I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Japan is a civil law country, and it has 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.

The core source of civil liability for product defects had been tort liability under the Civil Code, Law No. 89 of 1896 (CC). However, in order to mitigate difficulties faced by victims of defective products in establishing tort claims against manufacturers and other entities responsible for the product defects, the Product Liability Act, Law No. 85 of 1994 (the PL Act) was enacted to create strict liability (i.e., no proof of negligence for the defect is necessary) in product liability claims. Tort liability can also be pursued even if the 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: (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 to consumers (e.g., recall and remedy systems); and (3) to provide prompt and effective relief to consumers that have actually suffered losses from defective products (e.g., special measures or relief for losses from defective products and a compulsory insurance system).

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2 PL Act, Article 6.
Japan

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 described in Section I, supra. As for the administrative regulations, various administrative authorities oversee the safety of different categories of products as explained below.

i Food safety

The Food Sanitation Act, Law No. 233 of 1947, governs administrative matters to prevent the 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 food and additives, standards for the ingredients of food and additives, the mandatory labelling system for food and additives, and the procedures for investigating food poisoning causes and for reporting investigation results.

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. The MHLW administers the Act. This Act provides the regulations concerning the labelling, manufacturing methods, and false or exaggerated advertising of such products. It is necessary to obtain approval from the minister of the MHLW to manufacture and market drugs and quasi-drug ingredients covered under this Act. 3

iii Industrial products safety

Regarding industrial products, an important statute providing applicable regulations is the Consumer Product Safety Act, Law No. 31 of 1973 (the CPS Act). The Ministry of Economy, Trade and Industry (METI) and the Consumer Affairs Agency (CAA) administer the CPS Act. The CPS Act provides a certification system called PSC marks, which mandates manufacturers of products that pose high risks to the lives and bodies of consumers to comply with technical standards determined by the government, and to put labels on such products that satisfy national standards. 4 If a product lacks such labelling, the government can order certain measures to be taken, including the collection of such products. 5 If a product has caused a serious accident, the manufacturer and importer of the product must report it to the CAA. 6 The CAA may then announce such incidents to the public, if it deems it necessary. 7 The CPS Act also provides certain measures to

3 Drugs, Cosmetics and Medical Instruments Act, Article 14(1).
4 Consumer Product Safety Act, Article 4(1).
5 Id., Article 32.
6 Id., Article 35(1).
7 Id., Article 36(1).
prevent accidents from prolonged use of products. Incidents that are not serious must be reported to the National Institute of Technology and Evaluation (NITE).

Other relevant important statutes are as follows: (1) the Electrical Appliances and Materials Safety Act, Law No. 234 of 1961; (2) the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas, Law No. 149 of 1967; and (3) the Gas Business Act, Law No. 51 of 1954. The METI also administers these Acts. These Acts provide 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 secure the safety of vehicles. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) administers the RTV Act. The RTV Act mandates users of the vehicles to maintain mandatory safety standards that are issued by the MLIT under the RTV Act and also provides recall systems for manufacturers and importers of vehicles, tyres and child restraint seats that do not satisfy the mandatory safety standards.

v The Consumer Safety Act and the Consumer Affairs Agency

The administrative regimes explained above, depending on the category of the products, had a shortfall by which defective products were not regulated because they 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 for 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. The CAA then collects information on the accident and responds with responsive measures.

III CAUSES OF ACTION

The PL Act defines the term ‘product’ as a moveable item that is manufactured or processed. Therefore, no processed agricultural products are subject to the PL Act.

The PL Act applies to manufacturers, processors and importers (collectively, ‘manufacturers’). 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 that misleads

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8 Id., Article 32-2 et seq.
9 RTV Act, Article 40 et seq.
10 Id., Articles 63-2 and 63-3.
11 Consumer Safety Act, Article 12(1).
12 Id., Article 13 et seq.
13 PL Act, Article 2(1).
14 Id., Article 2(3)(i).
others into believing that he or she is its manufacturer. The PL Act further applies to any person who provides his or her name, trademark, or other indication on a product and that holds him or herself out as a substantial manufacturer of a product in light of the manner and other circumstances under which the product is manufactured, processed, imported or sold. The PL Act will not provide a cause of action against distributors or sellers of a product if such persons are not an entity specified above. Therefore, civil claims against distributors and sellers of a defective product (i.e., entities that may owe direct contractual liability to the consumers) must be brought on grounds of the warranty of defects, breach of contract or tort under the CC.

In order to prove liability under the PL Act, a plaintiff must establish (1) a defect in the product, (2) damage to life, body or property, and (3) causation between the defect and the damage. ‘Defect’ is defined under the PL Act to mean a lack of safety that the product ordinarily should provide, 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’ above is interpreted to include the following three types: defect in manufacture, defect in design and defect in instructions/warnings. As mentioned above, the PL Act creates strict liability.

In Japan, there are no administrative or criminal procedures for the government to bring a claim seeking remedies for personal injury or property damage against the manufacturer, distributor or seller of a product.

Conflict-of-law issues often arise in cross-border product liability cases. Japanese courts determine the applicable law by applying the Japanese code concerning conflict-of-law rules, entitled the Act on General Rules for Applications of Laws, Law No. 78 of 2006 (AGRAL). AGRAL provides a 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 formation and effect of such claim shall be governed by the law of the place where the victim received delivery of the product. However, the application of the general rule would be inappropriate especially where the manufacturer (or other entities mentioned above) could not have foreseen the distribution of a product in a particular market. Accordingly, in order to protect foreseeability regarding the applicable law, AGRAL provides an exception to the general rule that if delivery of the product at a certain place is ordinarily unforeseeable, then the law of the principal place of business of the manufacturer (or other entities mentioned above) shall apply.
IV LITIGATION

i Forum

Product liability civil claims are determined by professional judges in national courts. No jury system exists to try civil claims.

The alternative dispute resolution (ADR) system is also important in resolving civil product liability claims because of the widely recognised litigation-averse characteristics of Japanese society and practical difficulties in establishing defects and causation in litigation. Some industries have established their own ‘product liability centres’ intended to resolve product liability civil claims within the ADR systems. For example, the Electric Home Appliances PL Centre and Automotive Dispute Resolution Centre are two such institutions. Further, the National Consumer Affairs Centre of Japan also manages an ADR system and 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 (degree of proof), in Miura v. Japan, a medical malpractice case, the Supreme Court of Japan has defined the required degree of proof.22 In that case, the Supreme Court found causation of a patient’s injury due to 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 under the standard ‘proof of a high degree of probability’, but the majority of judges appear to require a 70 to 80 per cent probability to uphold facts based on evidence submitted in civil lawsuits.23

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 (this is called a ‘development risk’ defence).24 Further, where the product is used as a component or raw material of another product, the manufacturer of the component or raw material that is named as the defendant may be exempt from liability if the

21 For general explanations on Japanese civil procedure, see Yasuhei Taniguchi, et al. eds., Civil Procedure in Japan (Rev. 2nd edn.) (Juris Publishing, 1999, Binder/Looseleaf), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor.
24 PL Act, Article 4(i).
defendant successfully proves that the defect has occurred primarily due to compliance with the instructions concerning the design given by the manufacturer of the finished product, and the defendant is not negligent with respect to the occurrence of the defect.²⁵

In addition, the PL Act provides for limitations of the period in which a claim under the PL Act will extinguish: (1) if the victim does not exercise his or her claim within three years from the time when he or she becomes aware of the damage and the party liable for damages, or (2) 10 years have elapsed from the time the product was delivered.²⁶ This 10-year period is calculated from the time of the occurrence of the damage if such damage is caused by substances that become harmful to human health when they accumulate in the body, or if the symptoms that represent such damage appear after a certain latent period.²⁷ As for tort claims under the CC, the prescription period is three years from the time the victim becomes aware of the damage and the identity of the perpetrator.²⁸ A tort claim also cannot be brought when twenty years have elapsed from the time of the tortious act.²⁹

Comparative negligence is available with respect to the determination of the amount of damage to be compensated and can be asserted in defending a product liability claim either under the PL Act or as a tort under the CC.³⁰

Compliance with applicable regulations is considered one of the important factors in determining whether there is a defect in a product; however, compliance or non-compliance with applicable regulations by itself will not automatically give rise to liability or preclude liability.³¹

In a majority of US states, the ‘learned intermediary doctrine’ has been recognised. The ‘learned intermediary doctrine’ means that a manufacturer of prescription medications and devices is released of its duty to warn users of the risks associated with its products, by warning the prescribing physician of the proper use and risks of the manufacturer’s product. Japanese courts have not adopted such a doctrine as black-letter law, but a lower court decision involving a blood derivative manufacturer’s duties regarding warning labels suggests that the manufacturer’s duties to warn of risks is fulfilled if such warning is understandable to persons with the knowledge and skill of doctors who prescribe the medicine.³²

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²⁵ Id., Article 4(ii).
²⁶ Id., Article 5(1).
²⁷ Id. Article 5(2).
²⁸ CC, Article 724.
²⁹ Id.
³⁰ Id., Article 722(2).
³² X v. Japan Red Cross, 1749 Hanrei jihô 70 (Yokohama Dist. Ct., 17 November 2000).
iv  Personal jurisdiction (international jurisdiction)

No provision for product liability claims
The Code of Civil Procedure, Law No. 109 of 1996 (CCP), provides a set of international jurisdiction rules applicable to litigation in Japanese courts, but it does not include an express provision for product liability claims. Under the prevalent view, product liability claims are classified as tort claims for the purpose of determining their international jurisdiction. Regarding the international jurisdiction of tort claims, the CCP provides that the Japanese court has jurisdiction if the place where the tort took place is located in Japan, unless the result of a wrongful act committed in a foreign country occurred in Japan and the occurrence of such a result in Japan was ordinarily unforeseeable.\(^{33}\) Therefore, determining the jurisdiction of international product liability claims will follow the application of this provision. The stream-of-commerce doctrine, discussed in the US courts, was not introduced when the CCP was revised in 2011 to include international jurisdiction provisions.\(^ {34}\)

The place where the tort took place
This phrase generally includes the place of the wrongful act and the place of the result. The place of the wrongful act includes the place where the product was manufactured. Unless advertisement on the internet constitutes part of the wrongful act, such act by itself does not constitute the basis for the jurisdiction of Japanese courts. On some occasions, allowing international jurisdiction at the place of the result will cause substantial difficulties for the defendants. In such circumstance, the prevalent view recognises exceptions where Japanese courts do not have international jurisdiction over the defendants.

The place of secondary loss or economic loss
Whether the place of secondary loss or economic loss is included in the ‘place of the loss’ has also been discussed in Japan. If it is included, courts within the consumers’ place of residence will almost always have jurisdiction over the product liability claim, and the result will be too harsh for businesses. Therefore, lower court decisions rejected this theory.\(^ {35}\)

v  Expert witnesses
The CCP has a set of provisions providing procedures for the examination of court appointed expert witnesses. Where the issues to be determined by judges are highly specialised and difficult to determine, the court can appoint expert witnesses to assist fact finding by the judges.\(^ {36}\) After an expert witness has provided his or her opinion to the

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33 CCP Article 3-3(viii).
34 Law No. 36 of 2011.
36 See CCP Article 213.
court in writing or orally, both parties have an opportunity to examine the expert witness before the judges for the purpose of impeaching an unfavourable opinion, or to restore the credibility of a favourable opinion. A court may, when it finds it necessary, request a Japanese or foreign government agency or public office, or a juridical person that has adequate equipment, to give its expert opinion.\textsuperscript{37}

In Japanese litigation practice, parties to a 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 courts. Technically speaking, these private experts are classified as ‘witnesses’ rather than ‘expert witnesses’ under the CCP, because they are not appointed by judges. However, these private experts also perform an important role.

The court may require assistance from experts not only for fact finding, but also in the process of clarifying issues and conducting proceedings efficiently. In order to enable the court to obtain such assistance, the court may appoint an expert commissioner in the proceedings.\textsuperscript{38}

\textbf{vi} \textbf{Discovery}

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

\textbf{Request for document production order}

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

\begin{enumerate}[(a)]
  \item as a party, the possessor has cited the document in his or her arguments in the action; \(\text{(2)}\) the party applying for the DPO was otherwise entitled under the law to possess or inspect the document; \(\text{(3)}\) the document was executed for the benefit of the petitioner; or \(\text{(4)}\) the document was executed with respect to a legal relationship between the petitioner and the possessor; and
  \item the document does not fall under any exemptions provided in the CCP.\textsuperscript{39}
\end{enumerate}

The exemptions provided for in \(\text{(b)}\) above are as follows:

\begin{enumerate}[(a)]
  \item a document containing information with respect to which the possessor would have the right to refuse to testify, as self-incriminating or incriminating one’s family;
  \item a document containing a secret in relation to a public officer’s duties;
  \item a document containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;
  \item a document containing technical secrets or secrets useful for occupations;
\end{enumerate}

\textsuperscript{37} Id., Article 218(1).

\textsuperscript{38} Id., Article 92-2(1).

\textsuperscript{39} Id., Articles 220(i)–(iv).
Courts may decide not to examine documentary evidence if they deem it to be unnecessary, and courts are strict when considering the necessity for issuing the DPO. If the court finds that the fact that the party seeks to establish a DPO is unnecessary for resolution of the dispute, the court will decline to issue the DPO.

Japanese evidence law does not have strict rules to exclude evidence (as in the United States) where the evidence is in danger of being unfairly prejudicial, confuses the issues, misleads the judges, etc. Therefore, whether a judge orders the DPO regarding ‘other similar incidents’ of a product defect, for example, depends on the judge’s interpretation of the ‘necessity’ of such evidence to decide the issues in the case before him or her.

**Interrogatory**

A party, before the lawsuit is instituted, or while the lawsuit is pending, may inquire with the opponent to request information regarding the matters necessary for preparing allegations or proof. This system is analogous to the US interrogatory, but this is not frequently used in Japan in practice.

**Deposition**

No deposition of parties, witnesses or experts exists in Japan.

**Evidence preservation proceedings**

If the party establishes that any circumstances exist where it will be difficult to examine evidence, including where the other party may spoil the evidence, it may request the court to issue an order to preserve the evidence. The order is granted for an *ex parte* hearing of the petitioner, and the other party is notified of such an order only an hour or an hour-and-a-half before the judge executes the preservation order, which is issued to avoid another party spoiling the evidence.

**vii Apportionment**

When multiple entities are involved in a product liability case, such entities are jointly and severally liable for liability under the PL Act or tort. A named defendant that has compensated the victim exceeding the damages that it is required to bear may seek indemnification 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.

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40 Id., Article 181(1).
41 Id., Articles 132-2, 163.
42 Id., Article 234.
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 provision for US-style class actions. In practice, plaintiffs bringing mass actions relating to product liability have been solicited through announcements on the internet and by other methods. A new law, the Act for Special Measures with respect to Civil Proceedings to Collectively Restore Damages to Assets of Consumers (CPCRDAC), was promulgated in 2013 and is awaiting implementation, which is scheduled to occur in 2016. Upon the implementation of this Act, organisations certified by the Prime Minister of Japan pursuant to the Consumer Contract Act, Law No. 61 of 2000 (‘qualified consumer organisations’) may bring a claim in relation to consumer contracts against business operators for recovery of damages suffered by consumers with respect to (1) performance of a contract, (2) unjust enrichment, (3) claim for damages due to breach of contract, (4) warranty against defects, and (5) claim for damages arising out of tort; however, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, and pain and suffering are expressly excluded from the scope of claim that can be brought by a qualified consumer organisation. Therefore, the CPCRDAC will have relatively limited influence on the practice of bringing mass actions relating to product liability. Nevertheless, Japanese manufacturers are concerned about implementation of the CPCRDAC because consumers will be able to collectively seek to recover damages caused by a product defect up to the amount of damage caused to the product itself, and such an amount may be substantially higher if collectively recovered by the consumers than it would have been prior to implementation of the Act.

ix Damages

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

The PL Act limits its application to claims for damage arising from the infringement of life, body or property caused by the defect in the product. Damage that occurs only with respect to the defective product are excluded from the scope.

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44 CPCRDAC, Article 3(1).
45 Id., Article 3(2).
46 CC, Article 722(i), 417.
47 For punitive damages awarded in a foreign court, see *Northcon I, Oregon Partnership v. Mansei Kögyô Co Ltd*, 51 Minshû 2573 (Sup. Ct. 11 July 1997).
48 PL Act, Article 3 proviso.
However, such damage can be pursued in claims under the PL Act together with other types of damage.

With respect to criminal liability, if death or injury is caused because of a failure to exercise due care in pursuit of social activities, a criminal penalty may be imposed under the Penal Code, Law No. 45 of 1907.\textsuperscript{49}

\textbf{V \ YEAR IN REVIEW}

Since 2013, claims have been filed concerning serious consumer incidents involving cosmetics manufactured by Kanebo, a well-known Japanese cosmetics corporation. Skin-whitening products manufactured by Kanebo have caused blotches in users’ skin, affecting around 19,408 customers. So far, 8,393 victims have entered into out-of-court settlements with Kanebo, but some groups of victims filed lawsuits against Kanebo to claim damages at several different district courts. Notwithstanding the Kanebo matter, the number of product liability lawsuits in Japan has been relatively small. This is because product liability litigation has been the last resort for consumers due to its practical difficulties and the relatively small amount in damages Japanese courts have awarded in the past. The lack of a US-style class action system is another reason. However, it is still important for manufacturers to effectively handle product safety issues in Japan. Although Japanese consumers may be reluctant to file lawsuits in Japanese courts – a trend that may change after the implementation of the CPCRDAC – Japanese consumers are nonetheless very sensitive about the safety of products. Product manufacturers distributing products in Japan must be well prepared to protect their reputations should a serious incident occur involving their products.

Another major matter related to product liability involving a Japanese corporation, which was globally reported in 2014, involved defective airbags manufactured by Takata. According to reports, airbags manufactured by Takata erroneously deployed during vehicle operation and caused injuries to passengers located in the United States and Malaysia. In November 2014, a US congressional hearing was assembled to obtain testimony from Takata executives. In response, in December 2014, the Japanese MLIT began urging vehicle manufacturers to conduct ‘investigative recalls’ in Japan, and some Japanese vehicle manufacturers have commenced such recalls on a voluntary basis. ‘Investigative recalls’ are conducted when the cause of the alleged defect is yet to be identified, but vehicle manufacturers nonetheless conduct precautionary recalls resulting from safety concerns. Such ‘investigative recalls’ are conducted despite not being required under existing law and regulatory framework. Whether the existing vehicle recall procedure needs to be changed in response to this Takata issue is under discussion in Japan.

\textsuperscript{49} Penal Code, Article 211.
Appendix 1

ABOUT THE AUTHORS

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Akihiro Hironaka has been a partner of the dispute resolution group of Nishimura & Asahi since 2007. He has extensive experience dealing with large-scale and complex disputes, including successful representations of foreign and Japanese vehicle manufacturers in defending important product liability lawsuits. Mr Hironaka also successfully represented a foreign corporation in an international arbitration involving an alleged defect in the design of a foreign factory. Further, he successfully represented a foreign corporation in a cross-border M&A dispute involving a breach of representations concerning numerous product defects. Mr Hironaka is a graduate of the University of Tokyo (LLB, 1993) and Harvard Law School (LLM, 2003), and is admitted to the Bars of Japan and New York. He served as a Japanese district court judge from 1998 until 2000, and worked at Arnold & Porter (Washington, DC) from 2003 to 2004. Mr Hironaka has authored numerous publications concerning dispute resolution, including Yasuhei Taniguchi et al. (eds.), Civil Procedure in Japan (contributor, Juris Publishing) and International Arbitration and Corporate Strategy (co-editor, Yûhikaku). He is an individually ranked lawyer in the category of dispute resolution with Chambers Global/Asia-Pacific 2015 and Who's Who Legal 2014.

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