standards assessment procedures successfully, the assessed products are legally presumed to be safe and are entitled to be marked CE. This is believed to be an efficient way to legislate safety obligations. The legally binding fundamental safety requirements can remain abstractly vague and unchanged for many years, while the quickly adapted detailed standards can more easily keep pace with new developments and innovations in technology. Moreover, specific expertise is likely to be better applied in standardisation adaptations.⁵²

Another efficient characteristic of the New Approach model is that the assessment procedures connect perfectly to businesses' Total Quality Management prac-

⁴⁸ Article 10, Chapter V (Articles 11–13) and Annex II GPSD. The database is located at <http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm>.

⁴⁹ See: Hodges, "A New EC Directive on the Safety of Consumer Products" (2001), *op cit* at 278.

⁵⁰ Article 35 GFL, located at http://ec.europa.eu/food/food/rapidalert/index_en.htm.

⁵¹ Which is curious in the case of the RASFF, the rapid exchange system for food and feed, because it is based on article 35 GFL and this article is in Chapter III of this Regulation. This chapter is entitled: "European Food Safety Authority". Thus one logically might expect RASFF to be accessible via the website of EFSA: <http://www.efsa.europa.eu/en.html>.

⁵² Certainly, I am aware of serious criticism that has been put forward against this regulatory complex: the combination of mandatory fundamental safety requirements and voluntary standardised technical specifications has been characterised "private regulation in European public law". See: H. Schepel (2005), Chapter 7, especially 225–231. In spite of this, the build-in flexibility as such remains an attractive feature provided the democratic deficit will be taken care of. This subject is beyond the focus of this paper.

tices. The management function area of product quality covers all phases of the design, production, pre-sales and after-sales processes of all products (and services), hence it is called Total Quality Management. Product Quality Management procedures are incorporated in the “New Approach” subsystem: Quality Management *modules*⁵³ are the means to assess the conformity of products, product types, design and/or production processes to safety requirements. The higher the expected product safety risk, the more extensive the assessment procedure module. Conformity assessment results in CE-marking.

The GPSD has made this presumption of safety by conformity to standards an *overall* principle in non-food safety.⁵⁴ This principle is even broadened compared to products governed by the New Approach.⁵⁵ In circumstances where technical standards do not (yet) exist, the conformity of a product to the general safety requirement shall be assessed by taking into account in particular certain Directives on product safety assessment, sectoral product safety codes of good practice, the state of the art and technology and reasonable consumer expectations concerning safety. This principle does not interfere with the powers of national public enforcement authorities to take appropriate measures to restrict the marketing of hazardous products or to require withdrawals and recalls. This ultimate corrective is the final piece of the legal principle that safety is presumed and is therefore called “safeguard clause”.⁵⁶

So, the presumption of conformity principle is not an exclusive characteristic of the New Approach any more, but is nowadays a common part of the general safety requirement concerning all non-food products. What about food products in this respect? The GPSD applies to all consumer products “in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned” (Article 1(2) GPSD). Since 2002 the GFL Regulation is such a specific provision governing food product safety, thus the conclusion must be that the GPSD is not applicable to food products and the presumption of safety is absent in the food domain. While the GPSD states “A product shall be presumed safe as far as ...” (Article 3(2)), the GFL reads to the contrary “Food shall be deemed to be unsafe if ...” (Article 14(2)). Although the Articles 13 (international standards) and 14(7–9) (conformity to specific European or national provisions) GFL could be recognised giving the initial impetus to a similar approach, the presumption of safety concept is not (yet) a real part of the food law domain. Although the supply chain management focus, popularly referred to as *from farm to fork*, is not at all contrary to Total Quality Management practices, the GFL

⁵³ Abbott & Tyler (1997), Hanson (2005). See also Sebastian Farr, *Harmonisation of Technical Standards in the EC*, 2nd ed (Wiley & Son 1996) at Annex 5.

⁵⁴ See Chapter II (articles 3 and 4) GPSD.

⁵⁵ See: H. Schepel (2005) at 230.

⁵⁶ Hodges (2005) at 171. H. Schepel (2005) at 235–236 mentions a related matter which he calls “safeguard procedure”: it is about what to do if public authorities take the position that private standards do not meet public law safety requirements.

nevertheless does not refer to corporate quality management instruments. In food safety matters one relies heavily on public inspection by the authorities (see for instance Article 17 GFL).⁵⁷

7. Programme “Better Regulation”⁵⁸

A very big and long-term European law reform operation is going on, which can be characterised, roughly speaking, as a combination of the cleaning-up of parts of the existing legal acquis on the one hand and statements of good intentions for a better quality of future legal instruments on the other hand. In the Interinstitutional Agreement on better law-making,⁵⁹ the European Parliament, the Council and the Commission agreed to practice general principles such as democratic legitimacy, subsidiarity, proportionality and legal certainty. They promise a clear choice of legislative instrument and a clear statutory basis in the Treaty. In the context of this paper readers may well think of the choice for a regulation or a directive and legislative powers based on either the internal market or consumer protection and/or public health. Section 14 of the Agreement, for instance, states: “The Commission will provide a clear and comprehensive justification for the legal basis used for each proposal.” Section 35 announces to firstly update and condense existing legislation and, secondly, to simplify it significantly. In 2005, the Commission published a communication in which the connection is made with the so-called (revised) Lisbon Agenda “for achieving growth and jobs in Europe”.⁶⁰

This Better Regulation programme is extremely important. Several methods for the simplification of the body of legislation (the “acquis”) are mentioned, one of them being a modification of the regulatory approach. The approach could be modified in two ways.

1. Co-regulation of essential requirements, for instance standardisation of technical specifications by independent (private) bodies. An explicit reference is made to the New Approach and the CE-marking methodology.
2. The use of Regulations instead of Directives is propagated. In many cases, regulations are much more suitable legal instruments: they enable immediate application, represent genuine European supranational law

⁵⁷ Ladina Caduff & Thomas Bernauer, “Managing Risk and Regulation in European Food Safety Governance” (2006) 23 *Review of Policy Research* 153–168.

⁵⁸ Stephen Weatherill (ed.), *Better Regulation : Studies of the Oxford Institute of European and Comparative Law, Vol 6* (Hart Publishing, Oxford and Portland, Oregon 2007).

⁵⁹ OJ C 321/1, 31.12.2003.

⁶⁰ “Implementing the Community Lisbon Programme: A strategy for the simplification of the regulatory environment”, Brussels 25.10.2005, COM(2005) 535 final.

and therefore contribute to the simplification of existing and future legislation.

Concrete proposals are the following ones.⁶¹ The intention to concentrate several regulations of additives in foodstuffs, like sweeteners and colours, in one single act is mentioned. Furthermore, four related Directives concerning the labelling of foodstuffs should be reframed into one single Regulation. And finally, no less than 25 New Approach-Directives containing so-called essential safety requirements give rise to simplification of the certification rules, perhaps in a few or just one Regulation. Regularly, progress reports are published, providing information about the current state of affairs, also in the case of partial programmes, such as the consumer acquis review⁶² and recently the very interesting so-called “New Internal Market Package for Goods” proposals.⁶³

8. Summary of Observations and Findings

This paper’s point of departure was to observe that the EC Treaty offers several possibilities to base product safety provisions, either in the part that governs the establishment of the internal common market or in the part that enables the Community to support the member states in their policies concerning public health and consumer protection. Proposals must have a high level of protection, taking into account any new developments based on scientific facts. On this basic legal level there is no sign of the dichotomy food/non-food.

These are the fundamentals of a two-layer regulatory complex that could be named the Product Safety Law Acquis. On the general level we have found both possible legal instruments: a Regulation, and Directives. In the private law sphere of the Product Liability Directive there is no need to distinguish between food and non-food products. The distinction food/non-food has become eye-catching from the moment a self-executing Regulation General Food Law introduced general principles of food safety and put the European Food Safety Authority into function. On the European level a specific authority for the safety of non-food is absent. The safety of non-food products is still regulated in an indirect way by Directives: on the general level by a revised General Product Safety Directive and on product group level by the New Approach Directives (CE-Mark).

Insofar product safety policies could not legally be based on the establishment of the internal market and the free movement of goods, the combination of public health and consumer protection offers an excellent base for policy action: the prevention of injury and the promotion of safety, intrinsic to product safety, serve both

⁶¹ See Annex 2 to COM(2005) 535 final, pages 27, 47, 50 respectively.

⁶² COM(2006) 689, 690, 691 final, Brussels 14.11.2006.

⁶³ COM(2007) 35, 36, 37 an 53 final, Brussels 14.2.2007.

goals very well. The initially proposed programme of Community action in these fields for the period 2007–2013 would have made a proper fit. Although food safety was connected to public health, and the safety of non-food products to the field of consumer protection, at least the combined area of consumer product safety would have been served from under the one roof of a welcomed Executive Agency with a Health Department and a Consumer Institute department.

The precautionary principle is referred to in the food safety legislation and in the safety of non-food provisions as well. The principle legitimises taking provisional risk management measures in cases of safety uncertainties and matches a high level of protection with scientific developments. Speaking of risk management, the practical execution of the concept of traceability is a condition *sine-qua-non* for producers to avoid or limit the consequences of product liability and for public authorities to prevent injuries as much as possible. Regarding traceability the dichotomy food/non-food is not relevant at all. In terms of management science traceability is a kind of reverse logistics: another variety of the management of the supply chain. Expressions of consumer satisfaction and dissatisfaction with the use of products should enable product designers and developers to renew consumer products. Risk management actions and Total Quality Management procedures are related areas in which the dichotomy again is not relevant. The New Approach draws heavily on modules used in TQM. Having followed successfully certain assessment to standards procedures, conformity with fundamental safety requirements delivers a precious legal presumption of safety. This presumption of conformity principle has even been widened to the whole area of non-food products safety. Without much exaggeration one can stipulate that non-food products are legally presumed to be safe while according to the GFL food products are deemed to be unsafe.

Finally, the Better Regulation Programme stimulates more frequent use of the Regulation as a law-making instrument, and recommends the efficient legislative technique of reference to standardised essential requirements drafted by private normalisation organisations as in the non-food New Approach.

9. Discussion

Above all things, the right to safety is still considered a basic consumer right since the early days of the consumer movement and the emergence of consumer law.

A legal system supporting the prevention of injury and the promotion of safety is of crucial importance for Business-to-Consumer exchange relations. The Product Safety Law *Acquis* (food/non-food) is therefore connected to Business Law as well as related to Consumer Law. Indeed, it overlaps both areas of law. In this context the concept of the *Confident Consumer* draws attention. It has been argued that the “confident consumer” has been abused to justify the legislative powers of the Commission: the more substantive rights the European consumers have, the more they are supposed to be prepared to go cross-border shopping. But facilitating the

execution of procedural rights should even more strengthen consumer confidence under the heading “easy access to a counterparty”.⁶⁴ Product Safety law (food/non-food) contributes to consumer confidence by offering multi-party liability for compensation of damage caused by defective products, and also by providing easy access to national surveillance authorities in cases of already marketed hazardous products.

A different, complementary coloured concept of consumer confidence is even more relevant. The influence of EC Consumer Law (and Competition Law) on innovation and new technology is researched, and some preliminary thoughts have been offered on the relationship between consumer protection and innovation.⁶⁵ Indeed, consumer confidence is affected by the extent to which consumers are protected from faulty and unsafe goods. Undoubtedly, competition law and consumer law work together to support innovation.⁶⁶ Competition law aims at a better market performance of competing businesses by stimulating them to present innovative offerings to the public. Product safety law is considered to be a part of Consumer Law from the viewpoint of supporting consumer confidence by securing the safe use of a marketed product. Thus consumers are confident to buy new products and experience their characteristics. Product safety law should give producers reasonable indications about a product’s safety performance requirements consumers are entitled to. These requirements should combine flexibility, to enable product developers to innovate the product’s design, with a secure safety level in order not to undermine consumer confidence.

The European Safety Law *Acquis* is concerned with prevention of risks caused by defective products and compensation of damages and injuries. At the compensation side there is no sign of the distinction food/non-food; one Directive covers the whole area. At the prevention side the dichotomy plays a twofold role:

- On the general level, a Regulation contains general principles of food safety and gave birth to the EFSA and a Directive governs non-food safety;
- The New Approach principle presumption of conformity with safety requirements is reserved for non-food products.

This paper’s search for an explanation of the necessity of the dichotomy food/non-food has resulted in proof for the opposite: by researching some core concepts we have found strong indications to propose general principles of product safety management, food and non-food alike: the supply chain management focus, the precau-

⁶⁴ Thomas Wilhelmsson, ‘The Abuse of the “Confident Consumer” as a Justification for EC Consumer Law’ (2004) 27 JCP 317–337.

⁶⁵ Christian Twigg-Flesner, ‘Innovation and EU Consumer Law’ (2005) 28 JCP 409–432.

⁶⁶ See Jules Stuyck, ‘EC Competition Law After Modernisation: More than Ever in the Interest of Consumers’ (2005) 28 JCP 1–30. And *specifically*: Katalin Judit Cseres, *Competition Law and Consumer Protection*, European Monographs nr 49 (Kluwer Law International 2005).

tionary principle and other provisional risk management measures like traceability. The current Better Regulation programme⁶⁷ is an excellent opportunity to simplify the Product Safety Law Acquis by decreasing the number of provisions and increase transparency by the drafting of a General Product Safety Regulation (food/non-food), laying down general legal principles of product safety management. This legislative project also provokes an inquiry into the advisability of one European Product Safety Authority, probably with a food and a non-food department. At least one good reason to follow this proposal is the creation of the cross-fertilization of knowledge, a mutual learning experience of food and non-food safety policy surveillance officials. Besides, many consumer goods have both a food and a non-food dimension:⁶⁸ one can think of children who put toys in their mouth, the famous chocolate egg with a non-food surprise inside and the possible interaction or migration between the package and its food content. Despite obvious differences on the executive level of practical application and surveillance procedures, this situation enables taking advantage of the exploration of common grounds, and share progress instead of emphasizing differences. The present dichotomy is disadvantageous.

To bring the policy organisation in line with the structure of the Treaty is another proposal that increases transparency. One article is specifically devoted to public health policies and another one is related to consumer protection. Yet the Commission's DG SANCO is subdivided tripartitely: Food and Feed Safety, Consumer Affairs and Public Health. Non-internal market food safety matters are usually related to the public health policy area and non-food safety subjects are usually connected to the area of consumer protection under the label of "product safety". Both rapid alert systems RAPEX and RASFF demonstrate by numerous examples that food safety matters are as tightly related to consumer protection as non-food safety issues are related to public health. So again it seems not a good idea to split product safety in a food and a non-food part, at least not at this level and in this way. Product safety is overarching the whole area of public health (the prevention of injury) and consumer protection (the promotion of safety), being a joint-venture of these two departments it should be positioned as a collective subdepartment in DG SANCO. Only if a threesome should be inescapable, a subdivision in Public Health, Product Safety and Consumer Protection is to be considered.

This paper's reasoning to build a legal system on similarities instead of emphasizing differences in food and non-food safety management affairs encounters perhaps one impregnable barrier. Most striking of the present research on EC food and

⁶⁷ See R. Daniel Kelemen & Anand Menon, "The Politics of EC Regulation" (Ch. 10) in Stephen Weatherill (ed.) *Better Regulation, Studies of the Oxford Institute of European and Comparative Law, Vol 6* (Hart Publishing, Oxford and Portland, Oregon 2007) at 175–189 (especially section C: New Directions in EC Regulation 182).

⁶⁸ Bryan Harris, "A Comparison of U.S. and E.U. Product Safety Regulations: A Case Study" (1997) 8 *Risk: Health, Safety & Environment* 209. This paper compares approaches toward product safety regulations with particular reference to a selected product sector, namely products in which edible and inedible materials are combined.

non-food safety law has been the discovery of a fundamentally contrastive legal approach to food and non-food safety. In a way we do rely on the systems taking care of non-food safety.⁶⁹ Our attitude is inspired by what we are used to refer to as “New Approach”, with its core characteristic of *presumption of conformity* to fundamental safety requirements and a safeguard clause as final piece. The CE-mark is the icon of our trust.⁷⁰ On the other hand and quite to the opposite, agricultural disasters and diseases have made a tremendous impact on societal (dis)trust in the ability of the food industry to manage the production of sound foodstuffs. It might be a psychological block, an irrational lack of trust: “... food safety is mainly an emotional construct ...”.⁷¹ Does a careful execution of the embedded in a supply chain management approach (“from farm to fork”), of course completed with a safeguard clause, restore reliability? A recently published Dutch doctoral thesis’ survey reported:

“Consumers were found to have a rather simple view of who is responsible for food safety. They have a normative view of the function of each individual actor (...); at the same time, they simply expect that all actors together should contribute to safety from “farm to fork”. In the event of a food safety incident they want to know what caused the incident, but they are not interested in finding out who is *formally* responsible. Consumers’ perceptions of responsibility might differ from a juristic perception of blame and responsibility.”⁷²

Certainly, the consuming public will appreciate the use of a CE-marking for food products. Unlike Regulations (instead of Directives) and Safety Authorities, the CE-mark appeals to the consumer and is capable to help restore *consumer confidence* in (food) product safety. But do we societally dare to introduce the presumption of conformity rule for the safety of food products? Certainly, the (New Approach) technique of reference to private standards in use for many non-food products seems not at all conflicting with a supply chain management view.⁷³ It

⁶⁹ Although defective nonfood products can be as dangerous and even as fatal as defective food. While finalising this paper ultimo December 2007 a disaster happened in my country. In Arnhem (The Netherlands) four girls between 1 and 8 years of age, belonging to one family, died in their sleep by a fire in their home caused by an overheated electrical cord.

⁷⁰ Of course, the New Approach system with its CE icon does not guarantee product safety, but the recent Mattel toy safety recalls show that the system is in place and working as it should: *Health & Consumer Voice*, Newsletter on food safety, health and consumer policy from the European Commission’s Health and Consumer Protection DG, September 2007.

⁷¹ Vincent Wiegerinck *Consumer Trust and Food Safety – An attributional approach to food safety incidents and channel response*, doctoral thesis University of Tilburg 2006 (ISBN 90–72725–921) 202.

⁷² Wiegerinck (2006) at 192 (his *emphasis* in citation).

⁷³ Specially for food: Gabriele Jahn, Matthias Schramm & Achim Spiller, “The Reliability of Certification: Quality Labels as a Consumer Policy Tool” (2005) 28 JCP 53–73. Wiegerinck (2006) *supra*, 195 has characterised the supermarket as the “*gatekeeper*” of the channel; see therefore Tetty Havinga,

might be a good idea to apply the New Approach to packaged preserved foods for a start. The Better Regulation programme offers the opportunity.⁷⁴

10. Conclusion⁷⁵

The EC-Treaty provisions concerning the development of the internal market do not force a distinction between food safety and non-food safety. The EC-Treaty provisions concerning public health and consumer protection also do not oblige legislators to make the distinction between food and non-food in product safety law matters. There is no legal need for the classification of food safety to the domain of public health and arrange the safety of non-food products to the policy area of consumer protection. Moreover, the habit in policy development to speak of food safety on the one hand and “product safety” on the other hand is confusing. The aspiration of a high level of protection does not indicate the use of different legal instruments to deal with the safety of food (Regulation, EFSA) and non-food either.

Neither the precautionary principle, (other) risk management issues, liability rules concerning defective products, nor traceability obligations and monitoring duties urge to assess food and non-food safety issues differently. Public warning systems (RASFF, RAPEX) do not indicate a need for a relative higher attention to food safety or the use of more effective prevention methods. The need to cope with safety risks in the non-food area is as much urgent as in food matters.

The Better Regulation Programme offers an excellent opportunity to reform European product safety law:

- use (a) Regulation(s) for both food and non-food safety protection
- establish a balance in the scientific support of food and non-food product safety: enlarge the EFSA to a truly European Product Safety Authority – if need be organised in a food and a non-food department.

“Private Regulation of Food Safety by Supermarkets” (2006) 28 *Law & Policy* 515–533. See also: Bernd M.J. van der Meulen & Annelies A. Freriks, “Millefeuille – The Emergence of a Multi-Layered Controls System in the European Food Sector” (2006) 2 *Utrecht Law Review* 156–176 at <http://www.utrechtlawreview.org/archive.html>.

⁷⁴ Caoimhín MacMaoláin, *EU Food Law – Protecting Consumers and Health in a Common Market* (Hart Publishing, Oxford – Portland Oregon 2007) at 276.

⁷⁵ Although: “No simple conclusion regarding consumer safety problems can be drawn”, so to speak *avant-la-lettre*: Ludwig Krämer, “EEC Action in Regard to Consumer Safety, Particularly in the Food Sector” (1984) 7 *JCP* 473–485.

ANNEX**CONSOLIDATED VERSION
OF THE TREATY ESTABLISHING THE EUROPEAN COMMUNITY***Article 14*

1. The Community shall adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992, in accordance with the provisions of this Article and of Articles 15, 26, 47(2), 49, 80, 93 and 95 and without prejudice to the other provisions of this Treaty.
2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty.
3. The Council, acting by a qualified majority on a proposal from the Commission, shall determine the Directives and conditions necessary to ensure balanced progress in all the sectors concerned.

Article 94

The Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market.

Article 95

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.
2. (...)
3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on

scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. (...) 5. (...) 6. (...) 7. (...) 8. (...) 9. (...) 10.(...)

PUBLIC HEALTH

Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

(...)

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. (...) 5. (...).

CONSUMER PROTECTION

Article 153

1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.

2. Consumer protection requirements shall be taken into account in defining and implementing other Community policies and activities.

3. The Community shall contribute to the attainment of the objectives referred to in paragraph 1 through:

(a) measures adopted pursuant to Article 95 in the context of the completion of the internal market;

(b) measures which support, supplement and monitor the policy pursued by the Member States.

4. (...) 5. (...)