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BSE, CJD, mass infections and the 3rd US Restatement

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Introduction

In 1993 when I was writing Product Liability1 I wanted an example of a risk that was almost unanimously regarded as negligible. I wanted to ask the question of whether a bizarrely remote suspected risk could deprive a defendant of the development risk defence in the 1985 European Directive on Product Liability.2 My choice has turned out to be an even better illustration of the problems I was highlighting than I imagined. I wrote:3

Should those now supplying meat be held liable if eventually it is shown that the factor responsible for bovine spongiform encephalopathy (‘mad cow disease’) has been passed via that meat to humans to cause Creutzfeldt–Jakob disease – a risk which as yet is given little credence in scientific circles, but a risk for which the technical means of eventual detection do exist?

This article is one step in looking at the challenge that bovine spongiform encephalopathy (BSE), Creutzfeldt–Jakob disease (CJD) and other mass infections4 of product sectors throw out to the product liability regimes around the world. Certain characteristics make this challenge particularly severe. First, the dangerous

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4 On which see J. Cooke, Cannibals, Cows and the CJD Catastrophe (Milson’s Point, NSW: Random House, 1998).
infection is not part of the condition of the product which the supplier 'intended' in the sense of 'desired'. Secondly, the dangerous infection is known or suspected to be 'generic', that is, potentially it has affected an entire product sector such as the beef industry or the blood product sector. Thirdly, this sector is an 'essential' product sector in that it does not have realistic substitutes. Fourthly, the dangerous infection in the product type is not present in each item of the product but testing each item for that infection is impossible or impractical. Fifthly, the dangerous infection was present before any 'manufacturing' or 'production' process occurred. And sixthly, the infection is not necessarily limited to one generation of products but can be transmitted to following generations.

In this paper I will concentrate on the situation under the US Restatement (Third) of Torts: Products Liability published in 1998. In a companion work, I have already considered how such cases may be handled under the European Directive which has served as the template for the special products laws adopted in the EU Member States, Japan\(^5\) and Australia.\(^6\)

**General**

Recently, the Reporters of the Restatement (Third) of Torts: Products Liability, Professor James Henderson, Jr. and Professor Aaron Twerski, argued that the sparse provisions of the European Directive are 'inadequate substantive standards in the form of overly simplistic rules of decision [that] will present judges and lawyers with conceptual difficulties in trying to respond to products liability claims rationally, consistently, and fairly'.\(^7\) European complacency, the Reporters believe, is attributed to:\(^8\)

The idea that a vague, undifferentiating standard for defect is acceptable, and even preferable, because courts will 'work out the details' on a case-by-case basis ... But the experience in the United States over the past forty years

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\(^8\) Ibid., 14–15.
strongly suggests that courts – even fairly sophisticated courts that confront a substantial and steady caseload of design defect cases – may require thirty or forty years to 'get it right'... For the European Community... 'to leave it to the courts' is to overlook the obvious gains to be had from drawing on the American experience.

The Reporters even claim that 'a modern industrialised state’s system of products liability in tort [will be driven] to accept the organization of the defect concept reflected by recent developments in...[the United States]' and manifested by the Restatement (Third) of Torts: Products Liability.

In a recent article in the Washburn Law Journal I put forward a number of reasons why many non-Americans find this perspective less than compelling. Here I focus on what seems to be the principal complaint of the Reporters. This is that laws such as the 1985 Directive do not distinguish between types of defect. The reason the Reporters complain about this is that it blocks products regimes that use the Directive or its clones from adopting the distinctive approach that the Reporters say US courts found to be 'the only sensible standard for defect in classic design cases'.

This standard, they argue, is the requirement that the plaintiff adduce convincing proof of a reasonable alternative design (RAD) in most design cases but not in manufacturing cases. The Reporters argue that this requirement is mandatory in those design cases – the vast majority – that fall outside certain ‘special’ classes of product defect – a large residual class they call ‘classic design cases’.

A heated debate took place in the USA over this RAD requirement which I discuss elsewhere. Here I will argue that a consideration of BSE, CJD and other mass infection cases casts doubt on both of the twin assumptions on which the Reporters built the structure of the Restatement (Third) of Torts: Products Liability. The first of these is the assumption that it makes sense, either theoretical or pragmatic sense, to carve off for ‘special’ treatment classes of product claims according to certain proof shortcuts and according to product classes such as food. The second is the assumption that for ‘non-special’ products, such as clothing, it makes sense to treat product defect claims differently according to whether or not the product condition that caused the injury is classed as a ‘manufacturing defect’, a condition that the Reporters define as departing from its intended design. In short, my argument is that had the Reporters addressed their minds to the BSE/CJD phenomenon that was exploding in Europe at the time they formulated the Restatement (Third) of Torts:

9 Ibid.
13 See Restatement (Third) of Torts: Products Liability § 2(a). See text accompanying n. 39 below.
Products Liability in 1993 through 1998, they might well have realised the incoherence and inadequacy of both these fragmented arrangements of doctrine.

Structure of the Restatement: fragmentation according to certain proof shortcuts and according to product class

Structurally, the Restatement (Third) of Torts: Products Liability is an exceptionally elaborate affair. First, it gives special separate treatment to certain classes of products such as food and prescription drugs. The special classes are where there is a claim involving circumstantial evidence supporting inference of product defect (§ 3), a sort of generously reinterpreted res ipsa loquitur class; proof of non-compliance with product safety statutes or regulations (§ 4); manifestly unreasonable design, other terms for which are categorically defective design, generically defective design and egregiously dangerous product type (§ 2 cmt. e); components (§ 5); prescription drugs and medical devices (§ 6); food products (§ 7); and used products (§ 8).

While this separate treatment may reflect past case law fragmentation, it could be argued that the Reporters missed a critical opportunity for guiding US courts to a more coherent, less fragmented approach to product claims. For example, as we will see, the issues thrown up in the USA by ‘naturally occurring’ matter, such as bones in fish soup and viruses in oysters, are exactly some of those that constitute the core challenge that BSE/CJD-type infections present to our product regimes in whatever product type they occur. The BSE/CJD challenge is massively more serious because such risks can be generic to an entire class of ‘essential’ product such as beef, blood or vaccines.

It is similarly remarkable that human blood and human tissue, even when supplied commercially, are not subject to the Restatement (Third) of Torts: Products Liability. The Reporters briefly attempt to justify this omission on the basis that most States have ‘blood shield’ statutes limits:14 ‘The liability of sellers of human blood and human tissue to the failure to exercise reasonable care, often by providing that human blood and human tissue are not “products” or that their provision is a “service”. Where legislation has not addressed the problem, courts have concluded that strict liability is inappropriate for harm caused by such product contamination.’

Again, it could be argued that the Reporters lost a crucial opportunity to address the underlying policy dilemmas that led to such artificial and anomalous15 treatment of these infection cases. This is especially significant given that the issues

14 § 19, cmt. c. See also Reporters’ Note on § 19, cmt. c.
15 That, prima facie, blood products fall well within the catchment of US product rules is illustrated by the (pre-blood shield statute) case of Rostocki v. Southwest Florida Blood Bank, Inc., 276 So 2d 475 ( Fla, 1973) which held that sale of blood constituted sale of a product and that the defendant blood bank was subject to common law strict liability for products commercially supplied.
involved in the US experience with hepatitis and HIV-infected blood products presented the very sort of policy issues of public interest (especially availability of the essential product type) versus private interest that the BSE/CJD phenomenon does.

In general it is surprising for a Restatement published in 1998 that there is no mention at all of CJD or of BSE, while the sole mention of hepatitis and HIV occurs in the above obscure passage explaining the non-coverage of human blood and human tissue. Of course, the Reporters might defend this omission on the basis that there is little or no US products liability case law concerning such potentially 'generic' infections. But food chain contamination disasters, with the real prospect of inter-generational transmission, are not unknown in the USA. For example, in 1973 toxic chemicals were accidentally fed to dairy cattle in the State of Michigan with the result that virtually all of the 9 million in the State's human population became permanently contaminated by the hazardous chemical polybrominated biphenyl. Other cases include the toxic waste dump at Love Canal and the radiation leak from the Three Mile Island nuclear plant. Foreign food chain disasters, such as the mercury contamination of food chains in and around Minamata Bay (Japan) in the 1950s which killed more than 1,000 and crippled thousands more, have also received prominent coverage in the USA. Today American deer and elk carry a form of BSE and three American hunters have already died of CJD.

It is true that the most high profile of these cases were not formulated, and in many cases could not feasibly have been formulated, as products liability cases, but this merely goes to confirm the concern I share with other commentators that the

16 Or even of the Legionnaire's disease case law. See, e.g., Brennen v. Mogul Corp., 557 A 2d 870, 872 (Vt, 1988) where a plumber sued the manufacturer of water treatment equipment when he allegedly contracted Legionnaire's disease while working on a cooling tower on the basis that the manufacturer's equipment and chemicals did not prevent growth of Legionella bacteria; In re Horizon Cruises Litigation, 101 F Supp 2d 204 (SDNY, 2000) passengers sued after a defective whirlpool filter caused them to contract Legionnaire's disease while aboard the defendant's cruise ship; Humphrey v. Riverside Methodist Hosp., 488 NE 2d 877 (Ohio, 1986) where the plaintiffs sued the hospital for negligence resulting from contraction of Legionnaire's disease; Methodist Hospital v. Ray, 551 NE 2d 463 (Ind Ct App, 1990) aff'd 558 NE 2d 829 (Ind, 1990) where the hospital negligently allowed its premises to become infected with Legionella bacteria; Nell v. Western Inns, Inc., 595 NW 2d 121 (Iowa, 1999) where the plaintiff contracted Legionnaire's disease, allegedly while staying at a hotel operated by the defendant.

17 See J. Egginton, Bitter Harvest (London: Secker & Warburg, 1980), 14, 275, 281, 307: 'Scientists estimate that only about 10% of the body burden of PBB contamination being carried by 9 million people would be excreted in their lifetimes.' For case law, see e.g., Michigan Chemical Corporation v. American Home Assurance Company, 728 F 2d 374 (6th Cir, 1984); Oscoda Chapter of PBB Action Committee, Inc. v. Department of Natural Resources, 268 NW 2d 240 (Mich, 1978).


creation of special rules for injuries associated with commercially supplied products warps our law of obligation and blinkers us to important common themes that run through personal injury cases generally.22

**Structure of the Restatement: fragmentation according to classification of dangerous condition**

The second type of fragmentation under the Restatement arises where a product claim does not fall into one of the special product-type classes. In such circumstances the case will be dealt with under section 2 and thereunder according to whether the product condition is classed as a ‘manufacturing defect’, a design condition or a warning condition. Again, as we shall see, the Reporters of the Restatement (Third) of Torts: Products Liability lost the opportunity, squarely presented by the infection-in-food cases and HIV/CJD infection-in-blood cases, to examine the wisdom of the critical idea of a ‘manufacturing’ defect or, at the least, to forge an appropriate definition that would unambiguously classify such cases as within or outside the crucial notion of manufacturing defect.

In the fish soup case the deleterious element in the product, a residual stray bone, was present in the raw material well before any ‘manufacturing’ process began. In this case, as with the BSE/CJD cases, the production process was not the origin of the danger. In this sense such cases are not like the ‘classic’ form of manufacturing defect cited in the US products liability literature where the dangerous aspect is introduced into the product by the industrial process.

On the other hand, the Reporters’ definition of ‘manufacturing defect’ is where the product departs from its ‘intended’ design. Certainly the soup producer would not have intended his or her soup to retain the dangerous bone in the sense of ‘desiring’ that it be present. This suggests the soup condition would fall inside the Restatement definition of ‘manufacturing defect’. Moreover, the soup producer may well have been aware of the risk of its presence and have been unable to avoid that risk, at least by reasonable means. Emphasis on this aspect also brings the case close to another characteristic of the classic examples given in the literature of manufacturing defects, namely, where a producer of widgets suspects, fears or knows that one in 100,000 will contain a dangerous departure from the production line norm but rightly believes that it is impossible to avoid that risk, at least by reasonable means. This type of process-introduced but unavoidably dangerous condition was the very type that was targeted by the original reformers who, forty years ago, formulated the rule reflected in section 402A of the Restatement (Second): Torts. Today such conditions are unequivocally regarded as within the ‘manufacturing defect’ classification. That a plaintiff may be able to convince the court to accept this classification for his or her ‘infected product’ is critical because this classification brings

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with it an automatic determination of defectiveness, quite independent of the sort of cost/benefit and reasonable alternative design considerations that might otherwise plague the plaintiff’s argument for defectiveness.

**How would a BSE/CJD case be dealt with under the Restatement?**

We do not yet know how extensive the BSE/CJD infection has become. So far five and a half million animals have been slaughtered in Britain as a means of containing the BSE plague, and though only 113 humans are known to have died of the related wave of CJD, scientists have suggested that up to 135,000 people in Britain may have contracted CJD.\(^{23}\) Imagine a raft of claims brought in the future by people infected with BSE/CJD from generic products such as meat,\(^ {24}\) dairy products,\(^ {25}\) blood\(^ {26}\) and blood products (e.g., vaccines and plasma),\(^ {27}\) human tissue,\(^ {28}\) leather\(^ {29}\) or woollen clothing and the water supply.\(^ {30}\)

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\(^{23}\) See http://www.defra.gov.uk. In June 2001 it was reported that UK consumers might still be eating BSE-infected meat because of cross-contamination in abattoirs: J. Melklé, ‘BSE Meat Risk from Abattoir Culls’ *Guardian* (6 June 2001). So far the known human BSE/CJD death toll in the UK is at least 113 and scientists have suggested that up to 135,000 people in Britain have been infected: *The Telegraph* (15 January 2002); *The Times* (26 October 2001).

\(^{24}\) On 20 March 1996 the UK Government announced that BSE in cattle had been linked to CJD in people. Some months later the EU imposed a worldwide ban on British beef exports, which was lifted on 1 August 1999: D. Brown, “France Had “No Excuse” for Failing to Lift Ban on British Beef” *Daily Telegraph* (20 June 2001). See also V. Elliott, ‘Scientists to Test if Beef is the Cause of CJD’ *The Times* (18 May 1999). The UK adopted a policy of slaughtering an estimated 5 million cattle aged more than 30 months in an effort to eradicate BSE. See generally Lord Phillips *et al.*, *The BSE Inquiry*.


\(^{27}\) The UK government concedes that blood products including vaccines may be at risk of contamination by CJD: *The Sunday Times* (22 February 1998). Thenceforward the Department of Health advised (a) that the CJD risk with current blood supplies was ‘theoretical’ but (b) that experts agree that there is no way of guaranteeing this. See United Kingdom, *Hansard*, House of Lords, 11th Volume of Session 1997–8, 5 June 1998, volume 590, column 680; 5th Volume of Session 1999–2000, 30 March 2000, volume 611, column 985; 7th Volume of Session 1999–2000, 7 March 2000, volume 345, column 124 WH.

\(^{28}\) An early report of suspicions of the possibility of CJD infection from donated implanted tissue: *UK Mail*, 8–14 December 1997.

\(^{29}\) In the largest study to date, researchers found a link between CJD and exposure to leather including wearing it: C. Hall, ‘Research Fails to Find Link between Beef and CJD’ *Daily Telegraph* (10 April 1998).

\(^{30}\) On suspicions that part of the UK water supply is contaminated with BSE/CJD see *The Independent* (30 August 1997), 8.
The history against which such claims will be seen is certain to be complex. In relation to each chain of infection to the end type of product there will have been a period where the firm weight of official scientific opinion was that such infection could not enter that particular type of product (for example, the ‘cannot cross the species barrier into humans’ phase of the BSE/CJD ‘mad cow’ disease story). Then there will have been a period of growing professional speculation that this might be possible. A third period is where the general population can foresee a real possibility that such infection of the product type might occur. For example, in relation to the entire meat, dairy and blood supplies in the UK many citizens now speculate that there is a risk that an individual product may be BSE/CJD-infected (even if only a tiny fraction of individual products in the class are infected); they are ‘generically suspect’. That a similar suspicion exists abroad is illustrated by the banning in Australia, Canada and the United States of blood donations by people who had lived in the UK during the BSE/CJD outbreak. The stage is reached when the chain of infection into the product type is confirmed. There may then be stages where a screening test becomes available but is of low reliability and finally a stage when a highly reliable test becomes available.

How would such cases be dealt with under the Restatement (Third) of Torts: Products Liability? First, one must look to see if they might fall into one of the special classes.

There seems no way BSE/CJD cases could be handled under section 3, which allows a plaintiff with circumstantial evidence supporting the inference of product defect to get to the jury even though he or she has failed to show the following: that the product departed from its intended design; or that a reasonable alternative design could have been adopted; or what type of product defect (for example manufacturing, design or warning) was present. This is because section 3 rests on an inference of defect, and assumes a consensus about what defect means in relation to the relevant product. It follows that the clearest example of a case falling within section 3 is one where the product fails to perform its ‘manifestly intended function’ as where the brakes on a new car simply do not work and the driver is injured as a result. This falls squarely within section 3 because here, by definition, there is a consensus that this failure ‘bespeaks’ defect. But BSE/CJD-infected products will not usually fail in their intended function: infected clothing will still keep a person protected from the elements; infected food may still nourish; and infected blood may save a person from the threat of imminent death. It is not clear from section 3 what else besides a failure


32 It is worth noting that because the US rule applies in the first instance to all suppliers up the chain of distribution it is immaterial to this provision that the facts do not implicate the behaviour of any particular party. Contrast the classic ‘focused’ res ipsa loquitur rule under which the facts must not only bespeak negligence but they must bespeak the negligence of the defendant.
to perform its manifestly intended function might bring a product within the ambit of the section, so we may assume the BSE/CJD cases will rarely if ever be clearly covered by section 3.

Let us now posit the hardest plaintiff's case: that at the time of trial none of the infected products can be shown to have failed to comply with product safety statutes or regulations, and so would not fall into section 4.

Next we must also recognise that it would be extremely unlikely for a US court to declare that any of such cases fall into the class of manifestly unreasonable design contemplated in section 2, Comment e. This highly controversial provision was reluctantly included by the Reporters to accommodate a few isolated decisions where a US court had, even in the absence of proof of a reasonable alternative design, declared the product design to be defective 'because the extremely high degree of danger posed by...[it] so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use...the product'.\(^{33}\) The nature of BSE/CJD infection tends to apply to large market sectors where the risk seems low and the social utility is high in the context of available substitutes. UK citizens who eat beef\(^{34}\) or accept blood transfusions from domestic donors\(^{35}\) appreciate both sectors are generically BSE/CJD-suspect.

The end result, then, is that the treatment of the BSE/CJD cases under the Restatement (Third) of Torts: Products Liability would be highly fractured. BSE/CJD infection of vaccines will fall to be decided under section 6. BSE/CJD infection of meat and dairy products (and perhaps water) will fall to be decided under section 7, while BSE/CJD infection of human blood and human tissue will not be covered at all by virtue of section 19. BSE/CJD infection of leather or woollen clothing and so on will fall to be decided under the residual section, section 2, and therein will receive different treatment according to whether the product condition is classed as a manufacturing error (\(\S\) 2 (a)), a design condition (\(\S\) 2 (b)) or a warning condition (\(\S\) 2 (c)).

Despite the general claims of the Reporters for their Restatement, this fractured treatment that BSE/CJD cases would receive under the Restatement does not immediately seem to be the most effective way of addressing the 'conceptual difficulties in trying to respond to products liability claims rationally, consistently, and fairly'.\(^{36}\) In this context the 'gains to be had from drawing on the American experience'\(^{37}\) do not seem at all obvious. Perhaps the basic lesson from the USA here is that when a new legal rule emerges without a well-understood theoretical basis, which was certainly the birth conditions of section 402A of the Restatement (Second): Torts,\(^{38}\) there is a temptation for courts to give the rule 'structure' by artificially

\(^{33}\) Restatement (Third) of Torts: Products Liability \(\S\) 2, cmt. e.
\(^{34}\) See n. 23 above.  \(^{35}\) See n. 26 and n. 27 above.
\(^{36}\) Henderson and Twerski, 'What Europe, Japan and Others Can Learn'.  
\(^{37}\) Ibid.  \(^{38}\) See generally Stapleton, Product Liability.
compartamentalising fact situations. Certainly it is easy in theory (if not forensically) to distinguish fact situations involving infection from eating meat from those involving infection from wearing infected clothing. The question is: Does the law have sound reasons to afford separate treatment?

Another feature of these sections (6, 7 and 2) that would be relevant to BSE/CJD cases is that their treatment of the issues depends on whether the product condition that caused the injury is classed as a ‘manufacturing defect’ defined as ‘when the product departs from its intended design even though all possible care was exercised’.39 Crudely, under all these sections reasonable care is no answer in manufacturing defect cases for which liability is, therefore, strict no matter which supplier in the chain is sued.40 In contrast, in design or warning cases reasonable care is an answer. This means, for example, that a product with an unforeseeable design condition that causes harm cannot, by definition, be defective under the Restatement (Third) of Torts: Products Liability,41 while a product with an unforeseeable manufacturing error that causes harm is, by definition, defective.

The problem here is that the US experience as set out in the Restatement gives little conceptual guidance as to how and why, in design conditions, the determination of unforeseeability exculpates from liability; but that in manufacturing error conditions the determination of unforeseeability does not exculpate from liability. Moreover, since treatment of unforeseeability is so dramatically different according to how we define ‘manufacturing defect’, the fact that this is so unclear that it is not possible to say how we should classify mass biological infections such as HIV and, no doubt, BSE/CJD is, as a practical matter, a considerable gap in US jurisprudence. Are such infected products to be classed as manufacturing errors because they depart from the intended, in the sense of desired, condition of the end product? Or is the rationale for the strict liability imposed in the case of manufacturing defects embedded in the idea that such errors are introduced into the product by the process of manufacture, in which case such BSE/CJD-infected products fall outside that classification and outside the strict liability imposed on ‘manufacturing defects’ because the infection was present in the raw materials of the product?

The treatment of infection cases by the Restatement: raw materials versus food

Though, as the Appendix shows, US courts have had considerable experience of cases involving infected products, the Restatement (Third) of Torts: Products Liability, that is the case law it tracks, seems confused when dealing with such cases.

40 Strict liability may be defined as liability in relation to which it is not an answer for the defendant to prove that its conduct was reasonable.
41 Stapleton, 'Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective', 388, fn. 89.
It baldly classifies certain infection contexts as being ones of manufacturing errors and subject to strict liability because they depart from the intended design.\(^{42}\)

When raw materials are contaminated or otherwise defective within the meaning of s. 2(a), the seller of the raw materials is subject to liability for harm caused by such defects... a basic raw material such as sand, gravel, or kerosene cannot be defectively designed... The same considerations apply to failure-to-warn claims against sellers of raw materials.

[Concerning contamination of human blood and blood-related products by the hepatitis virus or the HIV virus.] Absent a special rule dealing with human blood and tissue, such contamination presumably would be subject to the rules of ss. 1 and 2(a). Those Sections impose strict liability when a product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.

On the other hand, the *Restatement (Third) of Torts: Products Liability* takes an exceptional attitude to food. Here the plaintiff cannot rely simply on the infection rendering the product a departure from its intended design and thus a manufacturing error. The plaintiff must also show the product fails the 'consumer expectations test'. Hence a harm-causing ingredient of the food product constitutes a defect only if a reasonable consumer would not expect the food to contain that ingredient.\(^ {43}\) Examples given include not only cases involving a failure to remove structural parts of the raw material such as a fish bone in fish chowder, a chicken bone in a chicken enchilada, and a pearl in an oyster, but also infection cases such as bacteria in clams and oysters.\(^ {44}\)

In fact, US case law on food infection cases is notoriously confused. It has failed to find a coherent line to distinguish 'adulteration' by infection, from infections that are 'an inherent aspect of the product'.\(^ {45}\) Moreover, this parallels the doctrinal confusion in the non-food infection contexts that have come to light. For example, to evade the difficult challenge to doctrine they present, certain (infected) live organisms such as parrots and gilts, have been judicially refused the classification of 'products' by US courts\(^ {46}\) in much the same artificial way some courts and statutes dealt with infected blood. In contrast, other courts have accepted the 'product' status of organic material but disagreed on the approach the law should take.

It is in this context of disarray that one should read the Third Restatement’s conclusion that, *in relation to food*, even infected substances are 'products' but that their defectiveness should be judged by 'consumer expectations':\(^ {47}\)

\(^{42}\) *Restatement (Third) of Torts: Products Liability* § 5, cmt. c; § 19, cmt. c.


\(^{44}\) *Ibid.*.  

\(^{45}\) *Ibid.*, § 2, cmt. h.


\(^{47}\) *Restatement (Third) of Torts: Products Liability* § 7, cmt. b.
A consumer expectations test in this context relies upon culturally defined, widely shared standards that food products ought to meet. Although consumer expectations are not adequate to supply a standard for defect in other contexts, assessments of what consumers have a right to expect in various commercial food preparations are sufficiently well-formed that judges and triers of fact can sensibly resolve whether liability should be imposed using this standard.

The embrace of the consumer expectation test here is anomalous and dangerous. Elsewhere I have argued that the consumer expectations test simply gives the fact-finder its head and is both normatively and empirically incoherent. Even so, one might accept that it could be a workable, albeit theoretically unattractive, test where the fact-finder is the ‘black-box’ of a jury and where the issue involves a ‘one-off’ product condition such as an isolated incident of bacterial poisoning of shellfish. But it is a wholly inadequate approach to the type of mass generic biological infection cases that are looming in Western Europe and perhaps elsewhere. According to the Restatement, the USA seems to have had no case law experience of such generic infection cases formulated as products liability claims apart from the blood infection cases. And in the latter cases the consensus admission was that they were too hard to accommodate coherently within the US products rule, in other words, with an adequately convincing explication of the policy and moral issues at stake.

**Contrasting gaps in case law experience**

How was it that the anomaly in US products liability case law between the treatment of infection cases depending on whether they are food cases or not could develop? This was because of an accidental gap in the US experience, specifically the absence of generic infection cases formulated as cases of products liability. Such gaps occur in any system, even one with experience of ‘forty years... [with] fairly

48 Contrast the vigorous rejection of that test by the Reporters for design/warning cases (where they argue a cost–benefit approach is the only coherent one) and for manufacturing error cases (where they use the production line norm): Restatement (Third) of Torts: Products Liability § 2, cmt. g. And see Henderson and Twerski, ‘What Europe, Japan and Other Countries Can Learn’, 17–20.


50 On the other hand, the test’s integrity, and hence its workability, will be immediately suspect in systems where the fact-finder is required to give empirical and/or analytical justifications for its determination. European and Australian judges will be acutely aware of what is expected of them and are therefore likely to reject consumer expectations as a controlling test of defect even in such one-off food cases.

51 BSE-infected animal feed and CJD-infected blood products have been exported by the UK: A. Osborn, ‘EU Beefs about BSE’ Guardian (16 February 2001).
sophisticated courts... [confronting] a substantial and steady caseload'. In the USA central gaps in the case law experience relate not only to these generic infection cases but also to development risks (unforeseeable dangers in the design) such as those at the centre of the thalidomide disaster in Europe which triggered products reform there.

In Europe the very low density across all jurisdictions of products liability cases, pre- and post-Directive, has also left a central but different gap in experience. There have yet to be many of the sort of claims that have put the main pressure on US products rules, namely those involving known or intended product conditions, that is advertent design choices, where the central issue is how much safety a consumer is entitled to. These so-called ‘classic design cases’ are ones that ‘do not involve product malfunctions, violations of safety regulations, or egregiously dangerous products’, yet the ‘plaintiffs nevertheless plausibly claim that the designs are unacceptably dangerous, and therefore, legally defective’. My example of such a case is where the design of a chair is unable to withstand the weight of a person (weighing, say, 300 pounds). The Reporters’ example is of an axle failure where a car driven at thirty miles per hour hits an eight-inch pothole. These are cases where the dangerous condition is part of the product line norm; it is known, it is intended and chosen by the producer, but there is not a consensus that this condition renders the product ‘defective’. There is, in other words, no agreement that it is a manifestly unreasonable design (under § 2, cmt. e). In such cases as the chair and axle, people disagree on how much safety is enough.

The reason the Restatement (Third) of Torts: Products Liability attracted such controversy in the USA was the Reporters’ concern to set out the tests they believed US courts had developed to control classic design cases. The Reporters assert that ‘to find a defect on those facts, the court will require the jury to apply some sort of general normative standard regarding how much axle strength automobile designs should require’. In other words, in these cases defectiveness would have to be determined by the cost–benefit (risk-utility) reasonableness principle to determine how much safety is enough. According to the Reporters, classic design cases would also only succeed if the plaintiff could bring evidence of a reasonable alternative design (RAD). I have argued elsewhere, however, that in simple classic design cases

53 Ibid., 17.
56 See Henderson and Twerski, Achieving Consensus, 877. 57 Ibid.
such as the chair and axle cases where the issue is simply how much strength and safety is enough, the issue of whether the plaintiff can show evidence of a RAD is a red herring because it is clear that the chair could be made stronger for more money or with loss of style values.  

In short, we seem to have a US regime that is incoherent in its approaches to infection cases. In particular, it would fail to provide any redress to BSE/CJD infections if they were contracted from human blood or human tissue. It might provide recovery in cases of BSE/CJD infections contracted from food only if a reasonable consumer would not expect the food to contain that ingredient. It might provide recovery in cases of BSE/CJD infections contracted from leather/woollen clothing without proof of defect, RAD or fault on the basis that these product conditions are to be classed, just as infected raw material cases are classed, as ‘manufacturing defects’ cases under section 2(a) (on the basis that the condition of such infected products departs from their intended design). Finally, the US regime might provide recovery only on the basis that the product condition was to be classed as a design case falling under section 2(b), namely defectiveness being determined by the cost/benefit reasonableness principle (and not the consumer expectations test) and RAD requirement.

The European Directive and its clones

Products case law experience on the Directive and its clones is still thin. Even now it has not exploded into the troublesome area of classic design cases and it is unclear whether the Directive will provide an acceptable structure within which to handle such cases as the chair and axle. However, the special experience of Europe in relation to thalidomide, a case of allegedly unforeseeable design condition, raises the question of whether it produced a products regime that will better be able to accommodate BSE/CJD mass infection cases than that set out in the Third Restatement. Certainly the Directive is not bedevilled by dubious classifications based on type of product or type of defect as the Third Restatement is.

Thalidomide ensured that unforeseeable product conditions received explicit treatment in the Directive, though ironically that treatment was pro-defendant: the highly controversial development risk defence. The critical ‘defect’ issue under Article 6 in unforeseeable product condition cases, as in all product cases under the Directive, is not what level of safety we actually expect, for we do not expect,


60 This cannot be the appropriate test for defectiveness under Article 6. Members of the public no doubt expect aspirin to be 100 per cent safe, but the fact that it is not 100 per cent safe does not, per se, render aspirin defective. See Stapleton, ‘Restatement (Third) of Torts: Products Liability, an
for example, that pregnancy drugs might deform our babies. The critical issue is what are we ‘entitled to expect’, and when should we consider this in relation to the product: the time it was supplied or at the time of trial when we know its ghastly effects for certain.

Issues European courts will need to address include: whether the defect standard involves an evaluation of various incommensurable factors of costs and benefits or some other standard; when the apparent costs of the product should be evaluated (because it may well be that by the time of trial these are revealed to be much higher than expected at the time the product was commercially supplied, as was the case with thalidomide), whether exculpatory motivations such as that behind the development risk defence (that there are some things even a reasonable producer can do nothing about and that, at least in some cases, that should provide exculpation) are also present in the definition of defect (for example, that the product may not be defective because it is essential, has no safer feasible substitutes, and the producer did all that the public interest could reasonably require); whether such infection cases are to be classed as ‘manufacturing error’ cases; and, if so, whether this excludes the development risk defence in Article 7(e).

So far the case law results under the Directive in relation to infected products have been mixed. The relatively unenlightening result in Worsley v. Tambrands Ltd, which concerned an allegation arising from toxic shock syndrome associated with tampon use, was that there was no case to answer. Similarly in the case of Lopez v. Star World Enterprises Pty., a mass infected food case, brought under the Australian legislative clone of the Directive, a judgment on the issues was precluded by the settlement of the action consequent on the bankruptcy of the defendant. Ryan v.

Anglo-Australian Perspective’, 376–9. Another example is penicillin, which is one of the safest of antibiotics but has in rare cases been implicated in the death of users: A. L. Diamond, ‘Product Liability and Pharmaceuticals in the United Kingdom’ in G. F. Woodroffe (ed.), Consumer Law in the EEC (London: Sweet & Maxwell, 1984), 129.

61 In contrast, this critical hindsight/foresight distinction on which the development risk defence clearly rests and which gives it its force was not central to the thinking of the reformers behind section 402A of the Second Restatement. It was only after insightful academic work and the embarrassment of cases such as Beshada v. Johns-Manville Prods. Corp., 447 A 2d 539 (NJ, 1982) (on which see Stapleton, Product Liability, 33) that it became widely appreciated in the USA that how its products regime treats unforeseeable defects is a litmus test for whether it imposes true strict liability; for strict liability is whether reasonable care is no answer and, as it is impossible to act carelessly in relation to a defect that is unforeseeable, imposition of liability for such a defect reveals that liability to be a strict one. US courts refuse to impose such liability for unforeseeable conditions classified as design conditions and warning conditions. This is why the Third Restatement correctly concedes that, despite the academic and judicial rhetoric of the ‘strict liability’ imposed on product manufacturers by the rule in section 402A, liability under that rule has always been based on unreasonableness in cases of conditions classified as design conditions and warning conditions.

Great Lakes Council, a hepatitis-in-oysters case, was brought under the same legislation. The judge found the product defective and yet allowed the development risk defence. Both findings were upheld on appeal. In A v. OLVG Hospital Amsterdam a blood transfusion resulted in HIV infection and the court held that while the blood was defective it was protected by the development risk defence. In contrast, in Re: Hepatitis CLitigation, A v. National Blood Authority over a hundred claimants sued the National Blood Authority over hepatitis C infection from blood. Mr. Justice Burton held that the blood was defective and that the development risk defence did not operate. Finally, Henning Vedelfd v. Arhus Amstikommune, the first product liability Reference for a Preliminary Ruling to be referred to the European Court of Justice concerning the Directive 85/374/EEC, concerned a tainted flushing fluid which ruined a kidney intended for transplantation. However, ‘defectiveness’ was not in issue and the questions for the court related only to general points not specific to infection cases, such as the meaning of the clause ‘put into circulation’ and whether the Directive imposed liability on non-profit suppliers.

More fundamentally, Ryan’s case, like most infection cases, highlights the artificiality of the product/service distinction in a law of obligations and the incoherence of the idea that products liability looks at the product and not the human behaviour surrounding its production and handling. In Ryan’s case the hepatitis infection of the oysters could have been prevented by the reasonable care of the defendants, so although the claim under the clone of the Directive failed, parallel claims in negligence succeeded. It shows how bizarre it is for there to be a liability regime that covers products alone. It is equally bizarre that we have a separate legal rule that covers BSE/CJD cases where the infection arose through contact with a tangible product such as food, which has been commercially supplied, but does...
not cover cases of BSE/CJD infection in a workplace such as a farm, dairy, abattoir or butcher's shop, by a service (for example, person-to-person infection in a commercial setting such as a doctor's or dentist's surgery), or by infection from environmental factors such as wind-carried pathogens. Why, for example, do we have a separate liability rule that covers only cases of foot and mouth infection by contact with infected products that have been commercially supplied, but not cases of infection by the wind from pyres burning slaughtered stock, or infection of those sent to do the slaughtering, 72 or other avenues of infection from not-yet supplied infected matter?

**Conclusion**

The Reporters of the *Third Restatement* are right to criticise foreign systems for their neglect of the important issues raised by classic design cases such as the strength-of-chair and strength-of-axle cases. But in relation to the challenge that mass infection cases pose to special product liability regimes, it would seem that the *Third Restatement* has little to offer in the way of coherent guidance. In contrast, it might have seemed that the Directive would provide a better model given that it does not require the classification of the defect, does not give separate treatment to claims based on certain evidentiary shortcuts, does not treat different product types such as food separately, and pays explicit attention to the exculpatory notion of the capacity of the defendant to respond to a risk. Yet the isolated case law concerning infected products that has so far emerged has not so far produced such a clear pattern.

Finally, it should be emphasised that, like classic design cases, mass infection cases would have, in any case, eventually arisen under pre-Directive legal rules such as the tort of negligence. 73 Ryan's case suggests that, despite all the energy thrown into the Directive and *Third Restatement*, the law of negligence may continue to provide citizens with a more flexible and coherent cause of action. Traditional general causes of action, such as negligence and warranty, also provide a clearer forum for courts to enunciate the complex moral and policy dilemmas that characterise generic mass infections of essential product sectors. The Canadian Supreme Court judgment in *Ter Neuzen v. Korn* 74 illustrates this. There, in a case involving HIV

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73 See, e.g., *The Creutzfeldt-Jakob Disease Litigation* QBD: 54 BMLR at 1 (7 April 1995); at 8 (19 July 1996); at 79 (19 December 1996); at 85 (18 November 1997); at 92 (18 December 1997); at 95 (23 March 1998); at 100 (27 April 1998); at 104 (22 May 1998); and at 111 (19 June 1998). Cases may also be taken under other statutory provisions, see, e.g., *Re: ‘E’ v. Australian Red Cross Society* (1991) 99 ALR 601; (1991) 105 ALR 53 (Full Federal Court) (an Australian case under Part V, Div 2 of the ‘Trade Practices Act 1974 (Cth)’ involving HIV-infected blood products).
infection from an artificial insemination procedure, the Court was able to explain in detail its finding that ‘it must be recognized that biological products such as blood and semen, unlike manufactured products, carry certain inherent risks. It would be inappropriate to imply a warranty of fitness and merchantability in the circumstances of this case. Moreover, any warranty would simply be to take reasonable care.’ Of course, such traditional causes of action can still present formidable barriers of proof of causation and, in the case of the tort of negligence, proof of carelessness, particularly in latent infection cases. But there is still much that could be done to reorient evidentiary rules to be more claimant-friendly in cases brought against powerful commercial concerns. An appreciation of how our liability rules cope with mass infections of major and/or important natural products will become even more critical as we cope with the recurrence of viruses such as foot and mouth disease and we move into the era of genetically modified flora and fauna.

**Appendix: A selection of US infection cases**

*Anderson v. Farmers Hybrid Co.*, 408 NE 2d 1194 (Ill App Ct, 1980) (diseased gilts).


*Branch v. Willis-Knighton Medical Center* 636 So 2d 211 (La, 1994) (hepatitis-infected blood).


76 One estimate of the number of animals slaughtered in an attempt to control the Spring 2001 outbreak of foot and mouth in the UK is at least 6.5 million animals or more than 10 per cent of Britain’s livestock: *Guardian Weekly* (10–16 October 2002). Compare the 5 million earlier slaughtered in an attempt to eradicate BSE in cattle; see n. 24 above.

Simeon v. Doe, 618 So 2d 848 (La, 1993) (oysters infected with naturally occurring Vibrio vulnificus).

