THE PRODUCT REGULATION AND LIABILITY REVIEW

Seventh Edition

Editors
Chilton Davis Varner and Madison Kitchens

THE LAWREVIEWS

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SEVENTH EDITION

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PREFACE

In today's global economy, product manufacturers and distributors face a dizzying array of overlapping and sometimes contradictory laws and regulations around the world. A basic familiarity with international product liability is essential to doing business in this environment. An understanding of the international framework will provide thoughtful manufacturers and distributors with a strategic advantage in this increasingly competitive area. This treatise sets out a general overview of product liability in key jurisdictions around the world, giving manufacturers a place to start in assessing their potential liability and exposure.

Readers of this publication will see that each country's product liability laws reflect a delicate balance between protecting consumers and encouraging risk-taking and innovation. This balance is constantly shifting through new legislation, regulations, treaties, administrative oversight and court decisions. But the overall trajectory seems clear: as global wealth, technological innovation and consumer knowledge continue to increase, so will the cost of product liability actions.

This edition reflects a few of these trends from 2019. Notably, several jurisdictions proposed or enacted landmark legislation to strengthen rules governing long-existing industries or, in some cases, emerging technologies (such as autonomous vehicles, artificial intelligence, robotics and the Internet of things). In 2019, for example, China amended its Pharmaceutical Administration Law and thereby established a product traceability system to ensure drug quality. The revised law also provides an array of enhanced criminal penalties and civil liabilities, including novel remedies such as punitive damages. Additionally, countries like Singapore, India and Switzerland implemented expansive new measures – whether by judicial decision or legislative decree – to improve regulatory oversight over food safety. Several jurisdictions also experienced a proliferation of product liability class actions, including countries that only recently began experimenting with class adjudication. In July, Russia ushered in class action suits at a time when product liability and consumer protection cases have surged in the wake of amendments to Russia's Consumer Protection Law. This has led to the coinage of a new term in Russia – 'consumer extremism' – to describe frivolous suits designed to extract a quick settlement from sellers and manufacturers. Yet, other legal refinements impacting product manufacturers have not arrived as quickly as planned. In October, the European Commission delayed the widely anticipated launch of the European Database on Medical Devices (EUDAMED), an initiative designed to strengthen market surveillance and transparency for medical devices. While EUDAMED is not slated to take effect until May 2022, the deadline for medical device companies to recertify their products under the EU's new Medical Device Regulation remains May 2020.

Other significant legal developments in 2019 were spawned in courtrooms rather than legislative bodies. For instance, the US Supreme Court decided a pivotal pre-emption

case that clarified what evidence a drug manufacturer must adduce to demonstrate that the Food and Drug Administration would not have approved the plaintiffs' proposed warning. The Supreme Court also held that the determination of whether a manufacturer met this evidentiary burden constituted a question of law to be resolved by the judge, not a jury. Although the Court's ruling provides valuable guidance to manufacturers seeking to limit their exposure to failure-to-warn claims arising under state law, it also left many questions unanswered (and, thus, open to lower court interpretation in the years to come). Moreover, courts in various jurisdictions grappled with issues concerning the types of entities within the supply chain that should be held liable for alleged product defects. For instance, the Supreme Court of Spain confronted the question of when a mere supplier can be considered the 'producer' of a product for purposes of strict liability. And courts in various jurisdictions are divided on whether online retailers that sell products supplied by third-party vendors can be deemed liable for product defects even though the online retailer never took possession or title of the vendor's product. Although these changes and trends may be valuable in their own right, they also create a need for greater vigilance on the part of manufacturers, distributors and retailers to ensure compliance with increasingly complicated and evolving product liability regimes.

This edition covers 15 countries and territories, and includes a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward at expected trends. Each chapter contains a brief introduction to the country's product liability framework, followed by four main sections: regulatory oversight (describing the country's regulatory authorities or administrative bodies that oversee some aspect of product liability); causes of action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, discovery, whether mass tort actions or class actions are available and what damages may be expected); and the year in review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements and any notable trends).

Whether the reader is a company executive or a private practitioner, we hope that this edition will prove useful in navigating the complex world of product liability and alerting you to important developments that may affect your business.

We wish to thank all of the contributors who have been so generous with their time and expertise. They have made this publication possible. We also wish to thank our colleague Luke Bosso, who has been invaluable in assisting us in our editorial duties.

Chilton Davis Varner and Madison Kitchens
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Chapter 8

JAPAN

Akihiro Hironaka, Kazuyuki Ichiba and Hidenori Sato[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Japan is a civil law country, with a unified national legal and court system under a single Supreme Court. National statutes are the main source of law for civil liability, but court precedents also play an important role in filling gaps and clarifying the meaning of statutes.

Initially, the core source of civil liability for defective products was tort liability under the Civil Code, Law No. 89 of 1896 (CC). However, to mitigate difficulties faced by victims of defective products in establishing tort claims against manufacturers and other entities responsible for product defects, the Product Liability Act, Law No. 85 of 1994 (the PL Act) was enacted to create strict liability (i.e., requiring no proof of negligence in association with the defect) in product liability claims. Tort liability can also be pursued even if claims under the PL Act are available to the victim.[2]

Multiple administrative statutes also play an important role in the area of product liability. The purposes of these administrative statutes are as follows:

a to prevent defective products from being distributed in the market (e.g., government approval and licensing systems);

b to prevent defective products in the market from causing damage or injury to consumers (e.g., recall and remedy systems); and

c to provide prompt and effective relief to consumers who have actually suffered losses as a result of defective products (e.g., special measures or relief for losses caused by defective products and a compulsory insurance system).

II REGULATORY OVERSIGHT

National courts decide the civil liability of the responsible entities by applying the relevant provisions of the CC and the PL Act, as described in Section I. With respect to the administrative regulations, various administrative authorities oversee the safety of different categories of products, as explained below.

1 Akihiro Hironaka is a partner, Kazuyuki Ichiba is a counsel, and Hidenori Sato is an associate at Nishimura & Asahi.

2 PL Act, Article 6.

i Food safety

The Food Sanitation Act, Law No. 233 of 1947, governs administrative matters to prevent public health risks arising from human consumption of food. It is administered by the Ministry of Health, Labour and Welfare (MHLW) and the Consumer Affairs Agency (CAA). This Act provides standards for methods of producing, processing, using, cooking or preserving foods and additives, standards for the ingredients used in foods and additives, and procedures for investigating the causes of food poisoning and for reporting the results of investigations. In 2013, the Food Labelling Act, Law No. 70 of 2013, was enacted to regulate the mandatory labelling system for foods and additives, incorporating the regulations provided by the Food Sanitation Act, the Act Concerning Regulation of Agricultural Goods and Appropriate Labelling of Qualities, Law No. 175 of 1950, and the Act to Promote Health, Law No. 103 of 2002. The Food Labelling Act entered into force in 2015, and its regulations on foods and additives are administered by the CAA.

ii Drug safety

Drugs, quasi-drugs, cosmetics and medical instruments are regulated by the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, Law No. 145 of 1960, as amended by Law No. 84 of 2013 (the PMD Act). The MHLW administers the PMD Act. The PMD Act provides regulations concerning labelling, manufacturing methods, and false or exaggerated advertising of products. It is necessary to obtain approval from the minister of the MHLW to manufacture and market drugs and quasi-drug ingredients covered by this Act.[3] The Pharmaceutical and Medical Devices Agency conducts safety testing of these products.

iii Industrial products safety

An important statute establishing regulations for industrial products is the Consumer Product Safety Act, Law No. 31 of 1973 (the CPS Act). The Ministry of Economy, Trade and Industry (METI) and the CAA administer the CPS Act. The CPS Act provides a certification system called 'PSC marks', which mandate that manufacturers of products that pose high risks to the lives and bodies of consumers must comply with technical standards determined by the government, and require the placement of labels that satisfy national standards on such products.[4] If a product lacks the required labelling, the government can order that certain measures be taken, including the recall of the products.[5] If a product has caused a serious accident, the manufacturer and importer of the product must report the occurrence to the CAA.[6] The CAA may then announce these incidents to the public.[7] The CPS Act also provides certain measures to prevent accidents caused by prolonged use of products.[8] Incidents that are not serious must be reported to the National Institute of Technology and Evaluation.

Other important, relevant statutes are the Electrical Appliances and Materials Safety Act, Law No. 234 of 1961; the Act on the Securing of Safety and the Optimisation of

3 PMD Act, Article 14(1).
4 CPS Act, Article 4(1).
5 id., Article 32.
6 id., Article 35(1).
7 id., Article 36(1).
8 id., Article 32-2 et seq.

Transaction of Liquefied Petroleum Gas, Law No. 149 of 1967; and the Gas Business Act, Law No. 51 of 1954. The METI administers these acts, which also provide for certification systems similar to PSC marks under the CPS Act.

iv Vehicle safety

The Road Transport Vehicle Act, Law No. 185 of 1951 (the RTV Act), provides measures to ensure the safety of vehicles. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) administers the RTV Act. The RTV Act requires that users of vehicles comply with mandatory safety standards that are issued by the MLIT under the RTV Act[9] and also provides recall systems for manufacturers and importers of vehicles, tyres, and child restraint seats that do not satisfy the mandatory safety standards.[10] The RTV Act was revised in 2019 to include additional provisions to ensure the safe operation of autonomous vehicles.[11]

v The Consumer Safety Act and the Consumer Affairs Agency

The administrative regimes explained above, depending on the category of the products, had shortfalls by which defective products were not regulated because the relevant products or defects inadvertently were not covered by the existing regimes. In response, in 2009 the government enacted the Consumer Safety Act, Law No. 50 of 2009, and created the CAA, to comprehensively administer matters relating to the protection of consumers, including protection from defective products. Under the Consumer Safety Act, when the national or local government, or another relevant government entity, is informed that a serious accident has occurred, the person in charge at these entities must immediately notify the CAA of the accident.[12] The CAA then collects information on the accident and responds with responsive measures.[13]

III CAUSES OF ACTION

The PL Act defines a 'product' as a movable item that is manufactured or processed.[14] Therefore, unprocessed agricultural products are not subject to the PL Act.

The PL Act applies to manufacturers, processors and importers (the Manufacturer).[15] The PL Act also applies to any person who provides his or her name, trademark or other indication on a product as its Manufacturer, and any person who provides his or her name, trademark or other indication on a product in a manner that misleads others into believing that he or she is its Manufacturer.[16] The PL Act also applies to any person who provides his or her name, trademark or other indication on a product and who may be considered substantially as the Manufacturer of a product in light of the manner and other circumstances under which the product is manufactured, processed, imported or sold.[17] The PL Act will not

9 RTV Act, Article 40 et seq.
10 id., Articles 63-2 and 63-3.
11 Law No. 14 of 2019.
12 Consumer Safety Act, Article 12(1).
13 id., Article 13 et seq.
14 PL Act, Article 2(1).
15 id., Article 2(3)(i).
16 id., Article 2(3)(ii).
17 id., Article 2(3)(iii).

provide a cause of action against distributors or sellers of a product if those persons are not among the entities specified above. Therefore, civil claims against distributors and sellers of a defective product (i.e., entities that may owe direct contractual liability to consumers) must be brought based on a warranty against defects, breach of contract or tort under the CC.

To prove liability under the PL Act, a plaintiff must establish:

a a defect in the product;

b damage to life, body or property; and

c a causal link between the defect and the damage (i.e., causation).[18]

'Defect' is defined under the PL Act to mean a lack of safety that the product ordinarily should possess, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time the product was delivered and other circumstances concerning the product.[19] 'Defect' is interpreted to include defects in manufacture, design, and instructions or warnings. As mentioned above, it is said that the PL Act creates strict liability. However, the Supreme Court of Japan reviewed the foreseeability of the injury from the perspective of the defendant company, and denied the existence of defective instructions or warnings, in *re Iressa*, where a Japanese subsidiary of a UK pharmaceutical company was sued for an alleged defect in its drug, stating that it was unforeseeable that 'Iressa had the side effect of causing interstitial pneumonia which could rapidly become severe.'[20]

The Acts described in Section II provide for administrative sanctions against the responsible party where applicable. With respect to criminal liability, if a failure to exercise due care causes death or injury, a criminal penalty may be imposed on the responsible individual under the Penal Code, Law No. 45 of 1907.[21]

Conflict-of-law issues often arise in cross-border product liability cases. Japanese courts determine the applicable law by applying the Act on General Rules for Applications of Laws, Law No. 78 of 2006 (AGRAL), the Japanese code concerning conflict-of-law rules. AGRAL establishes the general rule that where a claim against a manufacturer, processor, importer, exporter, distributor or seller of a product arises from a tort involving injury to life, body or property caused by a defect in the product that is delivered, the claim shall be governed by the law of the place where the victim received delivery of the product.[22] However, AGRAL also provides for an exception to this general rule, stating that if delivery of the product at a certain place is ordinarily unforeseeable, the law of the principal place of business of the manufacturer (or the other entities mentioned above) shall apply.[23]

18 id., Article 3.

19 id., Article 2(2).

20 *X v. AstraZeneca K.K.*, 67-4 Minshû 899 (Sup. Ct., 12 April 2013).

21 Penal Code, Articles 209-11.

22 AGRAL, Article 18.

23 id.

IV LITIGATION[24]

i Forum

Civil product liability claims are determined by professional judges in national courts. No jury system exists for civil litigation in Japan.

Alternative dispute resolution (ADR) procedures also play an important role in resolving civil product liability claims in Japan. Some industries have established their own 'product liability centres' intended to resolve civil product liability claims through ADR; for example, the Electric Home Appliances PL Centre and the Automotive Dispute Resolution Centre. In addition, the National Consumer Affairs Centre of Japan also manages an ADR procedure that deals with product liability matters.

ii Burden of proof

During civil proceedings, plaintiffs must prove each required element of a product liability claim. With respect to the issue of how much proof is necessary for the judges to be persuaded (the degree of proof), the Supreme Court of Japan defined the required degree of proof in *Miura v. Japan*, a medical malpractice case.[25] In that case, the Supreme Court found causation of a patient's injury resulted from the negligence of a doctor based on the following standard:

> *Proving causation in litigation, unlike proving causation in the natural sciences (which permits no doubt at any point), requires proof of a high degree of probability that certain facts have induced the occurrence of a specific result by taking into necessary and sufficient account that the judge has been persuaded of the truthfulness to a degree where an average person would have no doubt.*

It is difficult to express the required degree of persuasion using a numerical formula, given the standard of 'proof of a high degree of probability'. The Japanese standard is generally considered to be higher than a preponderance of evidence, but less than beyond a reasonable doubt.

iii Defences

If a claim is brought under the PL Act, the defendant may be exempt from liability if the defendant successfully proves that the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time the product was delivered (the 'development risk' or 'state of the art' defence).[26] Furthermore, where the product is used as a component of or ingredient for another finished product, a manufacturer of the component or ingredient that is named as a defendant may be exempt from liability if the defendant successfully proves that the defect occurred primarily owing to compliance with instructions that were given by the manufacturer of the finished product, and that the defendant was not negligent with respect to the occurrence of the defect.[27]

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24 For general explanations of Japanese civil procedure, see Yasuhei Taniguchi, et al. eds., *Civil Procedure in Japan* (3rd ed.) (Juris Publishing, 2018), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor.

25 *Miura v. Japan*, 29-9 Minshû 1417 (Sup. Ct., 24 Oct. 1975). See also X v. Y, 1724 Hanrei jihô 29 (Sup. Ct., 18 July 2000).

26 PL Act, Article 4(i).

27 id., Article 4(ii).

In addition, the PL Act provides for the following limitations on the period after which a claim under the PL Act will be extinguished:

a if the victim does not exercise his or her claim within three years (five years, if there was harm to life or body) of the time when he or she (or his or her legal representative) becomes aware of the damage and the party liable for the damages; or

b 10 years have elapsed from the time the product was delivered. In cases involving damage caused by substances that become harmful to human health when they accumulate in the body, or damage whose symptoms appear after a certain latent period, this 10-year period is calculated from the time when the damage occurred.[28]

As with tort claims under the CC, the prescriptive period is three years (five years, if there was harm to life or body) from the time the victim (or his or her legal representative) becomes aware of the damage and the identity of the perpetrator.[29] A tort claim also cannot be brought when 20 years (or more) have elapsed from the time of the tortious act.[30]

Plaintiffs' own negligence may be considered upon the determination of the amount of damages, and can be asserted in defending a product liability claim as a defence of comparative negligence, either under the PL Act or as a tort claim under the CC.[31]

Compliance with applicable regulations is considered one of the important factors in determining whether there is a defect in a product; however, non-compliance or compliance with applicable regulations, by itself, will not automatically give rise to or preclude liability.[32]

A majority of US states recognise the 'learned intermediary doctrine,' which states that a manufacturer of prescription medications and devices is released of its duty to warn users of the risks associated with its products upon warning the prescribing physician of the proper use and risks of the manufacturer's product. The Supreme Court of Japan, in *re Iressa*, in denying the existence of defective instructions or warnings, stated that 'it was known at least among physicians engaged in anti-cancer therapy targeting lung cancer that when interstitial pneumonia occurred owing to the administration of these drugs, including anti-cancer drugs, it could be fatal'.[33] This ruling of the Supreme Court is similar to the 'learned intermediary doctrine' referenced above, in that the Court considered the knowledge of the addressee of the information in determining whether a defect existed in the instructions or warnings for the product.

iv Personal jurisdiction

No specific provision for product liability claims

The Japanese Code of Civil Procedure, Law No. 109 of 1996 (CCP), contains a set of rules for domestic and international jurisdiction applicable to litigation in Japanese courts, but does not include an express provision for product liability claims. Under the prevalent view, product liability claims are classified as tort claims for purposes of determining jurisdiction.

28 id., Article 5.

29 CC, Article 724(i), 724-2.

30 CC, Article 724 (ii).

31 id., Article 722(2). See, e.g., *X v. K.K. Yuuka*, 2418 Hanrei jihô 38 (Fukuoka Dist. Ct., 18 July 2018); *X v. K.K. Yuuka*, LLI/DBL07450358 (Osaka Dist. Ct., 29 Mar. 2019).

32 See CAA, Consumer Safety Division, Chikujyô Kaisetsu Seizôbutsu Sekininhô (a commentary on the Product Liability Act) 82-83 (Shôjihômu, 2d ed. 2018).

33 *X v. AstraZeneca K.K.*, 67-4 Minshû 899 (Sup. Ct., 12 April 2013).

With respect to international jurisdiction over tort claims, the CCP provides that the Japanese court has jurisdiction if the tort took place in Japan, unless the claim involves a wrongful act committed in a foreign country where the resulting damage occurred in Japan and the occurrence of such a result in Japan was ordinarily unforeseeable.[34] Jurisdiction over international product liability claims will be determined pursuant to this provision. The stream-of-commerce doctrine, discussed in US courts, was not introduced when the CCP was revised to include international jurisdiction provisions in 2011.[35]

The place where the tort took place

This phrase generally includes both the place where the wrongful act occurred and the place where the result occurred. The place of the wrongful act includes the place where the product was manufactured. Unless an advertisement on the internet constitutes part of the wrongful act, the advertisement itself does not constitute a basis for the jurisdiction of Japanese courts. On some occasions, allowing international jurisdiction at the place where the result of the tort occurred will cause substantial difficulties for the defendants. In such circumstances, it is likely that Japanese courts will not exercise international jurisdiction over the defendants, as an exception to the general rule.[36]

v Experts

The CCP has a set of provisions providing procedures for the examination of court-appointed experts. Where the issues to be determined by judges are highly specialised and difficult, the court can appoint experts to assist the judges with fact-finding.[37] The court may order the expert to provide his or her opinion to the court in writing or orally. When an expert provides his or her opinion orally, the court may give both parties an opportunity to examine the expert, for purposes of impeaching an unfavourable opinion or to restore the credibility of a favourable opinion.

In Japanese practice, parties to litigation frequently find their own private experts and have them author expert opinions addressed to the court. The parties may also request to examine experts before the court. Technically, these private experts are classified as 'witnesses' rather than 'experts' under the CCP, because they are not appointed by judges. However, these private experts also perform an important role.

The court may request assistance from experts not only for fact-finding purposes, but also to clarify issues and to increase the efficiency of proceedings. To enable the court to obtain such assistance, the court may appoint an expert commissioner in the proceedings.[38]

vi Discovery

No extensive discovery system (as exists in the United States) exists in Japan; only limited document production requests are permitted. The Japanese discovery system, as explained below, is far from being an effective tool for litigants to request useful evidence from the other party or third parties.

34 CCP Article 3-3(viii).

35 Law No. 36 of 2011.

36 CCP Article 3-9. See also *X v. Y*, 70-3 Minshû 846 (Sup. Ct., 10 Mar. 2016) (claim dismissed in the Japanese court where related litigation was pending in Nevada state court in the US).

37 See CCP Article 213.

38 id., Article 92-2(1).

Request for document production order

A party may request that the court issue a document production order (DPO) against the other party or third parties. The CCP provides that the possessors of documents shall not refuse to produce the relevant documents in the following circumstances:

a where the possessor, as a party, has cited the document in his or her arguments in the action; the party applying for the DPO was otherwise entitled by law to possess or inspect the document; the document was executed for the benefit of the petitioner; or the document was executed with respect to a legal relationship between the petitioner and the possessor; and

b the document does not fall under any exemptions provided in the CCP.[39]

The exemptions provided for in (b) above are as follows:

a a document containing information with respect to which the possessor would have the right to refuse to testify, because the information is self-incriminating or incriminating to one's family;

b a document containing a secret relating to a public officer's duties;

c a document containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;

d a document containing technical secrets or secrets useful for occupations;

e a document held by the possessor exclusively for his or her own use; and

f a document relating to criminal proceedings or juvenile delinquency proceedings.

Courts may decide not to examine documentary evidence if they deem it to be unnecessary,[40] and courts meticulously scrutinise the necessity for issuing a DPO. If the court finds that the fact that the party is seeking to establish through a DPO is unnecessary for resolution of the dispute, the court will decline to issue the DPO. Japanese evidence law on civil cases does not have strict rules on admissibility of evidence. Therefore, in contrast with procedures in the United States, the court may admit evidence even if there is a danger that the evidence in question is unfairly prejudicial, confusing or misleading to the judges. Thus, whether a judge orders a DPO regarding 'other similar incidents' of a product defect, for example, depends on the judge's interpretation of the 'necessity' of such evidence to deciding the issues in the current case.

Interrogatories

Before a lawsuit is instituted, or while the lawsuit is pending, a party may inquire of the opponent to request information regarding matters necessary for preparing allegations or proof.[41] This system is analogous to the US interrogatory system, but in practice this process is not frequently used in Japan.

Depositions

No system for taking the depositions of parties, witnesses or experts exists in Japan.

39 id., Articles 220(i)–(iv).

40 id., Article 181(1).

41 id., Articles 132-2, 163.

Evidence preservation proceedings

A party (petitioner) may request that the court issue an order to preserve the evidence, if the petitioner provides prima facie evidence that circumstances exist in which it will be difficult to examine evidence, including circumstances where the other party may spoil evidence.[42] The order is granted pursuant to an *ex parte* hearing requested by the petitioner, and the other party is notified of such an order only several hours before the judge implements the preservation order, which may avoid the other party spoiling the relevant evidence.

vii Apportionment

When multiple entities are involved in a product liability case, the entities are jointly and severally liable for liability under the PL Act or in tort. A named defendant that has compensated the victim in excess of the damages that the defendant is required to bear may seek reimbursement from other entities. The portion of the burden that should be borne by each entity is determined on a case-by-case basis, considering the fair burden of damages and taking into account various circumstances such as the situation in which the act occurred and the connection between the act and the damage.[43]

Under Japanese law, the successor of an entity, for example, by way of merger, will be liable for its predecessor's liability.

viii Mass tort actions

In Japan, there is no legislation creating a US-style class action for mass torts. In practice, plaintiffs bringing mass tort actions have been solicited through announcements on the internet and by other methods.

In 2013, a new law relating to collective actions relating to consumer contracts was promulgated, which came in force in 2016: the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers, Law No. 96 of 2013 (the Collective Redress Act). This Act provides for two-stage proceedings: during the first stage, a certified qualified consumer entity files a lawsuit and, if the defendant loses at the first stage, either entirely or in part, the certified qualified consumer entity files a second stage proceeding, to which individual consumers may opt-in to confirm their individual damages. This Act permits collective claims to be brought against business operators for recovery of damages suffered by consumers relating to consumer contracts. A plaintiff consumer generally must have privity of contract with the business operator for the relevant claims to be eligible under this system. Therefore, it is difficult to use this collective redress system to sue a manufacturer for product liability claims, where manufacturers usually lack a direct contractual relationship with consumers. Furthermore, lost profits, personal injury, and pain and suffering are expressly excluded from the scope of claims that can be brought under the Collective Redress Act.[44] Therefore, in the context of this publication, the Collective Redress Act is relevant only when, for example, many consumers purchased defective products from a retailer, and the consumers collectively claim return of the purchase price of the product from the retailer. If the retailer loses the case, the retailer will seek

42 id., Article 234; Rules of Civil Procedure, Article 153(3).

43 See CAA, Consumer Safety Division, footnote 32, at 137–38.

44 The Collective Redress Act, Articles 3(2)(i)–(vi).

reimbursement (for the damages paid) from the manufacturer responsible for the defect in a separate, regular lawsuit. Since the Collective Redress Act entered into force, only three collective redress cases have been filed, none of which is related to product defects.

ix Damages

Recovery of economic damages, including lost profits and non-economic damages such as pain and suffering, is permitted in product liability cases under Japanese law, regardless of whether the claim is brought in breach of contract, tort, or under the PL Act. The remedy for damages is monetary compensation.[45] The amount of damages is determined by the judge because no jury system exists in Japan. There is no law limiting the amount of damages that may be ordered. However, Japanese law does not allow punitive damages. Punitive damages awarded in foreign litigation or arbitration will not be recognised in Japan, because they infringe upon public policy in Japan.[46]

The PL Act limits its application to claims for damage arising from an infringement of life, body or property caused by a defect in a product. However, damages that occur only with respect to the defective product may be claimed only if they are aggregated with the other types of recoverable damages described above.[47]

Criminal liability is explained in Section III.

V YEAR IN REVIEW

The first edition of the *Product Regulation and Liability Review* (2014) discussed mass damages to consumers caused by a facial soap, called 'Droplet of Tea', in Japan. The product at issue was a green tea-based cleansing bar of facial soap valued for its natural purity. This facial soap was treated as an over-the-counter drug and defined as a medication purchased without advice from pharmacists. The facial soap contained a hydrolysed wheat protein (product name: Glupearl 19S) and triggered immediate-type systemic wheat allergy; some users developed serious symptoms, including anaphylaxis and similar states of shock. The number of sufferers was reported to be approximately 2,000, approximately 1,300 of whom filed lawsuits in 28 district courts across Japan. Some courts rendered judgments in the first instance in 2018 and 2019.

These courts found that the facial soap was defective.[48] For example, one court[49] held essentially as follows: the frequency and seriousness of the damage significantly exceeded those expected during regular use of the facial soap, and the efficacy and social usefulness of the soap were not as imperative as medicines; moreover, the actual labelling on the soap could not be expected to prevent occurrence, or aggravating, of the damage, and Glupearl 19S was not indispensable to manufacturing a facial soap of the same efficacy. In addition, the damage exceeded the seriousness that common sense can tolerate.

45 CC, Article 722(i), 417; PL Act, Article 6.

46 For punitive damages awarded in a foreign court, see *Northcon I, Oregon Partnership v. Mansei Kôgyô Co Ltd*, 51-6 Minshû 2573 (Sup. Ct., 11 July 1997).

47 PL Act, Article 3 proviso.

48 *X v. K.K. Fenix*, LEX/DB25560273 (Kyoto Dist. Ct., 20 Feb. 2018); *X v. K.K. Yuuka*, LEX/DB25560920 (Tokyo Dist. Ct., 22 June 2018); *X v. K.K. Yuuka*, 2418 Hanrei jihô 38 (Fukuoka Dist. Ct., 18 July 2018); *X v. K.K. Yuuka*, LLI/DBL07450358 (Osaka Dist. Ct., 29 Mar. 2019).

49 *X v. K.K. Yuuka*, LEX/DB25560920 (Tokyo Dist. Ct., 22 June 2018).

With regard to the ingredient Glupearl 19S, the conclusions in the courts' decisions were split. Hydrolysed wheat protein is a generic material, which was contained in 19 medications and cosmetics at that time. Some courts found that Glupearl 19S was not defective.[50] One court held that the relationship between Glupearl 19S and the final product was weak, and that the ingredient did not necessarily trigger the damage; this was considered largely due to the design of the final product.[51] The other courts held that Glupearl 19S was defective.[52] One court held that, considering the seriousness and probability of the damage, the material was defective.[53]

50 *X v. K.K. Fenix*, LEX/DB25560273 (Kyoto Dist. Ct., 20 Feb. 2018); *X v. K.K. Yuuka*, LEX/DB25560920 (Tokyo Dist. Ct., 22 June 2018).

51 *X v. K.K. Yuuka*, LEX/DB25560920 (Tokyo Dist. Ct., 22 June 2018).

52 *X v. K.K. Yuuka*, 2418 Hanrei jihô 38 (Fukuoka Dist. Ct., 18 July 2018); *X v. K.K. Yuuka*, LLI/DBL07450358 (Osaka Dist. Ct., 29 Mar. 2019).

53 *X v. K.K. Yuuka*, 2418 Hanrei jihô 38 (Fukuoka Dist. Ct., 18 July 2018).

Appendix 1

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