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Good governance of private standardization and the role of tort law

PAUL VERBRUGGEN*

This paper inquires into the potential of tort law to control private standardization and foster good governance in regulatory decision-making. Private standardization has been characterized as a political game of winners and losers: while for some firms it brings about opportunities for product development, innovation and market access, for others it means switching costs and barriers to trade. With so much at stake, firms have strong incentives to influence standardization and ensure that it meets their narrow private interests. This dynamic puts pressure on the integrity and quality of private standardization and has led policy-makers to require standards development organizations (SDOs) to adhere to good governance principles such as stakeholder participation, transparency and the use of state-of-the-art scientific research. Drawing on case law from the United States and Europe regarding the liability for negligent standardization, the article finds that tort law currently offers limited incentives for SDOs to comply with good governance norms. The degree to which compliance with such principles can be required appears to fundamentally depend on an ex post weighing of interests under the circumstances. This balancing, the article argues, should at least involve consideration of (i) the magnitude of risk private standardization is concerned with; (ii) the existing internal rules and procedures for private standardization; (iii) the costs concerned with the (re)organization of such rules and procedures; and (iv) the character and societal benefit of private standardization.

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1. Introduction

1. Private standardization has been characterized as a political game of winners and losers.¹ For winners it brings about opportunities for product development, innovation and market access. For losers it means switching costs and barriers to trade. With so much at stake, firms have strong incentives to influence standardization so to meet their private interests. Many standards development organizations (SDOs) have therefore developed internal rules and procedures to prevent the pursuit of narrow private interests and ensure that private standardization delivers on efficiency, quality, safety, security, sustainability and other possible public policy objectives. Wide and meaningful involvement of interested stakeholders, access to (draft) standards, and expert-led deliberations appear to constitute the central pillars on which such rules and procedures are build.²

2. Adherence to such principles of good governance by SDOs has further been encouraged by law and policy. To the extent that legislatures and regulatory agencies use private standardization as a technique of market regulation, rules of administrative law suggest it to be open, balanced and consensus-based, allowing for a review process.³ Antitrust, intellectual property (IP) and international trade law equally proclaim procedural rules that should control private standardization and guide it to be inclusive, fair, transparent and non-discriminatory.⁴ Scholars have voiced similar calls for proceduralization in debates on the legitimacy and effectiveness of (transnational) private governance, while appreciating that the extent and form of such proceduralization should not be measured up to demands imposed on rulemaking in the democratic nation state.⁵

3. This paper inquires into the potential of tort law to control private standardization and foster its compliance with good governance principles. Tort law has long been identified as a means to control private standards development.⁶ It offers in the first place a remedy to

¹ T. BÜTHE & W. MATTLI, *The New Global Rulers. The Privatization of Regulation in the World Economy* (Princeton: Princeton University Press 2011), 8.

² H. SCHEPEL, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Oxford: Hart Publishing 2005), 412-413.

³ See e.g. Circular No. A-119 of the Office of Management and Budget on 'Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities' (2016) (promoting the adoption of private standards by U.S. Federal agencies provided they meet attributes of openness, balance of interest, due process, having an appeals procedure, and operate on the basis of consensus (at para. 4); Articles 3 to 7 Reg. 1025/2012/EU on European standardization [2012] OJ L 316/12 (detailing rules of participation and transparency in the development of standards for the European internal market).

⁴ See e.g. Communication from the Commission — Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, *OJ* [2011] C 11/1 (paras. 280-291); Submission of the United States to the OECD Working Party No. 2 on Competition and Regulation, 'Standard setting', DAF/COMP/WP2/WD(2010)28 (2010). See on trade law extensively MATAIJA in this Issue.

⁵ See e.g. J. FREEMAN, "The Private Role in Public Governance", 75. *New York University Law Review* 2000, p. (543); B. KINGSBURY, N. KRISCH & R. B. STEWART, "The Emergence of Global Administrative Law", 68. *Law and Contemporary Problems* 2005, p. (15); C. SCOTT, F. CAFAGGI & L. SENDEN, "The Conceptual and Constitutional Challenge of Transnational Private Regulation", 38. *Journal of Law and Society* 2011, p. (1).

⁶ EDITORIAL NOTE, "Developments in the Law: Judicial Control of Actions of Private Associations", 76. *Harvard Law Review* 1963, p. (983), at 1005 ("[G]enerally the explicit weighing of interests embodied in a tort approach (...) would seem likely to lead to fair solutions for most association cases while serving as an invitation

victims who have suffered physical or economic harm because of standards being inaccurate, incomplete, outdated or otherwise inadequate.⁷ Examples are standards that suggest a wrong product design,⁸ erroneous testing methods,⁹ or poor warnings.¹⁰ Victims of such “bad” standards include businesses relying on them in business operations, as well as businesses and consumers purchasing and using products manufactured in compliance with such standards.¹¹ There are various reasons why standard setting may lead to suboptimal outcomes: SDOs may fail to take into account state-of-the-art research, underestimate certain risks, or worse, unreasonably favor certain industry interests over safety concerns of potential end-users. Principles of good governance help to guard against these regulatory failures, control private standardization, and ensure its quality and integrity. The question is, then, whether tort law promotes compliance with these principles in civil liability claims for negligent standards development.

2. Tort law as an impetus for good governance of private standardization?

4. Few writers have considered the regulatory potential of tort law to foster compliance with good governance principles and ratchet up internal procedures for standard setting. Spindler has argued that tort law could ‘formulate fundamental principles for enacting private standards’.¹² Similarly, Schepel has held that it ‘should not be so hard to develop principles for the ‘exercise of due care’ that take account of the difficulties of decisionmaking under conditions of scientific uncertainty, that encourage the revision of outdated safety standards, and punish the pursuit of narrow private interests.’¹³ Cafaggi, in turn, has stressed the importance of governance design for private regulators in ensuring an adequate balance of different interests, adding that such a design ‘would be insufficient if it were not linked to a system of liability rules that provides incentives to regulate (addressing the failure to regulate) and to regulate correctly (addressing the problem of abusive or wrongful regulation)’.¹⁴ Perhaps most fundamentally, Teubner has proposed that private law more broadly is to provide fundamental rules of private rulemaking in the contemporary

to courts to explain their adjudications in a way meaningful for the eventual refinement of more precise rules in this area.”). See also Z. J. CHAFEE, "The Internal Affairs of Associations Not for Profit", 43. *Harvard Law Review* 1930, p. (993), at 1007-1010.

⁷ Those who suffer economic harm either because the standards restrict competition or violate IP rights will principally have to look to antitrust or IP law for protection rather than tort law. See in general on those topics the contributions in J. Contreras (ed.), *The Cambridge Handbook of Technical Standardization Law, Volume I: Competition, Antitrust and Patents* (New York: Cambridge University Press 2017).

⁸ *MT Højgaard A/S v. E.ON Climate & Renewables UK Robin Rigg East Limited and another* [2017] UKSC 59.

⁹ *Snyder v. American Association of Blood Banks* 676 A.2d 1036 (NJ.1996).

¹⁰ *Lockman v. S.R. Smith, LLC*, 405 Fed.Appx. 471, (11th.Cir.2010) (per curiam) WL 5158571, 473.

¹¹ Compare Schuck, who identifies similar groups that are most at risks of sustaining harm caused by negligent accreditation. P. H. SCHUCK, "Tort Liability to Those Injured by Negligent Accreditation Decisions", 57. *Law & Contemporary Problems* 1994, p. (185) at 185-186.

¹² G. SPINDLER, "Market Processes, Standardisation and Tort Law", 4. *European Law Journal* 1998, p. (316) at 331-332.

¹³ SCHEPEL, , (n 2) p. 399 (references omitted).

¹⁴ F. CAFAGGI, "Rethinking Private Regulation in the European Regulatory Space", in: F. Cafaggi (eds), *Reframing Self-Regulation in European Private Law* (Alphen aan den Rijn: Kluwer Law International 2006), pp. 3-75, at 39.

postmodernist regulatory space, which is shaped by privatization, globalization and polycentricism:

“The core function of private law is to juridify diverse processes of decentralized spontaneous norm-formation in civil society which are fundamentally different from processes of political regulation by the central authority of the State. Private law’s job in this broader sense is to constitutionalize spaces of social autonomy, not only economic forms of action but in particular noneconomic forms of contracting and other modes of consensual action, idiosyncratic private ordering, standardization, normalization, codes of practice, formal organization and loosely organized networks in different contextures of civil society.”¹⁵

5. Whether and to what extent does tort law indeed constitutionalize private standardization and set basic principles for its governance? Do such principles hold currency in the case law about the tort liability of SDOs, for example as a reference to establish the standard of reasonable care? More normatively, should courts hearing tort law claims require SDOs to comply with principles of good governance?

3. The order of the argument

6. In answering these questions, this paper discusses case law concerning the tort liability of SDOs in the United States (U.S.) and Europe Union (EU). Case law in these jurisdictions is most developed, best documented and electronically searchable and accessible.¹⁶ The case law that is discussed concerns the liability for private standards development only. Liability for harm caused by wrongful compliance monitoring or verification by private auditors, certifiers, or inspectors is beyond the scope of the analysis.¹⁷ Moreover, the analysis in this article is focused on product standards. Such standards set out technical specifications for the design, production and performance characteristics of manufactured goods. They typically prescribe physical attributes for products (e.g. dimensions, size, and composition), performance characteristics (e.g. interoperability, durability, safety), and/or methods of production, construction, assembly or testing.¹⁸

7. The analysis shows that courts only rarely allow tort law claims against SDOs for alleged harmful standards. While in the U.S. a body of case law has developed around liability for standards development, courts for the most part have declined to accept that the defendant

¹⁵ G. TEUBNER, "After Privatization? The Many Autonomies of Private Law", 51. *Current Legal Problems* 1998, p. (393), 399. See also T. WILHELMSSON, "Private Law 2000: Small Stories on Morality through Liability", in: T. Wilhelmsson & S. Hurri (eds), *From Dissonance to Sense: Welfare State Expectations, Privatisation & Private Law* (Aldershot: Ashgate 1999), pp. 221-251, at 235-236 and 238 (arguing that as rule-making power is shifting away from the state to powerful private actors, civil liability should ensure the involvement of those affected by private rules).

¹⁶ Data was retrieved by systematic searches using case law databases and secondary sources, such as academic literature, government reports, and industry policy briefs.

¹⁷ See extensively on this theme: LYTTON, VAN HO & TERWINDT, GLINSKI & ROTT, and DE BRUYNE in this Issue.

¹⁸ BÜTHE & MATTLI (n 1), p. 5; SCHEPEL, (n 2) p. 3-4; N. Brunsson & B. Jacobsson (ed.), *A World of Standards* (Oxford: Oxford University Press 2001), p. 4-5.

SDO owed a duty of care to the plaintiff. The lack of a specific relationship between the plaintiff and SDO, and general considerations of policy and justice have frequently led courts to argue against the imposition of such a duty. Of the cases in which courts imposed a duty, a majority is inconclusive about the relevance of good governance principles in defining the standard of care and in assessing whether the SDO's conduct fell short of exercising such care under the circumstances. The need to follow open, inclusive and transparent procedures, base standards on the state-of-the-art of scientific research, or regularly revise standards in the light of gained wisdom about their application is not always apparent. The degree to which principles of good governance have an impact fundamentally depends on an *ex post* weighing of interests under the circumstances. In the EU, case law on the matter is virtually absent. Current understandings on the liability of private auditors, certifiers and inspectors suggests that the elements of duty, breach and legal causation may prove formidable barriers for claims to succeed. These findings suggest that tort law, as it stands, offers only a limited impetus for SDOs to ratchet up internal procedures of standard setting and comply with good governance principles.

8. The paper is organized as follows. Sections 4 and 5 will discuss the current state of tort law regarding the liability for private standardization in the U.S. and EU respectively.¹⁹ They set out the conditions under which courts may impose liability on SDOs for negligent standardization, the policy considerations which favor or oppose such imposition and the standard of care required from SDOs that are deemed to owe a duty of care. This analysis prepares the ground to discuss in Section 6 to what extent tort law promotes compliance with good governance principles in standards development. Section 7 then discusses these findings in relation to the normative positions scholars have voiced on the desirability to employ tort law as an instrument to lay down fundamental principles for private standardization. It argues that what we can expect of SDOs in terms of good governance is in practice more limited and should primarily be determined on the basis of a balancing test involving (i) the magnitude of risk private standardization is concerned with; (ii) the existing internal rules and procedures for standardization; (iii) the costs concerned with the (re)organization of such rules and procedures; and (iv) the character and societal benefit of private standardization.

4. Tort liability for private standardization in the U.S.

9. Businesses and consumers in the U.S. have sought compensation from SDOs for harm caused by inadequate standards development based on several theories of tort law. Actions other than those sounding in negligence have been unsuccessful for the most part.²⁰

¹⁹ These sections build on P. VERBRUGGEN, "Tort Liability for Standards Development in the United States and European Union", in: J. Contreras (eds), *The Cambridge Handbook of Technical Standardization Law, Volume Ii: Administrative Law, Trade, Privacy, Tort, Copyright and Trademark* (New York: Cambridge University Press 2019), pp. forthcoming.

²⁰ These concern actions of products liability, breach of implied warranty and civil conspiracy. See for a discussion e.g. R. G. WELLINGTON & V. G. CAMISA, "The Trade Association and Product Safety Standards: Of Good Samaritans and Liability", 35. *The Wayne Law Review* 1988, p. (37); H. ROCKWELL, "Product Liability of Endorser, Trade Association, Certifier, or Similar Party Who Expresses Approval of Product", 5. *American Law Reports* 1992, p. (431), at §3 and §4 (collecting cases); R. C. FELDMEIERS, "The Risk of Negligence Liability for Trade Associations Engaged in Standards Setting or Product Certification", 34. *Tort & Insurance Law Journal*

4.1 A duty of care in negligence?

10. The elements of a successful action in negligence are a duty owed by the defendant to the plaintiff, a breach of that duty by the defendant, and damage proximately caused by that breach. Whether a defendant owes a duty of care is a question of law and should be determined by judges, not juries.²¹ This means that a defendant SDO may challenge that it owes a duty as a preliminary matter. It can do so via a motion to dismiss or, after discovery, in a motion for summary judgment. If either motion is granted, the action is rejected and the SDO is not answerable under ordinary negligence law for any of the harm sustained by the plaintiff. If, however, the motion is denied and the judge considers that a duty is owed, the SDO is exposed to potential civil liability for harm. Liability does not automatically follow, for the other elements have yet to be established, typically by the jury.²²

11. To decide whether an SDO owes a duty of reasonable care towards third parties at risk of suffering a loss from negligently developed standards U.S. judges – as they typically do when hearing negligence actions – balance competing considerations of policy and justice that determine the fairness of exposing the SDO to civil liability for harm allegedly caused by its standards development. These considerations include: the foreseeability of harm to the plaintiff as a result of the defendant’s conduct; the closeness of the connection between the defendant’s conduct and the plaintiff’s harm; the moral blame attached to the defendant’s conduct; the potential impact of imposing liability on preventing such harm in the future; the burden of liability on the defendant and the community; the availability and cost of insurance to cover the risk of liability involved; and the potential volume of litigation that liability would generate and its impact on the court system.²³ The weight of these factors may either be in favour or against imposing a duty.

12. The balancing of policy considerations has led to ‘no duty’ decisions in the majority of the cases in the U.S. involving the liability of SDOs for standards development.²⁴ In reaching that conclusion courts have drawn particular attention to the relationship between the defendant SDO and the addressees of its standards as a measure to construct the first two policy factors, namely the foreseeability of harm and the closeness of the connection between the defendant’s conduct and the plaintiff’s harm. In general terms, SDOs do not directly cause harm to others by developing inaccurate, incomplete or otherwise inadequate product standards. Harm follows only when these standards are relied upon in business operations of

1999, p. (785); R. H. HEIDT, "Damned for Their Judgment: The Tort Liability of Standards Development Organizations", 45. *Wake Forest Law Review* 2010, p. (1227).

²¹ The jury determines all other elements of the negligence action, unless no reasonable person can differ as to the correct answer. See D. DOBBS, P. T. HAYDEN & E. M. BUBLICK, *Hornbook on Torts* (St. Paul, Minn: West Academic Publishing 2016), p. 204 (with further references to case law and literature); Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 7, cmt. i (2010).

²² A final decision on liability is very likely not to follow after a positive duty decision, since the overwhelming majority of the cases never reach trial, for example because the defendant has settled the case. See also Lytton in this Issue in relation to negligence actions against private food safety auditors.

²³ DOBBS, HAYDEN, AND BUBLICK 2016 (n 21), pp. 208-209.

²⁴ See for a full discussion of the case law VERBRUGGEN (n 19).

the addressees of these standards, typically manufacturers, who design, construct, install or maintain products in accordance to these standards. To the extent that the bad standards lead to defective products, the standards' addressees are immediate or primary tortfeasors (and possibly answerable under product liability for the harm sustained by the plaintiff), while SDOs are only secondary tortfeasors.

13. A number of courts have therefore sought to understand the extent to which the SDO controls compliance with its standards by the primary tortfeasors as a way to bridge the gap between the SDO's conduct of developing standards and the plaintiff's harm. Such control has been considered absent based on the voluntary, non-binding nature of private standards, the purpose of the standards of being minimum standards only, and/or the lack of monitoring or oversight mechanisms to establish and sanction non-compliance.²⁵ In the absence of such control, these courts have argued, the harm of the plaintiff was not reasonably foreseeable for the defendant SDO and there is no sufficiently close relationship between the latter's conduct and the plaintiff's harm. In that case, an SDO does not owe a duty to exercise reasonable care in the development of its standards towards a third party who is injured by a product covered by its standards.

14. The obvious criticism against this thinking is that, in practice, industry members routinely follow product standards in their business operations. Even if the SDO cannot require compliance by the addressees of its standards based on contractual or associational rules, compliance rates among the addressees are usually high. This is particularly so if the SDO has a particular status as an expert-based institute, its standards enjoy a high market uptake, or compliance is promoted via government regulation. Moreover, contemporary research suggests that while private standards are typically voluntary and non-binding in legal terms, they become binding *de facto* where compliance is a necessary requirement for effective market access or competition.²⁶ This status also bolsters the capacity of an SDO to effectively exert control over industry practice through its standards.

15. Other courts in the U.S. have leveraged this idea to impose on SDOs that are dominant in the industry a duty of care in negligence law. The reasoning most prominently emerges in a line of cases that concerned patients who contracted HIV/AIDS after they had received a blood transfusion with contaminated blood. The defendant in these actions of personal injury

²⁵ See e.g. *Bailey v. Hines* 719 NE.2d 178, 182 (Ill.App.1999) (SDO that developed standards for the design and construction of wood trusses used for roof framing systems owed no duty to injured construction workers who relied on the standards to install such systems, since the SDO lacked oversight and control over its standards, which were intended as a guide only); *Commerce and Industry Insurance Company v. Grinnell Corp.* 1999 WL 508357 (ED.La 1999), 4 (SDO which developed fire safety standards owed no duty to building owners (or their insurers) who lost their property as a result of a warehouse fire as the SDO 'does not list, inspect, certify or approve any products or materials for compliance with its standards. It merely sets forth safety standards to be used as minimum guidelines that third parties may or may not choose to adopt, modify or reject.');

Beasock v. Dioguardi Enterprises 494 NYS.2d 974, 979 (Sup.Ct.1985) (SDO that set dimensional standards for tires and rims owed no duty of care to plaintiff for a fatal injury caused by a mismatch combination of a tire and rim, because the standards were voluntary in nature and the SDO 'neither mandates nor monitors the use of its standards by any manufacturer').

²⁶ See for private standardization in particular e.g. BÜTHE & MATTLI (n 1) p. 14.

or wrongful death was the American Association of Blood Banks (AABB), a private, not-for-profit trade association setting national standards for blood banking and blood transfusion services. It was alleged that the SDO had failed to timely implement changes in its standards to ensure that its member blood banks employed surrogate testing or alternative practices that could prevent the collection and distribution of contaminated blood at the time it became clear that HIV could spread by transfusion.

16. The first in this line of cases, *Snyder v. AABB*, the New Jersey Supreme Court carefully assessed the role the SDO played in the blood-banking industry. The Supreme Court held in its considerations regarding the foreseeability of injury to others from AABB's standard-setting activities that by the time the plaintiff received the contaminated transfusion, the SDO 'exerted considerable influence over the practices and procedures over its member banks' and '[i]n many respects, the AABB wrote the rules and set the standards for voluntary blood banks'.²⁷ Such dominance was fostered by AABB's annual inspection and accreditation of its members to assure compliance with its standards, its presentation as an industry leader in setting policy and standards of practice,²⁸ as well as the strong deference of federal and local governments to AABB standards and inspection results.²⁹

17. In holding that AABB's standard-setting activities created a foreseeable risk of injury to recipients of blood transfusions the Supreme Court further gave weight to the fact that AABB standards were not only adopted for the benefit of the industry, but also for patients, who had to rely on those standards for the safety of donor blood.³⁰ The court also considered that the risk of contracting HIV/AIDS through transfusions of contaminated blood was severe and foreseeable based on government reports and scientific publications.³¹ Other considerations of policy and fairness as raised by the SDO, including the interference with constitutionally-protected rights to participate in the political process and the consequences of the burden of liability on AABB's standards development and the availability and costs of blood for the community, could not trump the existence of a duty of care.³² Accordingly, the Supreme Court held, the trial jury could have found that AABB had been negligent in not recommending in its standards surrogate testing and that this negligence was a substantial

²⁷ *Snyder v. American Ass'n of Blood Banks* 676 A 2d 1036 (NJ 1996), 1048.

²⁸ *Ibid*, 1048 ('Society has not thrust on the AABB its responsibility for the safety of blood and blood products. The AABB has sought and cultivated that responsibility. For years, it has dominated the establishment of standards for the blood-banking industry. (...) By words and conduct, the AABB invited blood banks, hospitals, and patients to rely on the AABB's recommended procedures.')

²⁹ *Ibid*, 1040 ('Both the state and federal government, as well as the blood-banking industry, generally accept AABB standards as authoritative. Consequently, blood banks throughout the nation rely on those standards.')

and at 1043 ('Thus, if a blood bank failed the annual AABB inspection on the taking of medical histories, that bank could lose its [state] license to operate in New Jersey. In sum, (...) the AABB was not a mere advisory body. It exercised control of its member banks (...)').

³⁰ *Ibid*, 1048 ('Blood banks, hospitals, and patients rely on the AABB for the safety of the nation's blood supply. A patient contemplating surgery cannot assure the safety of blood drawn from others. Of necessity, patients rely on others, including the AABB, for that assurance.')

³¹ *Ibid*, 1048-1049.

³² *Ibid*, 1049-1050.

factor in causing the plaintiff to contract HIV/AIDS. The SDO was in the end held liable to pay damages in excess of USD 400,000.

18. *Snyder* was followed by courts in Louisiana, New York and Virginia.³³ It was rejected, however, by the California Court of Appeals in *N.N.V.*³⁴ In this case, which involved a minor who contracted AIDS after receiving a contaminated donor blood during surgery, the court ruled that liability should not be imposed on AABB as a matter of public policy and fairness. In reaching that conclusion it, by and large, rejected all factors that were considered relevant in *Snyder* to establish a duty of care, and in particular the SDO's dominance in the sector and patients' reliance on AABB standards for their safety. In *Snyder*, AABB had advanced the argument that it should not be found liable 'for taking the "wrong side" of a debate involving medical uncertainties and public policy.'³⁵ The California Court of Appeals agreed and placed strong emphasis on the lack of medical or scientific consensus regarding the effectiveness of available methods and practices to reduce the risk of HIV/AIDS contamination via blood transfusion. Such absence made it not reasonably foreseeable for the SDO that the promotion of new testing methods in its standards would have reduced the risk of AIDS contraction for the plaintiff. This state of evolving knowledge also led the court to hold that imposing liability on the SDO would not further the goal of preventing future harm under the circumstances.³⁶

19. Also a number of other considerations of policy and justice weighed against the imposition of a duty of care on AABB. The SDO, the California Court of Appeals considered, had to balance the legitimate concern of the safety of blood supply against the equally legitimate concern of the availability of blood to needing patients and the costs of rejecting unaffected blood through new testing methods. As the implications for availability and costs of blood supply were unknown, the SDO's conduct 'warrants no moral blame'.³⁷ The court also expressed the fear that the SDO would be exposed to an extensive burden of litigation if a duty of care were to be imposed. Such an opening of the floodgates would also have a chilling effect on the SDO and would be detrimental for the community in that the SDO would be held back to further pursue its standard setting activities, which support otherwise

³³ *Weigand v. University Hospital of New York* 659 NYS.2d 395, 399 (1997) (AABB's motion to dismiss is denied); *Douglass v. Alton Ochsner Medical Foundation* 696 So.2d 136 (La.App.5th Cir. 1997) (overturning a summary judgment in favor of AABB); and *Jappell v. American Ass'n of Blood Banks*, 162 F.Supp.2d 476, 481 (E.D.Va. 2001) (AABB's motion to dismiss is denied).

³⁴ *N.N.V. v. American Ass'n of Blood Banks*, Cal.App.4th 1358 (1999).

³⁵ *Snyder* (n 27), 1049.

³⁶ *N.N.V.* (n 34), 1383.

³⁷ *Ibid*, 1382-1383. The *Snyder* court (n 27, at 1050) had dismissed this argument by holding that such concerns should not have diverted AABB from 'its paramount responsibility to protect the safety of the blood supply'.

laudable public policy goals such as health and safety.³⁸ Finally, the costs of taking out insurance against such liability could also be high.³⁹

4.2 Affirmative duties

20. An alternative way to impose a duty on SDOs and subject them to potential tort liability is by applying the rules concerning the doctrine on affirmative duties in the U.S. American common law, like English common law, makes a distinction between misfeasance and nonfeasance for the purposes of establishing whether the defendant owes a duty of care to the plaintiff.⁴⁰ Whereas misfeasance – understood as active conduct working positive harm to others – generally creates a duty of care in relation to physical harm, nonfeasance – held to be passive inaction to protect from harm – does not.⁴¹ Thus, if the defendant does not directly create the risk of harm for others, the failure to prevent or minimize that risk does not normally expose him to liability. Nonfeasance is not a tort, unless there is a duty to act imposed on the defendant in specific circumstances.⁴² Put differently, affirmative duties (i.e. duties to protect others from existing risk of harm) only exist in special circumstances.

21. One such special circumstance is when an SDO voluntarily undertakes to perform an activity that is aimed at reducing the risk of harm for another caused by some other source.⁴³ American common law may impose a duty of care on the SDO to the other or third parties. One articulation of this so-called ‘voluntary undertaking’ rule is found in Section 43 of the Restatement (Third) of Torts:

An actor who undertakes to render services to another and who knows or should know that the services will reduce the risk of physical harm to which a third person is exposed has a duty of reasonable care to the third person in conducting the undertaking if:

- (a) the failure to exercise reasonable care increases the risk of harm beyond that which existed without the undertaking,
- (b) the actor has undertaken to perform a duty owed by the other to the third person, or

³⁸ *N.N.V.* (n 34), 1384 (‘If liability were imposed here, then the AABB and other similar medical associations could be faced with a significant burden of litigation that might be impossible to avoid’) and at 1386-1387 (‘[W]e believe imposition of liability here would have adverse consequences to the public by chilling scientific and medical debate on important issues (...) Additionally, we note imposition of liability could hinder reconsideration of established standards.’). See in the same vein *FELDMEIERS* (n 20), p. 795 (arguing that the result of cases like *Snyder* could be ‘an unwarranted expansion of liability that could have the detrimental effect of discouraging trade association standards setting’) and *HEIDT* (n 20), p. 1254-1255 (noting that cases like *Snyder* ‘herald an area of increased liability’ and raise ‘the specter of unlimited liability once a duty was imposed’).

³⁹ *N.N.V.* (n 34), 1388.

⁴⁰ See also *LYTTON* and *VAN HO & TERWINDT* in this Issue.

⁴¹ Cf. *W. P. KEETON e.a., Prosser and Keeton on Torts* (St. Paul, Minn: West Pub. Co. 1984), p. 373.

⁴² See in general *DOBBS, HAYDEN & BUBLICK 2016* (n 21), p. 615 and *Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 37* (2010).

⁴³ See also *LYTTON* in this Issue.

(c) the person to whom the services are rendered, the third party, or another relies on the actor's exercising reasonable care in the undertaking.⁴⁴

22. Plaintiffs have frequently relied on the voluntary undertaking rule in damages actions against SDOs, sometimes in parallel to actions in negligence.⁴⁵ The majority of these actions have proven unsuccessful, however. The plaintiffs frequently fail to show that the defendant SDO, by developing product standards aimed to prevent or minimize risk of physical harm, increased the risk of harm they were exposed to as required under (a), or that they had actually relied on the contentious standards or required under (b).⁴⁶ Most of the substantive discussion on successful application of the voluntary undertaking rule as proposed by Section 43 of the Restatement concerns the situation under (b). A duty of care exists, the Restatement suggests, if the SDO has undertaken to perform a duty that one of its members (i.e. a manufacturer) owed to the plaintiff. More concretely, by developing safety standards, the SDO must have assumed the duty its members have under product liability laws to business and consumers to produce or sell safe products. In determining whether that duty was indeed assumed, courts have, too, relied on the extent to which an SDO wields control over compliance with its standards by its membership, or in the industry more broadly.⁴⁷ The lack of such control was then typically considered sufficient for a no duty decision.⁴⁸

23. In *King v. NSPI*, however, the lack of control did not withhold the Alabama Supreme Court from imposing on the National Spa and Pool Institute (NSPI), a trade association which promulgated standards for the size, shape and dimensions of residential swimming pools, a duty to exercise due care under the voluntary undertaking rule proposed by the Restatement. In this case, the plaintiff's husband broke his neck after diving into his pool from the jump board. Some months later he died of pneumonia secondary to his injury. In previous claims involving diving injuries, courts in New Jersey and New York had forthrightly refused to accept that NSPI owed a duty to pool users based on the theory that it had no control over pool manufacturers or sellers.⁴⁹

⁴⁴ Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 43 (2010). This guideline was previously laid down in similar wording in § 324A Restatement (Second) of Torts, which 'has been widely recognized by the court'. DOBBS, HAYDEN & BUBLICK 2016 (n 21), p.628 (with references to case law).

⁴⁵ See e.g. *Bailey* (n 25) and *Commerce and Industry Insurance Company* (n 25). In *N.N.V.* (n 34) the plaintiff relied on § 324A Restatement (Second) of Tort in its appeal against AABB's summary judgment, which had been granted in first instance in relation to a general negligence action.

⁴⁶ See more extensively VERBRUGGEN (n 19), Section B.3.

⁴⁷ Cf *Commerce and Industry Insurance Company* (n 25), 4 ('Under the Restatement analysis advanced by plaintiffs, most courts have focused on the amount, if any, of control a trade association wields over the behavior of its members concerning, for example, the proper implementation of its standards.')

⁴⁸ See e.g. *Bailey* (n 25), 185. ('[The SDO's] instructions were advisory. [It] could not force the carpenters to abide by its admittedly general instructions.'). See also the case law at n 49 below.

⁴⁹ See *Meyers v. Donnatacci* 531 A.2d 398, 406 (NJ.Super 1987) ('NSPI had no authority to mandate compliance nor did it attempt to force its members to comply. It acted merely as a secretariat for its members; a forum where those who chose to make suggestions could do so. There were no penalties for failing to respond to the survey') and *Howard v. Poseidon Pools* 133 Misc.2d 50 (N.Y.Misc. 1986), 55 (aff'd in part and rev'd in part on other grounds, 522 NYS.2d 388 (1987)), 55 ('NSPI did not have the duty or the authority to control the manufacturers who did produce the product here in question, viz., the swimming pool') (discussing the existence of a duty of care in an action sounding in negligence).

24. The Alabama Supreme Court held differently in *King*. Reading the case as premised on malfeasance rather than nonfeasance, it considered that NSPI ‘had no statutorily or judicially imposed duty to formulate standards’, but nonetheless did so voluntarily.⁵⁰ The fact that NSPI standards were based on the voluntary consensus of its members did not absolve the SDO from a duty to exercise reasonable care when it undertook to promulgate standards.⁵¹ NSPI had adopted its standards having in mind ‘the needs of the consumer’ and it had declared that safety was ‘one of the basic considerations upon which these design and construction standards are founded’.⁵² Under those circumstances, the Supreme Court held, harm for consumers was foreseeable for NSPI if due care was not exercised when promulgating its standards.⁵³

25. The approach in *King* was confirmed by the Washington Court of Appeals in *Meneely*, in which NSPI was held liable for rendering a young swimmer quadriplegic who dove from a jump board into a pool, while it knew that the combination of the specific pool and board at hand posed a risk for certain divers and failed to amend its safety standards accordingly.⁵⁴ The damages award against NSPI of \$6.6 million, along with settlements in other cases, sent the SDO into insolvency.⁵⁵ Emerging from bankruptcy in 2004, the SDO was again faced with a personal injury action of an injured swimmer. In assessing the action, however, the courts in first instance and on appeal reinvigorated the control factor as a key determinant for the existence of a duty of care.⁵⁶

26. Applying the voluntary undertaking rule to impose a duty of care on an SDO finds it limit in the courts’ sense of policy and justice: even if a duty can be imposed on SDO’s following Section 43 of the Restatement, considerations of policy and justice may trump the existence of a duty.⁵⁷ Thus, again, considerations on the foreseeability of harm to the

⁵⁰ *King v. National Spa and Pool Institute* 570 So 2d 612, 614 (Ala 1990).

⁵¹ *Ibid*, 618.

⁵² *Ibid*, 615-616.

⁵³ *Ibid*, 616. See also *Rountree v. Ching Feng Blinds Industry Co, Ltd*, 560 F.Supp.2d 804 (D.Alaska 2008), in which the U.S. District Court of Alaska considered (at 809) that is of no consequence that the defendant SDO, which undertook to develop safety standards intended to reduce strangulation hazard posed to infants by cords of window coverings, ‘did not have control over the blinds because [it] had control over the content of the warning. The warning itself provides a critical nexus between [the SDO], the manufacturer and the consumer.’

⁵⁴ *Meneely v. Smith* 5 P 3d 49, 57 (Wash.App.2000) (applying the Washington voluntary rescue doctrine, which is broadly similar to the rule proposed in Restatement (Third) of Torts, §43(b)).

⁵⁵ See in detail HEIDT (n 20) 1231, at n 15.

⁵⁶ The U.S. District Court in Georgia found at first instance that the ‘standards are voluntary, consensus standards’ and that the association ‘has no power to enforce compliance with those standards’ and ‘had no control over [the contractor’s] installation of the [plaintiff’s family] pool or over whether [the contractor] complied with the NSPI Standard when installing the pool’. *Lockman v S.R. Smith, LLC*, 4:07-CV-0217-HLM, 2010 WL 11566367 (N.D.Ga. 2010), 7. The Eleventh Circuit Court confirmed these findings on appeal and added that the SDO did not owe a duty to warn consumers about the danger of swimming pools and diving boards covered by its standards following the Restatement. *Lockman v S.R. Smith, LLC*, 405 Fed.Appx. 471, (11th.Cir. 2010) (per curiam) WL 5158571, 474.

⁵⁷ DOBBS, HAYDEN & BUBLICK 2016 (n 21), p.630 and Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 43, cmt. b (2010). See also LYTTON in this Issue.

plaintiff, the closeness of connection between the defendant's conduct and the plaintiff's harm, the moral blame attached to the SDO's conduct, the policy of preventing future harm, the burden on the defendant and the consequences to the community if a duty is imposed, the availability and cost of insurance to cover the risk involved.⁵⁸

4.3 Standard of care and breach

27. Once an SDO is considered to owe a duty of care, the next question is what that duty is, expressed as a standard of care. In the absence of a more specific standard, the ordinary standard of care to which the defendant SDO must conform is that of the reasonable person, who, under the circumstances, avoids physical harm to others.⁵⁹ The cases in which an SDO has been considered to owe a duty to the plaintiff, it was held to exercise 'reasonable', 'ordinary' or 'due' care in the development of its standards. The SDO was thus required to avoid harm that was known to it or reasonably foreseeable. However, if the harm was considered to be unknown or not reasonably foreseeable, the SDO did not breach its standard of care.⁶⁰ Under those circumstances, the reasonable person would neither have avoided the harm to others.

28. American common law permits the plaintiff to present at trial a wide range of evidence to show that the defendant SDO breached its duty and that the process of standards development administered by it fell short of the level of care it was reasonably required to exercise. Such evidence generally includes internal company rules or rules of association, industry practice, private standards, statutes, government regulation and guidance, and cost-benefit analysis.⁶¹ Accordingly, a violation of the SDO's own guidelines or bylaws for standards development can be considered as evidence showing breach, but also non-compliance with government or industry-endorsed principles on how standard setting procedures should be organized may be used to demonstrate that the defendant SDO fell short of the level care required.

29. In this regard, particularly relevant appear to be the good governance principles set out in Circular No. A-119 of the Office of Management and Budget (OMB), which is part of the Executive Office of the U.S. President.⁶² The Circular provides further guidance to Section 12(d) of the National Technology Transfer and Advancement Act of 1995, which directs Federal agencies to use private standards for their regulatory activities on the condition that these standards were developed following certain procedural safeguards. Circular No. A-119 lays down those safeguards and provides that agencies should use private standards where these were developed by SDOs ensuring openness in participation, a balance of interests, due process and an appeals procedure. In addition, the SDO must operate on the basis of

⁵⁸ See e.g. *Rountree* (n 53), 810-811 (holding that these policy considerations do not weigh against the imposition of a duty on an SDO which undertook to develop safety standards intended to reduce strangulation hazard posed to infants by cords of window coverings).

⁵⁹ Restatement (Third) of Torts (Liability for Physical and Emotional Harm) §§ 7(a) and 43 (2010).

⁶⁰ See e.g. *N.N.V.* (n 34), 1394. If foreseeability is part of the duty inquiry, the unforeseeability of harm will likely lead to a no-duty decision.

⁶¹ See in general DOBBS, HAYDEN, AND BUBLICK 2016 (n 21), pp. 263-289. See also LYTTON in this Issue.

⁶² Circular No. A-119 (n 3).

consensus, which is defined as a ‘process attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.’⁶³

30. The Circular guidance on the governance of standards development is further detailed in the ‘Due Process Requirements for American National Standards’ adopted by the American National Standards Institute (ANSI).⁶⁴ ANSI is the non-profit private associations that administers the product standardization system in the U.S. SDOs that are part of this system have had their standardization procedures accredited by ANSI and must, as part of their contractual arrangement with ANSI, follow the due process requirements to keep their accreditation.⁶⁵ The requirements involve the obligation to publicly notify to suitable media the creation, revision or withdrawal of standards to all known affected interest groups.⁶⁶ ANSI members are also required to give consideration to objections voiced against proposed standards in public consultations, and provide each commentator a written and reasoned opinion as to the objections.⁶⁷ Furthermore, an appeals process should be available.⁶⁸ ANSI also requires that different interest categories (i.e. industry, users, general interest) are involved to ensure a balance of interests in standards development. For safety-related standards it holds that single interest categories shall not hold more than one-third of the membership of the technical committee developing the standard.⁶⁹ The majority of the SDOs that were exposed to civil liability claims, are in fact ANSI-accredited members.⁷⁰

31. In the cases reviewed here no reference was made to Circular No. A-119, ANSI’s due process requirements, or any other public or private guidelines on standards development to establish the reasonable care the defendant SDOs were required to exercise. In fact, there is very little consideration around the question of what constitutes reasonable care for SDOs. In *Meneely* and *Snyder* – the only two cases resulting in a damages award against the SDOs involved – the issue of breach turned on the narrow question of whether the SDOs could have reasonably refused to amend their safety standards while being aware of a risk these standards posed.⁷¹ In *NNV*, the no-duty decision of the California Court of Appeals, the court went on to consider the relevant community to determine the standard of care. The

⁶³ *Ibid*, para. 4.

⁶⁴ ANSI Essential Requirements: Due process requirements for American National Standards (2018), <https://share.ansi.org/Shared%20Documents/Standards%20Activities/American%20National%20Standards/Procedures%2C%20Guides%2C%20and%20Forms/ANSI-Essential-Requirements-2018.pdf>.

⁶⁵ See for a critical evaluation of participation and transparency in standards development procedures of ANSI-accredited SDOs whose standards are incorporated by reference in agency or other state body regulation: N. A. MENDELSON, "Private Control over Access to Public Law: The Perplexing Federal Regulatory Use of Private Standards", 112. *Michigan Law Review* 2014, p. (737) at 757-761.

⁶⁶ ANSI Essential Requirements (n 64), Sections 1.1 and 1.5.

⁶⁷ *Ibid*, Section 1.6.

⁶⁸ *Ibid*, Section 1.8.

⁶⁹ *Ibid*, Section 2.3.

⁷⁰ These include those developing standards for blood banking and transfusions (AABB), plywood products (APA), fire safety (NFPA), swimming pools (NSPI), and safety standards for window coverings (WCMA).

⁷¹ *Snyder* (n 27), 1038 and *Meneely* (n 54) 57.

plaintiff argued that this community could not be constituted by the private organizations concerned with investigating and setting standards relating to blood products and transfusions, for they are biased and in fact only reflected the SDO's determination of the standard of care. The *NNV* court disagreed and held the relevant community also involved government organizations investigating and making recommendations on the transmission of AIDS. As none of the public and private organizations involved recommended new testing methods for donor blood, the SDO's standards were consistent with and did not breach the relevant community's standards. Moreover, there was no evidence supporting the assertion that the private organizations did not actively participate in the issuance of standards. Finally, the Court considered that these organizations did not represent industry voices since each one has members representing different interests and many voices.⁷²

32. While these considerations on breach in *NNV* were all *obiter* for a lack of duty, they do reveal that concerns around stakeholder participation in standards development can weigh in on the determination of whether the SDO reasonably decided on its standards under the circumstances.⁷³ What is undoubtedly important to establish breach is the question of whether the SDO used the knowledge and insights gained from practical experience with its standards to direct its decision-making. This is what *Meneely* and *Snyder* make clear. In both cases the courts imposed liability on the SDOs involved for refusing to amend their safety standards in the light of compelling evidence that these standards posed a significant risk of harm to others.⁷⁴ Thus, an SDO that does not take into consideration the state-of-the-art when revising its standards, or that altogether fails to adopt new standards in the face of evidence showing the existence of apparent risks, does not act with ordinary care.⁷⁵

33. Importantly, the standard of ordinary care does not require a perfect decision from the SDO, yet only that it is reasonable at the time of consideration. Standard setting typically is an 'imperfect and evolving process'.⁷⁶ While delay in setting a particular standard in relation to a known and foreseeable risk may be negligent, SDOs enjoy a certain level of discretion in making choices on what the standard is that it adopts, particularly in times of uncertain knowledge about risks.⁷⁷ Private standardization, like public law-making, is a political process that requires the making of policy-bound trade-offs between conflicting interests of

⁷² *N.N.V.* (n 34), 1393-1394.

⁷³ In *Meyers*, for example, the court also drew attention to the practice of public solicitation of comments and suggestions of non-members on draft standards to ensure a fair representation of interests to argue that the element of foreseeability was lacking. See *Meyers* (n 49), 403.

⁷⁴ *Snyder* (n 27), 1038 and *Meneely* (n 54), 57.

⁷⁵ See also *Commerce and Industry Insurance Company* (n 25), 4 (holding that if the NFPA had owed a duty to plaintiffs, it would not have breached the duty because the plaintiffs did not provide evidence that the SDO knew or should have known of the alleged fire safety risk. Instead, NFPA periodically reviews and revises its standards 'to keep current with new fire protection knowledge and technologies' and 'to include fire safety lessons learned from significant fires'.)

⁷⁶ *Commerce and Industry Insurance Company* (n 25), 3.

⁷⁷ Cf. *Jappell* (n 33), 481 ('Where delay in setting a particular standard would be negligent, the duty to act without negligence may require Defendant to make difficult choices somewhat earlier than it would prefer.'). See also Amos, J. dissent in *N.N.V.* (n 34), holding at 1404 that 'If a duty were imposed on AABB, it would not be breached if there was an ongoing debate and the state of knowledge in a particular area was still evolving'.

the owners, users and potential beneficiaries.⁷⁸ Concerns of health and safety may thus need to be balanced against concerns of cost, inconvenience and consumer choice.⁷⁹ In evaluating these trade-offs courts should allow from some discretion and defer to the policy choices made whenever fair and reasonable.

34. What can be reasonably expected of SDOs is further limited by the costs involved for SDOs to ensure open, participatory and transparent procedures for standardization that take into account current knowledge and wisdom about the risks it seeks to address through its standards. Those costs can be significant as good governance demands such as these do not come for free and may in fact be very laborious for SDOs and their staff. For example, SDOs may have to revise its internal procedures or put in place new ones, these have to be administered by staff, media space needs to be bought to ensure sufficient and meaningful notification of the adoption, revision or withdrawal of standards, and public meetings and consultations need to be organized, hosted and reported upon.⁸⁰

35. Applying the eloquent formula defined by Judge Learned Hand ($B < PL$),⁸¹ the costs associated with good governance, seen here as the SDO's burden (B) to prevent the risk of harm from inadequately developed standards, need to be balanced against the probability of harm resulting from those standards (P) and the extent of loss (L) when that harm occurs in order to determine the SDO's negligence. This efficiency test would suggest that an SDO that develops standards which do not concern health or safety risks, and which are not widely recognized by industry, government or the general public, will not breach the duty it owes to a third party injured by its standards if it did not care for open, participatory and transparent procedures in standard setting. However, if the standards address imminent health and safety risks, and enjoy a strong degree of authority as a result of a high market uptake or government recognition, more prudence more is expected of the SDO. In that case, greater demands can be placed on it in terms of assuring fair representation and openness in procedures for standards development. Thus, from this efficiency perspective, the New Jersey Supreme Court in *Snyder* was right in sanctioning the absence of inclusive and transparent procedures of the AABB along with its commitment to promote the financial interests of the blood banking industry at the expense of patients' health and safety.⁸²

⁷⁸ BÜTHE & MATTLI, (n 1), 8.

⁷⁹ HEIDT (n 20), 1227-1232.

⁸⁰ See for an empirical account of the various costly institutional changes the administration of GLOBALGAP, the most widely implemented private food safety standard around the world, has made in order to respond to diverse legitimacy claims from business members, consumers and governments: D. CASEY, "Interactions, Iterations and Early Institutionalization: Competing Lessons of Globalgap's Legitimation", in: S. Wood e.a. (eds), *Transnational Business Governance Interactions: Enhancing Regulatory Capacity, Ratcheting up Standards and Empowering Marginalized Actors* (Cheltenham: Edward Elgar 2019), pp. **forthcoming**.

⁸¹ *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d.Cir.1947), 173.

⁸² *Snyder* (n 27), 1050 ('Although the AABB's mission doubtless has altruistic overtones, the bottom line is that the AABB represents its interests and those of its members. At stake for its members was a substantial financial interest in the regulation of the industry. (...) Blood is big business.') and at 1053 ('The internal AABB meetings that yielded the decision not to recommend surrogate testing were not open to the public. Nor were minutes of those meetings publicly available.')

5. Tort liability for private standardization in the EU

36. Liability for private standardization has not attracted much attention in Europe. There is very little case law on the matter. Judicial control over private standards development has instead taken place for the most part in the context of EU competition law⁸³ and judicial review, at both the EU⁸⁴ and Member State level.⁸⁵ Very few European scholars have considered the civil liability of SDOs, what policy considerations should support or limit the imposition of such liability, or how their liability position relates to that of public regulators, individual professionals or collective associations engaged in standardization or certification.⁸⁶ Since no general EU law framework exists that governs the liability for private standardization, the national tort laws of the EU Member States apply.

5.1 Liability under the New Approach

37. Product standardization in the EU is regulated through a general legal framework called the ‘New Approach’. This framework was developed in the 1980s to improve the free movement of goods within the internal market.⁸⁷ Within the program, the legislative institutions of the EU adopt secondary legislation that sets out the ‘essential requirements’ with which products have to comply to be lawfully traded in the EU. The precise technical specifications are then laid down in a European harmonized standard that is developed by a recognized European standardization organization. Compliance with a harmonized standard creates a presumption that products also comply with the essential requirements of the relevant EU legislation. In practice, showing compliance with a harmonized standard is the most important way for manufacturers in the EU to show legal compliance and access the internal market.⁸⁸

38. Regulation 1025/2012/EU currently establishes the legal framework underpinning the New Approach. It recognizes CEN, CENELEC and ETSI as the European standardization organizations.⁸⁹ It does not govern their liability, however. CEN and CENELEC are private

⁸³ See M. MATAIJA, *Private Regulation and the Internal Market: Sports, Legal Services, and Standard Setting in Eu Economic Law* (Oxford: Oxford University Press 2016), p. 233-244.

⁸⁴ CJEU 27 Oct 2016, C-613/14, *James Elliott Construction Ltd v Irish Asphalt Ltd*, ECLI:EU:C:2016:821, on which see VAN LEEUWEN in this Issue.

⁸⁵ H. SCHEPEL & J. FALKE, *Legal Aspects of Standardisation in the Member States of the Ec and Efta, Volume 1: Comparative Report* (Luxembourg: Office for Official Publications of the European Communities 2000), p. 131-134

⁸⁶ Notable exceptions are SPINDLER (n 12); SCHEPEL (n 13), 384-387 and CAFAGGI (n 14), 58-73. See also VERBRUGGEN (n 19). More discussion exists around the liability of certification bodies, which perform audits and inspections to verify compliance with product standards. See in detail VAN HO & TERWINDT, GLINSKI & ROTT, and DE BRUYNE in this Issue.

⁸⁷ See in detail VAN LEEUWEN in this Issue.

⁸⁸ H. SCHEPEL, "The New Approach to the New Approach: The Juridification of Harmonised Standards in Eu Law", 20. *Maastricht Journal of European and Comparative Law* 2013, p. (521) at 528.

⁸⁹ CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute) develop standards for different sectors. Art. 2(8) read in conjunction with Annex I of Reg. 1025/2012/EU on European standardization [2012] OJ L 316/12.

non-profit associations established under Belgian law.⁹⁰ ETSI is a private non-profit association under French law.⁹¹ The liability of these European SDO is therefore principally governed by Belgian and French tort law. The civil liability of national SDOs that are members of CEN, CENELEC and ETSI is equally governed by national law. These national SDOs participate in the creation of European harmonized standards and implement them at the national level, that is, they translate the standards and make them available to the public, usually upon payment of a fee.

39. Only very few national courts in the EU have been reported to be involved in claims concerning the negligence liability of SDOs, both within and beyond the New Approach. A comprehensive comparative study called ‘Legal Aspects of Standardization’, which was commissioned by the European Commission and the European Free Trade Association in the late 1990s, concluded as regards the potential of tort law to hold liable SDOs for negligent standard setting: ‘[E]ven though the theoretical possibility is open in all jurisdictions under discussion here, France and Italy seem to be the only Member States where it has actually happened’.⁹² The Italian case involved the alleged violation of intellectual property rights for the use of geographical denominations by the national standards body as it developed a new standard to compete with an existing one.⁹³ The outcome of the case was unknown at the time of reporting and could not be traced more recently.

40. The French case concerned the liability of the national SDO for technical standards called *Association Française de Normalisation* (AFNOR). Whenever AFNOR develops standards for products covered by New Approach legislation, it is considered to fulfil a public law function (*mission de service public*) under French administrative law.⁹⁴ The rules of state liability then govern the liability of AFNOR and the French administrative courts hold the exclusive competence to hear related damages actions.⁹⁵

41. In the reported case, AFNOR had licensed a manufacturer of a certain type of concrete pavement to use its conformity mark ‘NF’. After a very severe winter, however, the pavements had cracked. The manufacturer was held liable by the municipalities where the defective pavements had been placed and by the contractors that placed them there. It then enjoined AFNOR in the proceedings and sued to recover its economic loss allegedly caused by

⁹⁰ CEN ‘Statutes’ (2015) ftp://ftp.cencenelec.eu/CEN/AboutUs/Governance/Statutes/Statutes_CEN-EN.pdf and CENELEC ‘Articles of association’ (2015) ftp://ftp.cencenelec.eu/CENELEC/ArticlesOfAssociation/1_CLCArticlesOfAssociation2015_EN.pdf. CEN and CENELEC have as their membership national standardization bodies of the EU Member States and a number of additional European countries.

⁹¹ ETSI ‘Statutes’ (2017) https://portal.etsi.org/directives/37_directives_apr_2017.pdf. ETSI has over 800 members including standardization bodies, government representatives, trade associations and individual businesses.

⁹² SCHEPEL & FALKE (n 85), p. 238.

⁹³ P. MENCHETTI, “Legal Aspects of Standardisation in Italy”, in: H. Schepel & J. Falke (eds), *Legal Aspects of Standardisation in the Member States of the Ec and Efta, Volume 2: Country Reports* (Luxembourg: Office for Official Publications of the European Communities 2000), pp. 499-543, at 540.

⁹⁴ Conseil d’Etat, Section S, 17 February 1992, No. 73230. See also Décret No. 2009-697 of 16 June 2009 relatif à la normalisation.

⁹⁵ See in general C. VAN DAM, *European Tort Law* (Oxford: Oxford University Press 2013), pp. 533-536.

AFNOR's 'inadequate' standards. The *Tribunal Administrative de Paris* denied the claim. First, it upheld exclusion clause AFNOR had included in the license contract for use of its NF mark, implying that it could not be held liability for all defects in products that were awarded that mark. Second, it considered AFNOR not to be at fault given that its standards could not be held to cover all possible characteristics of the products they concern. Moreover, as soon as AFNOR became aware of the problems concerned, it amended the relevant standard.⁹⁶

42. The fact that the liability of an SDO is governed by rules on state liability, as in France, may be seen as an important factor to explain the limited liability exposure of national SDOs operating under the New Approach in the EU.⁹⁷ Indeed, in the context of state liability, policy considerations may put more stringent demands on the elements of duty, breach or causation in negligence actions.⁹⁸ Thus, to the extent that SDOs make use of their public law status or powers to develop product standards in the context of the New Approach, such policy considerations may further limit the liability risk for SDOs.⁹⁹

43. The British Standards Institute (BSI) previously admitted to owe a duty of care to anyone relying on its standards in its 'Standard for Standards'.¹⁰⁰ Such a bold assumption of responsibility is no longer found in the version of the standard currently in force.¹⁰¹ The study on 'Legal Aspects of Standardization' also reported the German *Deutsches Institut für Normung* (DIN) to admit to a duty of care (*Garantenstellung*) to users of its standards.¹⁰² Still, the reporters of the study considered that the liability exposure of the British and German SDOs was relatively low since they had put in place a number of procedural safeguards that would mitigate against a breach of the duty.¹⁰³ Such safeguards concern the ambition to ensure participation of interested stakeholders and knowledgeable experts in standards development, to have available to these actors all relevant technical and scientific information, and to ensure that standards are developed for the common good only and not for individual commercial benefit.¹⁰⁴ The *AFNOR* case discussed above demonstrates that it

⁹⁶ *Tribunal Administrative de Paris*, 9 March 1993, *Société Les Grands Travaux de l'État c/ Pottier et Oth*, not reported. See in detail: J. CHAMPIGNEULLE-MIHAILOV, "Les Aspects Juridiques De La Normalisation En France", in: H. Schepel & J. Falke (eds), *Legal Aspects of Standardisation in the Member States of the Ec and Efta, Volume 2: Country Reports* (Luxembourg: Office for Official Publications of the European Communities 2000), pp. 231-322, at 318-319.

⁹⁷ Attention may also be drawn to the extensive use of liability limitation and indemnification clauses by SDOs via general terms of sale or service or via internal regulations and bylaws as a factor explaining the limited liability exposure of SDOs. See in detail VERBRUGGEN (n 19).

⁹⁸ VAN DAM (n 95), p. 579.

⁹⁹ SCHEPEL & FALKE (n 85), p. 239.

¹⁰⁰ Section 6.9.1.5, BS 0: 1997 A Standard for Standards, Part 2 – Recommendations for committee procedures.

¹⁰¹ BSI, 'Rules for the structure and drafting of UK standards' (April 2017), <https://www.bsigroup.com/Documents/standards/guide-to-standards/Rules-for-structure-and-drafting-of-UK-standards-2017.pdf>.

¹⁰² SCHEPEL & FALKE (n 85), pp. 240-241.

¹⁰³ *Ibid.*, pp. 241-242.

¹⁰⁴ See e.g. the BSI Rules for the structure and drafting of UK standards 2017 (n 120) and DIN 'DIN 820-1. Normungsarbeit - Teil 1: Grundsätze', <https://www.din.de/de/ueber-normen-und-standards/din-norm/grundsaeetze>.

is also helpful in this respect to have in place a standards review procedure once shortcomings become clear.

5.2 Liability beyond the New Approach

44. The European standardization organizations and national SDOs are free to engage in the development of standards beyond the scope of the New Approach. The setting of such market-based standards now constitutes an important business activity for many. Also in domains that are not covered by New Approach legislation, the liability for private standardization is principally governed by the national tort laws. Here, again, relevant case law is virtually absent. While damages actions against SDOs have reached the supreme courts of a number of Member States, these actions first and foremost disputed the certification activities the SDOs were engaged in, rather than any standards development *per se*.¹⁰⁵ Damages actions involving the liability for private standardization are extremely rare and plaintiffs may not be able to meet the elements that national tort laws require for their actions to prevail.¹⁰⁶

45. In English common law, for example, policy considerations around the existence of a duty of care are likely to defeat most claims, as they do in American common law. The leading case law of the Supreme Court on the tort of negligence and on negligent misstatements suggests that no such duty exists because of a lack of a sufficiently proximate relationship between the plaintiff and defendant SDO, or the absence of the assumption of a responsibility by the SDO on which the plaintiff reasonably relied.¹⁰⁷ Policy factors concerning the public role of SDOs in society as non-profit organizations promoting the collective welfare and the consequences in terms of liability exposure for SDOs and their public role if a duty were imposed would further militate against a duty being recognized, in particular if the plaintiff is suing for economic loss.¹⁰⁸

¹⁰⁵ See e.g. for England *Marc Rich & Co AG and others v. Bishop Rock Marine Co Ltd and others* (The Nicholas H) [1995] UKHL 4 (A classification society does not owe a duty of care to cargo owners arising from negligent inspections of a damaged ship); for France Cour de Cassation 2 October 2007 (Chambre civile 1), Case no. 06-19.521, Bulletin 2007, I, N° 315 (A certifier is not liable for economic losses caused by a defect that arose in a certified television within the period of warranty set by the producer); for Germany Bundesgerichtshof, VII ZR 36/14 (2017) (a certifier is not liable for personal injury caused by defective breast implants if the manufacturer of the implants had used materials not intended to be used for manufacturing such medical devices and had fraudulently concealed that use from the certifier); for the Netherlands Hoge Raad 29 June 2007, ECLI:NL:HR:BA0895 (*Strawberry Mite*) (certifier is liable for pure economic loss sustained by a strawberry farmer and caused by the violation of its own certification standards for pest control in horticulture products).

¹⁰⁶ The Supreme Court of the United Kingdom recently considered the *MT Højgaard A/S* case (n 8), which involved a claim for economic loss caused by a defective product standard for offshore wind farms. The litigation did not extend to the matter of SDO liability, however. Instead, it turned on the question of whether a contractor who complied with the standard in designing and constructing two offshore wind farms, as required under the ‘design and build contract’, was nonetheless liable to the promisee for the remedial works to the compliant, yet failing (and therefore not ‘fit for purpose’) foundation structures of these farms.

¹⁰⁷ *Hedley Byrne & Co. Ltd. v. Heller & Partners Ltd.* (1964); *Caparo Industries plc v. Dickman* (1990); and most recently *Banca Nazionale del Lavoro SPA v. Playboy Club London Ltd. & others* (2018).

¹⁰⁸ *Cf. Marc Rich* (n 105), at 12-13 (Per Lord Lloyd of Berwick) and 28 (Per Lord Steyn).

46. This might just be different in cases of personal injury. In *Perrett v. Collins*, the Court of Appeal held that the one who inspects an aircraft in order to determine its airworthiness owes a duty to passengers of that aircraft to act with reasonable care so to ensure that they are not injured by reason of a defect in the aircraft's construction.¹⁰⁹ In cases where the defendant engages in conduct that imports a foreseeable risk of personal injury to the plaintiff and had 'a measure of control over and responsibility for' that risk, Hobhouse L.J. reasoned, there is sufficient proximity between the parties.¹¹⁰ Questions around directness are then reserved for the causal link between the breach of the duty and plaintiff's harm.¹¹¹ Recognising that this case involved the liability for wrongful inspections only, the reasoning in *Perrett* may arguably be extended to SDOs that have a significant degree of control over the existence of a foreseeable risk of personal injury, such that the manufacturer or seller, by merely complying with the inadequate standards in its business practices, places on the market a product that is by design harmful to users. The U.S. case law discussed above offers various examples of how the existence of such control may be constructed.

47. In civil law countries, in particular those that may be considered to stand in the Napoleonic tradition (e.g. Belgium, France, Italy, the Netherlands, Spain), the duty element in negligence liability (or any equivalent concept used) does not involve the same kind of considerations as in American or English common law. Nonetheless, considerations around the foreseeability of the type of plaintiff's harm, the moral blame attached to the SDO's conduct, the closeness of connection between that conduct and the harm, and the societal function of standard-setting are likely to surface in the determination of breach and legal causation.¹¹² Accordingly, breach and causation serve as the main control mechanisms to guard against overly burdensome liability for SDO. These elements are, unlike in the U.S., decided by judges only.

5.3 EU law as a catalyst for liability for private standardization

48. The role of EU law may not be completely over, however. Violations of EU law may serve as a catalyst of damages actions against SDOs based on national tort law, in particular in relation to economic loss. The case of *Fra.bo v. Deutsche Vereinigung des Gas- und Wasserfaches eV* may serve to illustrate that role.¹¹³ The case involved Fra.bo, an Italian manufacturer of copper fittings for water and gas piping that wanted to place its products on the German market.¹¹⁴ For that purpose, it applied to DVGW, a private, non-profit

¹⁰⁹ [1998] 2 Lloyd's Rep 255 (CA). See VAN HO & TERWINDT, ROTT & GLINSKI and DE BRUYNE, in this Issue.

¹¹⁰ *Ibid*, 262. Such understanding of proximity is based on *Donoghue v. Stevenson* [1932] A.C. 563, 581 in which there was closeness between the plaintiff and defendant both in time and in space, and there were no intervening human activities as to the state of the harmful product concerned.

¹¹¹ *Ibid*, 262. See in detail C. WITTING, "Negligent Inspectors and Flying Machines", 59. *Cambridge Law Journal* 2000, p. (544) (describing the different roles proximity may play in classes of cases in negligence law).

¹¹² See in general VAN DAM (n 95), 208-217 (discussing the different policies and control mechanisms used in English, France and Germany law to limit the scope of protection offered by tort law in the context of pure economic loss).

¹¹³ CJEU 12 July 2012, C-171/11, *Fra.bo v. DVGW*, ECLI:EU:C:2012:453.

¹¹⁴ The litigious copper fittings fell outside the scope of the New Approach legislation on the sale of construction materials in the EU.

association that promulgated technical standards for the performance of construction materials used in the gas and water sector in Germany. DVGW also certified products based on those standards. German product safety law required manufacturers like Fra.bo to show that their products complied with recognized rules of technology as condition to enter the German market. DVGW certification, it turned out, was the only practical way that compliance could be established.

49. Fra.bo's initial application for certification was successful. However, soon after DVGW suspended and eventually withdrew Fra.bo's certification. It did so following a competitor complaint about Fra.bo's fittings and the introduction of new, more demanding performance testing in its product standards. In response, Fra.bo brought a damages action against DVGW for breach of contract and EU law. It argued, among other things, that the introduction of the new standard was arbitrary and had no other goal than to limit its access to the German market. Fra.bo moreover contended that the test results provided by a state-accredited Italian laboratory showed its compliance with the original technical standards and there was no reason for DVGW to deny these results as they were produced according to the procedures DVGW had itself stipulated.¹¹⁵

50. The district court in Cologne denied the claim. The court hearing the appeal referred several preliminary questions to the Court of Justice of the EU as it was unsure how to interpret and apply the EU rules of internal market law concerned. In delivering its judgment, the European Court of Justice held that the standardization and certification activities of DVGW are covered by the EU rules on free movement of goods, which prohibits the imposition of measures by Member States that limit the import of products from other Member States. Even though DVGW is a private entity, the Court applied a functional approach and considered that it restricted the free movement of goods 'in the same manner as do measures imposed by the State' based on the status its certification had under national safety regulations.¹¹⁶ DVGW could thus effectively regulate access to the German market. This led the Court to hold that DVGW's standardization and certification activities within the scope of the free movement of goods provisions of the Treaty on the Functioning of the EU.¹¹⁷

51. After this preliminary ruling, the referring court in Germany held that DVGW was liable vis-à-vis Fra.bo for breach of contract. It considered that DVGW's newly adopted product standards for certification were contrary to the free movement of goods, as these could restrict the import of goods otherwise lawfully traded in other Member States. DVGW could not make the continuity of Fra.bo certification dependent on the meeting of those standards and related testing procedures. Accordingly, the revocation of Fra.bo's certification was

¹¹⁵ Cf. Landgericht Köln, 12 March 2008, 28 O (Kart) 529/07, (28. Zivilkammer), paras. 31, 32 and 36.

¹¹⁶ *Fra.bo* (n 113), para. 26.

¹¹⁷ *Ibid*, paras. 27-32.

without any ground and unlawful.¹¹⁸ Moreover, DVGW was wrong to discard the testing results of an accredited laboratory in another Member State, since this is contrary to the mutual recognition principle underpinning EU free movement law.¹¹⁹

52. DVGW's breach of EU law, the court of appeal further reasoned, could not be justified. The protection of public health, as DVGW claimed, did not serve as an appropriate justification for the adoption of the standards. The SDO failed to provide evidence that the adoption of the new standard was instrumental to such protection, for example by offering a detailed risk analysis of the hazards it claimed to control by introducing additional testing, that is, bacterial contamination of water or gas explosions caused by failing copper fittings. Apparently, such risks did not play any role when DVGW adopted the new standard. Moreover, DVGW did not sufficiently establish that the new testing was the accepted state-of-the-art, which might as well be less demanding.¹²⁰ In conclusion, DVGW unlawfully and negligently withdrew Fra.bo's certification, which likely caused the latter's (pure economic) losses consisting in the loss of profit it could have made the period in which it was cut off from the German market.¹²¹

53. The case of *Fra.bo* illustrates how national private law and EU internal market law complement each other in the regulation of technical standardization and certification. As shown, a civil damages claim gave rise to a discussion of whether EU rules applied and were violated. While in this case the rules at stake concerned free movement of goods, in others it may involve directly effective rules of competition law or non-discrimination. After the Court of Justice established that EU rules did apply, the national court held that these rules were violated in the performance of contractual obligations, thus giving rise to a remedy in private law. Clearly, in *Fra.bo* it was contract law that provided the plaintiff with a remedy against the SDO, but had a contractual relationship been absent between the two, as is usually the case of harm caused by standardization, an action in tort could have provided similar means for addressing any allegedly wrongful activities. More generally, any breach of EU law that is directly applicable to the activities of an SDO and that is protective of the interests of the actor affected by those activities, constitutes a ground to bring a claim in tort against the SDO.¹²² Tort law constitutes a key branch of the law to privately enforce those EU law rules at the national level and can, as such, be said to contribute in significant ways to the regulation of private standardization in the EU.

¹¹⁸Oberlandesgericht Düsseldorf, 14.08.2013, VI-2 U (Kart), (2. Kartellsenat), paras. 48-50.

¹¹⁹ *Ibid*, para. 54.

¹²⁰ *Ibid*, paras. 63-64.

¹²¹ *Ibid*, para. 78.

¹²² P. VERBRUGGEN, "The Impact of Free Movement of Goods and Services on Private Law Rights and Remedies", in: H.-W. Micklitz & C. Sieburgh (eds), *Primary Eu Law and Private Law Concepts* ((Cambridge: Intersentia 2017), pp. 47-91.

6. Tort law's current role in promoting good governance of private standardization

54. Academic commentators have emphasized the potential of tort law as a way to foster compliance with good governance principles in private standardization and constitutionalise private norm development by setting fundamental rules for it.¹²³ The previous analysis suggests that, in practice, considerations around good governance of private standards development play only a limited role in holding SDOs liable for harm caused to others, both in the U.S. and EU. These considerations become relevant in so far as, to adopt common law terminology, the SDO has been held to owe a duty to the plaintiff to exercise reasonable care in the promulgation of its standards. However, the duty element, at least in the U.S. and arguably also in English common law, proves to be formidable barrier to expose SDOs to civil liability.

55. The existence of such a duty depends, as noted, on the weighing of a number of competing considerations of policy and justice discussed in the light of the relationship between the plaintiff and defendant SDO. In the U.S. such considerations have frequently turned on the question to what extent the SDO exercises control over the addressees of its standards to ensure compliance. In these actions, formal control is seen a necessary proxy for establishing the foreseeability of harm to the plaintiff as a result of the development of standards and/or the closeness of the connection between that activity and the plaintiff's harm.¹²⁴ The SDO's lack of such leverage over compliance with its standards usually leads to a no-duty decision. Some courts have looked beyond formal control relationships and have imposed a duty of care by reference to the degree to which the standards enjoy a high level of market uptake, receive government endorsement, and to public representations made by the SDO as regards its expertise in developing standards in the field.¹²⁵ Considerations of whether the standards serve the purpose of protecting third parties against personal injury or property damage have been further added to the mix of relevant circumstances that justify the imposition of a duty.¹²⁶

¹²³ See at notes 12-15 above.

¹²⁴ The exponent of this position perhaps is *Meyers* (n 49), in which a New Jersey Superior Court granted summary judgment for NSPI because 'the crucial element of foreseeability is lacking' upon the finding that the SDO 'had absolutely no power to force a member to comply with its promulgated standards' (at 403).

¹²⁵ See e.g. *Meneely* (n 54), 56; *Snyder* (n 27), 1040 and 1048. See also *Prudential Property and Cas. Ins. Co. v. American Plywood Ass'n* 1994 WL 463527 (S.D.Fla. 1994), 3 (SDO for plywood roofing construction and nailing patterns owes a duty to exercise due care in promulgating its standards vis-à-vis homeowners who incurred extensive property damage as a result of a hurricane because these standards enjoyed wide public law recognition and the association had made representations to the public as the world leading expert body in the field).

¹²⁶ See e.g. *Snyder* (n 27), 1048 and 1050; *King* (n 50), 616; *Rountree* (n 53), 810. All cases concerned personal injury actions. There appears to be only one case in which a duty of care was imposed on an SDO in relation to property damage: *Prudential Property and Cas. Ins. Co. v. American Plywood Ass'n* (1994), 3 (SDO setting standards for plywood roofing construction and nailing patterns owes a duty of care vis-à-vis homeowners who incurred extensive property damage as a result of a hurricane because the standards enjoyed wide public law recognition and the SDO had made representations to the public to be the world's leading expert body in the field).

56. Other considerations of policy and justice may nonetheless militate against imposing a duty to exercise reasonable care in standards development in negligence. Some U.S. courts have awarded particular weight to the moral blame attached to the defendant's conduct, the potential impact of imposing liability on the policy of preventing plaintiff's harm in the future, and the consequences of exposing SDOs to liability on their important societal function of promulgating standards in a given domain.¹²⁷ Another way in which courts in the U.S. have been able to shield SDOs from liability is by playing on the distinction between malfeasance and nonfeasance. By strategically characterizing a plaintiff's allegations as nonfeasance (or omission) of the SDO, some courts have argued that no duty of care was owed in negligence in the absence of any special circumstances.¹²⁸ Finally, no court has accepted a duty of care in relation pure economic loss allegedly caused by inadequate standards.

57. If an SDO is considered to owe a duty of care, it is held to exercise reasonable care in the development of its standards. The previous analysis showed that in determining whether the SDO's conduct fell short of this standard, courts have made reference to considerations of stakeholder participation and transparency in rule-making, as well as the need to update standards through periodic evaluation and review based on the state-of-the-art in scientific research. In the U.S. cases of *Meneely* and *Snyder*, the defendant SDOs involved were held liable after they had refused to amend their safety standards in the light of compelling evidence that these standards posed a significant risk of personal injury to others.¹²⁹ In the *AFNOR* case the French court held that the SDO could not be at fault for developing standards for it had swiftly amended these standards once inadequacies surfaced.¹³⁰ Likewise, the German court in *Fra.bo* considered the SDO to have breached its duty under EU law because it had failed to provide evidence that the adoption of a contentious new standard was necessary and proportionate to the protection of health and safety.¹³¹

58. However, judicial references to principles of good governance are selective. Where reference to them is made, they concern only a limited number of procedural principles. Substantive principles, such as 'illegality' or 'rationality' as enforced upon public law bodies under administrative law, are not relied on. Moreover, courts only refer to good governance principles as auxiliary arguments in their considerations on breach. Courts also do not develop a strong understanding of what these principles actually entail in the context of private standardization. In that respect, no references are made to accepted governance

¹²⁷ See e.g. *Meyers* (n 49), 404; *N.N.V.* (n 34), 1382-1387. See also *Marc Rich* (n 105).

¹²⁸ See e.g. *Meyers* (n 49), 401 (New Jersey Superior Court interpreting the claim against the SDO as allegations concerning the failure to take action to prevent harm resulting from shallow water diving while being aware of the correlation between the two, and not that the standards the SDO undertook to set were inaccurate, false or improper). See also *People v. Arcadia Machine & Tool, Inc.* 4095, 2003 WL 21184117, 21 (Cal.Super. 2003) (granting a motion for summary judgment by trade associations in the gun industry after holding that the claim is premised on nonfeasance and that the plaintiffs failed to present authority that these associations owed a duty to develop standards for gun safety design).

¹²⁹ *Snyder* (n 27), 1038 and *Meneely* (n 54) 57.

¹³⁰ See at note 96.

¹³¹ See at notes 119-120.

practices for the development of private standards as set out for example by Circular No. A-119 or the ANSI Essential Requirements for Due Process in the U.S. It may thus be said that courts hearing negligence actions against SDOs provide judicial controls over private standardization that, as Beermann has noted, ‘resemble a weak form of administrative and due process law’.¹³² It is in this rather limited sense, then, that tort law may currently be seen to stimulate SDOs to ensure an elementary level of good governance when promulgating standards.

7. Conclusion: Tort law’s proper role in promoting good governance of private standardization

59. Should tort law’s current role in stimulating compliance with principles of good governance in private standardization be strengthened, as a number of commentators have suggested?¹³³ Regardless of the empirical question of whether tort law creates sufficiently strong incentives to ensure compliance with such principles amongst SDOs,¹³⁴ the governance demands that tort law can impose on private standardization are limited. Given the character of tort law, such demands cannot be fixed and will necessarily depend on a weighing of different interests of the plaintiff, the SDO and of society under the specific circumstances. What can be reasonably expected from an SDO in terms of good governance when adopting or reviewing private standards should therefore be determined on the basis of a balancing test. Considering the case law analysed in the U.S. and EU, that test should at least involve:

- (i) *The magnitude of risk private standardization is concerned with.* The magnitude of risk is a function of the amount and seriousness of foreseeable harm, and the likelihood that this harm will occur.¹³⁵ Where an SDO develops standards that are designed to manage known and significant health and safety risks for the benefit of the plaintiff, higher demands should be placed on how it adopts and reviews its standards than where the standards concerns only the economic interests of the industry (e.g. interoperability, marketing or market integration). Personal injury has traditionally received stronger protection in tort law than (pure) economic loss has, both in duty and in breach inquiries. A significant amount and serious degree of potential harm resulting from inadequate standards should therefore require the SDO to exercise

¹³² J. BEERMAN, "The Reach of Administrative Law in the United States", in: M. Taggart (eds), *The Province of Administrative Law* (Oxford: Hart Publishing 1997), pp. 171-195, at 187. It follows from his analysis of cases involving disputes between private associations and (applicant) members, that contract, tort and corporate law have each developed principles of procedural and substantive fairness with a strong resemblance to administrative law, albeit in substantially weakened form. These principles involve questions such as whether the private body followed its own rules or bylaws, whether evidence is given for decisions, whether decisions are taken by a fair and impartial body, whether the body acted with fraud, malice or collusion, and whether the standards violated law or public policy (at 186-191).

¹³³ See at notes 12-15 above.

¹³⁴ SPINDLER is critical in this regard. See Spindler (n 12), pp. 331-332. See for a U.S. perspective in relation to the liability of private auditors LYTTON in this Issue.

¹³⁵ See e.g. § 293 Restatement (Second) of Torts ('Factors Considered in Determining Magnitude of Risk'); VAN DAM (n 95), pp. 239-241.

greater care in terms of ensuring a balanced representation of the interests concerned in standardization, openness in procedures leading up to the promulgation of standards, and the use of expert knowledge and state-of-the-art scientific research to inform the adoption and review of standards. The amount and severity of the harm may require compliance with such governance demands even if the probability that the harm will occur is low.¹³⁶

(ii) *The internal rules and procedures for private standardization.* Where an SDO has set internal rules and procedures to adopt and review its product standards, and thus manage the risks its standards address in a structured and efficient way, these rules and procedures should be taken as a measure of the standard of care required from it. The defendant's internal rules have been accepted in tort law as evidence to show that the defendant recognized that its conduct created a foreseeable risk of harm for others and that compliance with these rules represents a means of reducing that risk.¹³⁷ In the case of standards development, the use of notice and comment procedures, stakeholder consultations, involvement of experts in decision-making, and periodic reviews of standards could all be seen as instrumental to the development of the most accurate and informed standards that limit the risks of product for businesses and consumers. It is fair to hold the SDO to such internal rules and procedures when ignorance will place businesses and consumers at risk.

(iii) *The costs concerned with the (re)organization of procedures for private standardization.* What can be reasonably expected from an SDO in terms of following procedural principles of good governance finds its limit in the costs concerned with such compliance. Clearly, the harnessing of private standardization with procedural safeguards such as a balanced representation of affected interest and access to (draft) standards may be instrumental in ensuring the accuracy of private standards and preventing harm caused by inadequate standards. However, these safeguards do not come for free. The related costs, along with the financial and organizational capacity of the SDO, should therefore also be considered when assessing what can be expected from an SDO in terms of following principles of good governance.

(iv) *The character and societal benefit of private standardization.* The standard of care for an SDO should also be informed by the character of the SDO's conduct and its utility to society.¹³⁸ As noted, private standardization requires an SDO to make policy-bound

¹³⁶ Cf. *Snyder* (n 27), 1049 ('By 1983, ample evidence supported the conclusion that blood transmitted the AIDS virus. In early 1984, the AABB knew that AIDS was a rapidly spreading, fatal disease and that apparently healthy donors could infect others. The AABB also knew that blood and blood products probably could transmit AIDS and that each infected blood donor could infect many donees. Thus, the AABB knew, or should have known, in 1984 that the risk of AIDS infection from blood transfusions was devastating'); *Meneely* (n 54) 58 ('NSPI has promulgated specific safety standards relating to diving boards. And, it failed to change the standard after it knew of the risk [of serious personal injury for young male drivers]').

¹³⁷ See e.g. *DOBBS, HAYDEN & BUBLICK* 2016 (n 21), p. 287.

¹³⁸ See e.g. §§ 292-293 Restatement (Second) of Torts offer a number of factors relevant for determining the negligence of the defendant's conduct, including 'the social value which the law attaches to the interest which is

trade-offs between conflicting interests.¹³⁹ In determining what can be reasonably expected from an SDO in terms of good governance when adopting or reviewing private standards courts should be responsive to this policy dimension and show a degree of deference when evaluating the policy choices made. Also the expected gains of the SDO's standard-setting activities to the whole community should be considered. The benefit created for society by engaging in private standardization may make it reasonable for an SDO to create more-than-greater risks for harm to others. The alternative may be that business conduct is unregulated, thus leaving third parties to exposed to even greater risks.

These circumstances echo the test that is commonly applied in tort law analyses to determine the negligent character of the defendant's conduct. It is in this determination that considerations of good governance principles are most appropriately applied given that these principles first and foremost concern the reasonableness of the SDO's conduct in developing standards.

to be advanced or protected by the conduct' (at § 292(a)). See for a detailed discussion S. G. GILLES, "On Determining Negligence: Hand Formula Balancing, the Reasonable Person Standard, and the Jury", 54. *Vanderbilt Law Review* 2001, p. 825-830. See for a European perspective VAN DAM (N 95), pp. 239-241 (discussing this factor as 'the character and benefit of the conduct').

¹³⁹ See at notes 78-79.