IN-DEPTH

Product Regulation And Liability

JAPAN



Product Regulation and Liability

EDITION 12

Contributing Editors

Chilton Davis Varner, Madison Kitchens and Franklin Sacha

King & Spalding LLP

In-Depth: Product Regulation and Liability (formerly The Product Regulation and Liability Review) provides an incisive overview of the product liability frameworks in major jurisdictions worldwide. It also examines the most consequential recent changes and developments, and looks forward to expected future trends. Topics covered include key legislation; regulatory oversight; causes of action; litigation procedures; and much more.

Generated: March 13, 2025

The information contained in this report is indicative only. Law Business Research is not responsible for any actions (or lack thereof) taken as a result of relying on or in any way using information contained in this report and in no event shall be liable for any damages resulting from reliance on or use of this information. Copyright 2006 - 2025 Law Business Research



Japan

Akihiro Hironaka, Kota Hoshina and Chisa Fukudome

Nishimura & Asahi (Gaikokuho Kyodo Jigyo)

Summary

INTRODUCTION
YEAR IN REVIEW
LEGAL FRAMEWORK
REGULATORY OVERSIGHT
CAUSES OF ACTION
LITIGATION
OUTLOOK AND CONCLUSIONS
ENDNOTES

Introduction

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. National courts decide the civil liability of responsible entities by applying the relevant provisions of the Civil Code (Law No. 89 of 1896) and the Product Liability Act (Law No. 85 of 1994). Administrative regulations empower various administrative authorities to oversee the safety of different categories of products. In addition, the Consumer Affairs Agency (CAA) has comprehensive administrative oversight with regard to matters relating to the protection of consumers, including protection against defective products.

Year in review

Red yeast rice supplement product incident

In March 2024, it was reported that a red yeast rice supplement product manufactured by Kobayashi Pharmaceutical led to deaths and kidney disorders in people who took it. The company issued a warning and implemented recalls of the product. The first product liability lawsuit was filed against the company in Japan, and a consumer group filed a lawsuit in Taiwan, both in September 2024. The Japanese government reinforced the reporting system for health harm from foods with functional claims and foods for specified health uses in response to this incident.

A new Supreme Court judgment regarding the limitations period

In 2024, the Supreme Court overturned existing case law regarding the nature of the long-term limitations period for general torts, as set forth in the old version of the Civil Code. [1] The Supreme Court previously interpreted the 20-year limitations period set forth in the former Civil Code as meaning that claims are extinguished once 20 years have elapsed without being invoked by a party. However, this interpretation faced harsh criticism. The new version of the Civil Code, which entered into force in 2020, changed the language of the provision and denied the previous interpretation of the nature of the 20-year limitations period and allows claims to survive the 20-year limitations period under certain circumstances. In the judgment in 2024, the Supreme Court held that the treatment under the former version of the Civil Code was too strict, because a claimant cannot claim any damages after 20 years have elapsed, and therefore decided that claims will not extinguish if doing so would be egregiously contrary to justice and fairness. This Supreme Court judgment was issued in a case in which claimants claimed damages from the government of Japan for compulsory sterilisation under the old Eugenics Protection Law (Law No. 156 of 1948), which was performed for reasons that included, without limitation, having, or being the spouse of a person who had, hereditary mental or physical disorders. A person with Hansen's disease or the spouse of such a person was also subject to the Law. The government of Japan issued circulars to the prefectural governors in 1953, 1954 and 1957, to encourage them to implement the Law. The plaintiffs in the case were sterilised

for reasons that included deafness, difficulty listening and cerebral palsy. Approximately 25,000 persons were sterilised pursuant to the Law. The Supreme Court held that the provision of the Law establishing the compulsory sterilisation violates personal rights and equality under the Japanese Constitution, and that the government of Japan was not allowed to invoke the 20-year limitations period in this case, because doing so would be inconsistent with the good faith principle and an abuse of rights. The scope of the rationale behind this judgment will be raised in product liability cases to defeat the 20-year limitations period where plaintiffs allege damages arising from long-term tortious acts by defendants.

Lower court decisions awarding damages for product liability

In 2024, the Japanese lower courts awarded damages to plaintiffs in several product liability cases. In a case involving a roll-up window screen, a line used to wind up a window screen became wrapped around the neck of a six-year-old girl, who died as a result. The victim's family filed a product liability lawsuit against the manufacturer of the roll-up window screen, and others. The district court dismissed the claim, holding that the product was not defective. On appeal, the high court reversed the lower court judgment, holding that the user warning on the product was insufficient to ensure implementation of the safety measures on a daily and continuous basis by the user. In another case, a baby died after being caught between the bed and a bed guard manufactured by a Taiwanese manufacturer. The victim's family filed a product liability lawsuit against the importer of the bed guard. The district court held that there was no defect in the product design, because it followed the manufacturing standards established by the relevant industry in Japan and the United Kingdom, but that there was a lack of warning to users, for which the defendant was held liable. The court applied comparative negligence and decreased the damages by 30 per cent because of the plaintiffs' fault.

Legal framework

Initially, the core source of civil liability for defective products was tort liability under the Civil Code. 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 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 Product Liability Act are available to the victim. ^[5]

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

- 1. to prevent defective products from being distributed in the market (e.g., government approval and licensing systems);
- 2. to prevent defective products in the market from causing damage or injury to consumers (e.g., recall and remedy systems); and

3.

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).

Regulatory oversight

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 CAA. The Act provides:

- 1. standards for methods of producing, processing, using, cooking or preserving food and additives;
- 2. standards for the ingredients used in food and additives; and
- 3. procedures for investigating the causes of food poisoning and for reporting the results of investigations.

The Act was revised in 2018 and fully enforced in 2021 to enhance food safety, including a new cooperative system among administrative bodies for dealing with food poisoning; new standards for sanitation management in accordance with HACCP (Hazard Analysis and Critical Control Points); advance notification required for business relevant to food, except for that with low sanitation risk; and a mandatory recall reporting system. ^[6] In September 2024, in order to reinforce a reporting system for health harm from foods with functional claims and foods for specified health uses, a mandatory information-gathering and reporting system was introduced for these products. ^[7] In 2013, the Food Labelling Act (Law No. 70 of 2013) was enacted to regulate the mandatory labelling system for food and additives, incorporating the regulations provided by the Food Sanitation Act, the Act on Standardisation and Proper Quality Labelling of Agricultural and Forestry Products (Law No. 175 of 1950) and the Health Promotion Act (Law No. 103 of 2002). The Food Labelling Act entered into force in 2015, and its regulations on food and additives are administered by the CAA. The Food Labelling Act was revised in 2018 and fully enforced in 2021, and it introduced a mandatory recall reporting system. ^[8]

Drug safety

Drugs, quasi-drugs, cosmetics and medical instruments are regulated by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (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 Health, Labour and Welfare to manufacture and market drugs and quasi-drug ingredients covered by this Act. [9] The Pharmaceuticals and Medical Devices Agency conducts safety testing of these products.

Industrial product 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 mandates that manufacturers of products that pose high risk to the lives and bodies of consumers must comply with technical standards determined by the government, and requires the placement of labels that satisfy national standards on those products. ^[10] If a product lacks the required labelling, the government can order that certain measures be taken, including the recall of the product. ^[111] If a product has caused a serious accident, the manufacturer and importer of the product must report the occurrence to the CAA. ^[12] The CAA might then announce these incidents to the public. ^[13] The CPS Act also provides certain measures to prevent accidents caused by prolonged use of products. ^[14] 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 Optimization of 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.

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, ^[15] and also provides recall systems for manufacturers and importers of vehicles, tyres and child restraint seats that do not satisfy the mandatory safety standards. ^[16]

The Consumer Safety Act and the Consumer Affairs Agency

The administrative regimes described above were insufficient because they did not cover all product categories. In response, in 2009, the government enacted the Consumer Safety Act (Law No. 50 of 2009) and created the CAA. 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 those entities must immediately notify the CAA of the accident. The CAA then collects information on the accident and responds with responsive measures. [18]

Causes of action

The Product Liability Act defines a 'product' as a movable item that is manufactured or processed. ^[19] Therefore, unprocessed agricultural products are not subject to the Product Liability Act. Software is not subject to the Product Liability Act.

The Product Liability Act applies to manufacturers, processors and importers (the Manufacturer). The Product Liability Act also applies to any person who provides their name, trademark or other indication on a product as its Manufacturer, and any person who provides their name, trademark or other indication on a product in a manner that misleads others into believing that they are its Manufacturer. The Product Liability Act also applies to any person who provides their 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. The Product Liability Act will not 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, breaches of contract or tort under the Civil Code.

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

- 1. a defect in the product;
- 2. damage to life, body or property; and
- 3. a causal link between the defect and the damage (i.e., causation). [23]

'Defect' is defined under the Product Liability 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. Defect' is interpreted to include defects in manufacture, design and instructions or warnings. The Product Liability 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*, whereby 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. [25]

The acts described in 'Regulatory oversight' provide for administrative sanctions against the responsible party where applicable. In respect of 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). [26]

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 Application of Laws (Law No. 78 of 2006) (the AGRAL), the Japanese code concerning conflict-of-law rules. The 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. I- However, the 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.-

Litigation

Forum

Civil product liability claims are determined by professional judges in national courts. No jury system exists for civil litigation in Japan. [29]

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, such as the Electric Home Appliances PL Centre and the Automotive Dispute Resolution Centre. In addition, the National Consumer Affairs Centre of Japan manages an ADR procedure that deals with product liability matters.

Burden of proof

During civil proceedings, plaintiffs must prove each required element of a product liability claim. In respect of 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. ^[30] In that case, the Supreme Court found that 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.

Some court precedents have shifted the burden of proof in product liability cases from the plaintiff to the defendant. For example, in a case arising from an accident involving a helicopter sold to the Self-Defence Forces of Japan, a lower court stated that if the accident occurred in the course of regular use of the product, the plaintiff was not required to provide a detailed explanation as to how the incident resulted from the alleged defect. ^[31] This principle is similar to that of *res ipsa loquitur* in other jurisdictions.

Defences

If a claim is brought under the Product Liability Act, the defendant may be exempt from liability if they successfully prove 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). [32] Furthermore, where

the product is used as a component of or an 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 in respect of the occurrence of the defect. [33]

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

- if the victim does not exercise their claim within three years (five years if there was harm to life or body) of the time when they (or their legal representative) became aware of the damage and the party liable for the damage; or
- after 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. [34]

As with tort claims under the Civil Code, the prescriptive period is three years (five years if there was harm to life or body) from the time the victim (or their legal representative) became aware of the damage and the identity of the perpetrator^[35] or 20 years from the time of the tortious act.^[36]

Plaintiffs' own negligence may be considered on 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 Product Liability Act or as a tort claim under the Civil Code. [37]

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.-

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'. ^[39] This ruling of the Supreme Court is arguably 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.

Personal jurisdiction

No specific provision for product liability claims

The Japanese Code of Civil Procedure (Law No. 109 of 1996) (the 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. In respect of 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 the result in Japan was ordinarily unforeseeable. I 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. [41]

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 those circumstances, Japanese courts may refuse to exercise international jurisdiction over the defendants as an exception to the general rule. [42]

Expert witnesses

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. [43] The court may order the expert to provide their opinion to the court in writing or orally.

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 this assistance, the court may appoint an expert commissioner to the proceedings. [44]

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.

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:

- 1. where the possessor, as a party, has cited the document in their arguments in the action;
- 2. 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 in respect of a legal relationship between the petitioner and the possessor;
 and
- 4. the document does not fall under any exemptions provided in the CCP. [45]

The exemptions provided for in item (d), above, are as follows:

- documents containing information in respect of which the possessor would have the right to refuse to testify because the information is self-incriminating or incriminating to their family;
- 2. documents containing a secret relating to a public officer's duties;
- 3. documents containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;
- 4. documents containing technical secrets or secrets that are useful for occupations;
- 5. documents held by the possessor exclusively for their own use; and
- 6. documents relating to criminal proceedings or juvenile delinquency proceedings.

Courts may decide not to examine documentary evidence if they deem it to be unnecessary, and courts meticulously scrutinise the necessity of 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 the evidence for deciding the issues in the current case.

Interrogatories

Before a lawsuit is instituted, or while the lawsuit is pending, a party may enquire of the opponent to request information regarding matters necessary for preparing allegations or proof. ^[47] This system is analogous to the US interrogatory system, but, in practice, this process is not frequently used in Japan.

Deposition

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

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 might spoil evidence. The order is granted pursuant to an *ex parte* hearing requested by the petitioner, and the other party is notified of the order only several hours before the judge implements the preservation order, which might avoid the other party spoiling the relevant evidence.

Apportionment

When multiple entities are involved in a product liability case, the entities are jointly and severally liable under the Product Liability 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. [49]

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

Mass tort actions

In Japan, there is no legislation creating a US-style class action for mass tort. In practice, plaintiffs bringing mass tort actions have been solicited through announcements on the internet and by other methods. However, the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers (Law No. 96 of 2013, as amended by Law No. 59 of 2022) (the Collective Redress Act) provides for collective actions with respect to consumer contracts. The Collective Redress 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. The Collective Redress Act permits collective claims to be brought against business operators, as well as certain individuals who are not business operators under specific circumstances, I-^{50]} for recovery for damage 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 (except under certain circumstances)-[51] are expressly excluded from the scope of claims that can be brought under the Collective Redress Act. ^[52] 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 reimbursement (for the damages paid) from the manufacturer responsible for the defect in a separate, standard lawsuit.

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, in tort or under the Product Liability Act. The remedy for damages is monetary compensation. ^[53] 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 will not be recognised in Japan, because they infringe upon public policy in Japan. ^[54]

The Product Liability 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 in respect of the defective product may be claimed only if they are aggregated with the other types of recoverable damages described above. [55]

Criminal liability is explained in 'Causes of action'.

Outlook and conclusions

In the past, it was believed that Japanese society was not litigious. However, Japanese consumers are increasingly scrutinising product safety, and the activities of activist lawyers representing consumers' interests have become more sophisticated and international. As the internet and social media have become more developed and prevalent, it has become much easier to organise large numbers of plaintiffs globally and to file litigation against manufacturers. Once trust in the safety of a product is undermined through negative media coverage, the harm to the corporate image of the manufacturer, and sometimes other associated companies, is tremendous and difficult to recover from. The issue sometimes even compels a company to cease operations, and even if the company survives, the scandal may invite many other significant stakeholder lawsuits, including derivative suits. It is important for manufacturers to monitor day-to-day design and production activities and, when they identify something wrong, to deal with the matter promptly and properly before the issue becomes serious.

Endnotes

- 1 X v. The Government of Japan, Sup. Ct., G.B., 3 July 2024. A Back to section
- 2 X v. Y, 2569 Hanrei jiho 59 (Osaka Dist. Ct. 17 Nov. 2022). ^ Back to section

- 3 X v. Y, LEX/DB 25599016 (Osaka High Ct., 14 March 2024). ^ Back to section
- 4 X v. Y, LEX/DB 25620672 (Tokyo Dist. Ct., 22 March 2024). ^ Back to section
- 5 Product Liability Act, Article 6. ^ Back to section
- **6** See, in particular, Food Sanitation Act, Articles 21-2, 21-3, 51, 57 and 58. <u>Ack to section</u>
- 7 Regulation for Enforcement of the Food Sanitation Act, Appended Table 17(ix)(c). Back to section
- 8 Food Labelling Act, Article 10-2. ^ Back to section
- **9** Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Article 14(1). ^ Back to section
- 10 Consumer Product Safety Act, Article 4(1). ^ Back to section
- 11 id., Article 32(i). ^ Back to section
- **12** id., Articles 35(1) and 56(1). ^ Back to section
- 13 id., Articles 36(1) and 56(1). ^ Back to section
- 14 id., Articles 32-21 and 32-22. ^ Back to section
- 15 Road Transport Vehicle Act, Article 40 et seq. ^ Back to section
- 16 id., Articles 63-2 and 63-3. ^ Back to section
- 17 Consumer Safety Act, Articles 12(1) and 47(1). ^ Back to section
- 18 id., Article 13 et seq. ^ Back to section
- 19 Product Liability Act, Article 2(1). ^ Back to section
- 20 id., Article 2(3)(i). ^ Back to section
- 21 id., Article 2(3)(ii). ^ Back to section
- 22 id., Article 2(3)(iii). ^ Back to section
- 23 id., Article 3. ^ Back to section
- 24 id., Article 2(2). ^ Back to section

- 25 X v. AstraZeneca K.K., 67-4 Minshû 899 (Sup. Ct., 12 April 2013). ^ Back to section
- 26 Penal Code, Articles 209–211. ^ Back to section
- 27 Act on General Rules for Application of Laws, Article 18. ^ Back to section
- 28 ibid. ^ Back to section
- 29 For general explanations of Japanese civil procedure, see Yasuhei Taniguchi, et al. (eds), *Civil Procedure in Japan*, Third edition (Juris Publishing, 2018), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor. ^ <u>Back to section</u>
- **30** *Miura v. Japan*, 29-9 Minshû 1417 (Sup. Ct., 24 October 1975). See also *X v. Y*, 1724 Hanrei jihô 29 (Sup. Ct., 18 July 2000). ^ <u>Back to section</u>
- **31** *Japan v. Y*, L06730924 (Tokyo Dist. Ct., 30 January2012), aff'd, *Y v. Japan*, 2208 Hanrei jihô 46 (Tokyo High Ct., 13 February 2013). ^ <u>Back to section</u>
- 32 Product Liability Act, Article 4(i). ^ Back to section
- 33 id., Article 4(ii). ^ Back to section
- 34 id., Article 5. ^ Back to section
- 35 Civil Code, Articles 724(i) and 724-2. ^ Back to section
- 36 Civil Code, Article 724 (ii). ^ Back to section
- 37 Product Liability Act, Article 6; Civil Code, Article 722(2). ^ Back to section
- 38 See Consumer Affairs Agency (CAA), Consumer Safety Division, Chikujyô Kaisetsu Seizôbutsu Sekininhô (a commentary on the Product Liability Act), Second edition (Shôjihômu, 2018), 82–83. ^ Back to section
- 39 X v. AstraZeneca K.K., 67-4 Minshû 899 (Sup. Ct., 12 April 2013). ^ Back to section
- 40 Code of Civil Procedure (CCP), Article 3-3(viii). ^ Back to section
- 41 Law No. 36 of 2011. ^ Back to section
- 42 CCP, Article 3-9. ^ Back to section
- 43 id., Article 213. ^ Back to section
- 44 id., Article 92-2(1). ^ Back to section

- 45 id., Article 220(i)-(iv). ^ Back to section
- 46 id., Article 181(1). ^ Back to section
- 47 id., Articles 132-2 and 163. A Back to section
- 48 id., Article 234; Rules of Civil Procedure, Article 153(3). ^ Back to section
- 49 See CAA, Consumer Safety Division, footnote 38, at 137–138. ^ Back to section
- 50 The Collective Redress Act permits the following to be named as defendants: (1) employees of business operators who, either intentionally or through gross negligence, caused damage in connection with the performance of consumer contracts; and (2) business supervisors who, either intentionally or through gross negligence, failed to exercise reasonable care in appointing those employees or in supervising business. See the Collective Redress Act, Article 3(1)(v) and (3)(iii). ^ Back to section
- 51 However, the Collective Redress Act permits recovery for pain and suffering if (1) the primary facts on which the calculated damages are based are common among a significant number of consumers and (2) pain and suffering are claimed along with property damages where the causes of action for the pain and suffering are the same as those giving rise to the property damages or caused by the intentional acts of the business operator. See the Collective Redress Act, Article 3(2)(vi). A Back to section
- 52 The Collective Redress Act, Article 3(2)(i)–(vi). ^ Back to section
- 53 Civil Code, Articles 722(1) and 417; Product Liability Act, Article 6. ^ Back to section
- **54** 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). ^ Back to section
- 55 Product Liability Act, Article 3 proviso. ^ Back to section



Akihiro Hironaka Kota Hoshina Chisa Fukudome a.hironaka@nishimura.com k.hoshina@nishimura.com c.fukudome@nishimura.com

Nishimura & Asahi (Gaikokuho Kyodo Jigyo)

Read more from this firm on Lexology