



ICLG

The International Comparative Legal Guide to:

Product Liability 2015

13th Edition

A practical cross-border insight into product liability work

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Japan



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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

If there is no contractual relationship between a person who sustains damages caused by a defective product (the “Injured Party”) and the Manufacturer of such defective product, traditionally, the Injured Party’s only option to seek compensation was to bring a tort claim against the Manufacturer under Article 709 of the Civil Code of Japan (Law No. 89 of 1896; the “Civil Code”). To prevail on such claim, the Injured Party must prove (a) the Manufacturer acted intentionally or negligently in producing and/or selling the defective product, (b) the Injured Party sustained damages, and (c) causation linking the Manufacturer’s act and the Injured Party’s damages. However, because information regarding the manufacturing process of a product is generally not accessible by the Injured Party, it is normally quite difficult for the Injured Party to prove fault on the part of the Manufacturer.

To correct this unfairness, the Diet enacted and put into force the Product Liability Law of Japan (Law No. 85 of 1994; the “PL Law”), whose primary purpose is to protect the interests of victims whose death or injury to body or property is caused by a defective product. The PL law serves as an exception to the general principle of fault based liability applicable to torts under Article 709 of the Civil Code. The PL Law reduced the Injured Party’s burden of proof by holding Manufacturers (as defined in question 2.1 below) strictly liable for injuries and damages caused by their defective products (in other words, the Manufacturer’s intentional act or negligence in relation to the defective product need not be proven). Thus, to prevail on a claim under the PL Law, the Injured Party need only prove the existence of a defect in the product, his/her damages and causation.

The PL Law is applicable in regard to any movable property that is manufactured or processed (Paragraph 1, Article 2 of the PL Law). The term “movable property” is defined under the Civil Code as tangible property, excluding land and any fixtures thereto. According to the PL Law, a product is “defective” when it lacks the level of safety normally expected of such product, taking into account the nature of such product, its ordinary foreseeable manner of use, the date when the Manufacturer delivered the product and other relevant circumstances concerning the product. For the PL Law to apply, damages separate from those to the defective product must exist.

On the other hand, if there is direct contractual relationship between the Injured Party and the Manufacturer, the Injured Party may assert a claim seeking damages against the Manufacturer based on contractual liability under Article 415 of the Civil Code or, in the case of a sale of a product, a claim to establish statutory liability for a latent defect as stipulated in Article 570 of the Civil Code.

1.2 Does the state operate any schemes of compensation for particular products?

The Pharmaceuticals and Medical Devices Agency (the “PMDA”), an administrative agency established based upon the Act on the Pharmaceuticals and Medical Devices Agency (Law No.192 of 2002), operates the Relief Services for Adverse Health Effects (the “Relief Services”). The Relief Services is designed to provide prompt relief to people who sustain health-related problems or damages caused by adverse drug reactions or infections from biological products. Under the Relief Service, the PMDA provides medical expense benefits, disability pensions, and bereaved family pensions for those who suffer illnesses or disabilities caused by adverse drug reactions. The national treasury subsidises about one-half of the expenses necessary for the operation of the Relief Services. Also, pharmaceutical companies are charged fees that contribute to funding the Relief Service.

Another scheme of compensation is operated by the Consumer Product Safety Association (the “Association”) established under the Consumer Product Safety Act of Japan (Law No. 31 of 1973, the “CPSA”). The Association operates a product certification system, the SG-Mark (the abbreviation of “safe goods” mark) system, which includes a compensation scheme for persons injured by products bearing the SG-Mark. The Association stipulates the SG-Mark standard, a safety standard for specified products that could endanger human life or cause injury in terms of their structure, the material from which they are made and/or the mode of usage. Only those products that comply with such safety standard are authorised to bear the SG-Mark as products approved by the Association. Although obtaining the SG-Mark for their products is not mandatory, Manufacturers are motivated to do so for their reputational interest. Compensation of up to JPY100 million per person may be awarded by the Association in the case of injury or death caused by a defective product bearing the SG-Mark.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the PL Law, manufacturers (the “Manufacturers”) bear responsibility for defects in their respective products. The term

“Manufacturers” is defined under Paragraph 3, Article 2 of the PL Law as (i) any person who manufactures, processes, or imports products in the course of trade, (ii) any person who represents or misrepresents themselves as a Manufacturer by putting their name, trade name, trademark or any other similar indication on a product, and (iii) any person who, in light of the manner concerning the manufacturing, processing, importation or sales of the product, represents themselves as a Manufacturer-in-fact by putting their name, trade name, trademark or other indication on the product. A person who only sells, installs, packs or transports products is not liable under the PL Law, unless they fall within the category of (ii) or (iii) above.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

While the PL Law and the Civil Code do not explicitly impose an obligation on Manufacturers to recall defective products, the CPSA does impose such an obligation under certain circumstances with respect to consumer products. Under the CPSA, the term “consumer products” is defined as any product which is supplied mainly to general consumers for use in performing their routine, everyday activities (except for those products listed in the appendix to the CPSA).

In situations where a serious accident resulting from a defect in a consumer product occurs or where a defect creates a serious danger to the safety or lives of consumers, or the occurrence of such danger is considered imminent, Paragraph 1, Article 39 of the CPSA authorises the competent minister to order the relevant Manufacturer or importer to conduct a product recall or take such other necessary measures to prevent the occurrence of, and an increase in the severity of, such danger, as such minister deems appropriate. Accordingly, a Manufacturer or importer is obligated to implement a product recall when so ordered under the CPSA, and if it fails to comply with such order, it and its officers and employers may be subject to certain punishment under the CPSA. It should be noted, however, that, as indicated by the broad definition of “consumer products” under the CPSA, the regulations of the CPSA do not apply to products to which certain sectorial laws apply. For example, the Road Trucking Vehicles Law (Law No. 185 of 1951) and its Enforcement Ordinance regulate vehicle safety (including regulations dealing with mandatory product recall with respect to vehicles), and thus vehicles are not regulated by the CPSA.

1.5 Do criminal sanctions apply to the supply of defective products?

The PL Law and the Civil Code do not provide for criminal sanctions. However, under Article 211 of the Penal Code of Japan (Law No. 45 of 1907; the “Penal Code”), if a company manufactures and sells defective products and persons who use or consume such products consequently suffer physical damage (i.e., death or physical injury), the company’s officers and employers who are responsible for such defect may be punished by imprisonment with or without work for not more than 5 years or a fine of not more than JPY1,000,000. It should be noted that Article 211 of the Penal Code applies only to individuals (i.e., persons whose acts or negligence causes the death or injury of another), not companies.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

As mentioned in question 1.1 above, the PL Law reduced the Injured Party’s burden of proof by imposing strict liability on the Manufacturers. On the other hand, in a claim brought under Article 709 of the Civil Code, the Injured Party must prove the Manufacturer’s misconduct or negligence which likely entails substantial difficulty.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Neither the PL Law nor Article 709 of the Civil Code provides a specific test to establish causation in product liability cases. Therefore, to establish causation, typically it is not sufficient for a claimant only to prove that the Manufacturer had wrongfully exposed such claimant to an increased risk of a type of injury known to be associated with the product. However, recognising that establishing causation can be very difficult, the courts have, in some cases, lightened the claimant’s burden of proof by inferring causation from certain indirect facts that the claimant can prove.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Neither the PL Law nor the Civil Code provides for market-share liability. In order to claim damages in relation to a defective product under such laws, the Injured Party must specifically identify the party who is in fact responsible for the defective product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

While the PL Law does not expressly provide for categories of product defects, the courts have generally recognised, in addition to manufacturing defects and design defects, the defect of failing to provide adequate instructions or warnings. Thus, when the foreseeable risks of harm posed by the product could have been

reduced or avoided by providing reasonable instructions or warnings, the failure to do so may render the product defective. In connection with this, it is worth noting that in a recent Supreme Court case addressing whether the Manufacturer of an anti-cancer drug provided sufficient warnings of the possible side effects thereof, the Supreme Court held that whether the user of the drug could have been aware of its potential side effects by a warning printed on its packaging should be determined taking into consideration, among other things, the fact that the anticipated users of such drug are doctors engaging in lung cancer treatment, and the Supreme Court ultimately concluded that there was no warning defect in relation to such drug.

The Civil Code also does not expressly impose on Manufacturers an obligation to warn with respect to a product which is found to be defective. Therefore, a failure to warn may not directly give rise to tort liability. It should be noted, however, that such failure may be considered by the court as a substantial factor disadvantageous to the Manufacturer in a product liability case when the court determines whether and to what extent a Manufacturer is liable to the Injured Party.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Article 4 of the PL Law expressly provides for the following defences which will absolve a Manufacturer from liability if proven:

- (i) the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time when the Manufacturer delivered the product; and
- (ii) in the case where the product is used as a component or raw material of another product, the defect occurred primarily because of the Manufacturer's compliance with the instructions concerning the design given by the Manufacturer of such other product, and thus the Manufacturer is not negligent with respect to the occurrence of such defect.

It is understood that "scientific or technical knowledge" means the highest level of knowledge available, and includes all relevant information available (such as relevant information in published documents) at the time when the product was delivered by the Manufacturer, not at the time when the product was developed.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The PL Law provides for a state of the development risk defence. (See the response to question 3.1 (i).)

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

While compliance with regulatory/statutory safety standards is one of the major factors in determining whether a product has a defect, it is not necessarily a complete defence. The Manufacturers may nonetheless be held liable under the PL Law for damages caused by a product which complies with such safety standards.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Since a product liability lawsuit is an individual action in which an Injured Party asserts a claim for damages sustained due to a defective product against the Manufacturer of such product, it will not prevent others injured by the same product from suing such Manufacturer in separate proceedings.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

A Manufacturer which is sued based on a defective product under the PL Law or the Civil Code (the "Original Suit") may seek indemnification/contribution from a third party (including another Manufacturer) which is fully or partially responsible for the defect in the relevant product. Such indemnification/contribution claim against the third party (the "Second Suit") may be brought while the Original Suit is pending, and the defendant Manufacturers may then request the court to consolidate these two suits at its discretion. The Second Suit can also be filed after the Original Suit is over.

Depending on the legal nature of the Second Suit, the time limitation for making a claim may differ. If a tort claim under the Civil Code or a claim under the PL Law is to be asserted, the Second Suit must be filed within 3 years from the time when the Injured Party first comes to know of the damages and the third party responsible therefor, or (a) in case of a tort claim, within 20 years from the time of the tortious act by the third party, and (b) in case of a claim under the PL Law, within 10 years from the date of delivery of a product. If a claim is brought seeking to establish contractual liability, the Second Suit must be filed within 10 years from the time of payment of the damages awarded in the Original Suit.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, if there is any fault on the part of the Injured Party, courts may take such fault into account in determining the amount of damages to be awarded.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

While Japan has implemented a lay judges (*saiban-in*) system by which selected citizens participate as judges (and not as members of a jury) in certain felony criminal trials, for civil actions trials are by professional judges only.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

After hearing the positions of the parties, a judge may order the

appointment of an expert commissioner (*senmon-iin*) to provide the Judge with “explanations” based on his/her technical expertise, in the course of proceedings. In certain situations (e.g., during examinations of witnesses), such expert commissioner may sit next to the judge.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure ‘opt-in’ or ‘opt-out’? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The Act on Special Provisions of Civil Procedure for Collective Recovery of Property Damage of Consumer (Law No. 96 of 2013) introduced “opt-in consumer collective actions” which only certified consumer organisations can bring. The scope of claims that may be brought under such collective actions is limited and excludes claims made under the PL Law.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

While certified consumer organisations can bring injunctive relief suits against business operators under the Consumer Contract Act (Law No. 61 of 2000) in order to prevent the occurrence of damages to consumers, such type of suits does not seek to compensate consumers for their damages sustained due to defective products.

4.5 How long does it normally take to get to trial?

Under the Code of Civil Procedure (Law No. 109 of 1996) (“CCP”) there is no distinction between trial and pre-trial phases of a lawsuit. Shortly after a lawsuit is brought, hearings are held to address all relevant issues and matters (both procedural and substantive in nature). For contested cases, the average duration from the filing of a complaint to the issuance of the judgment in the first instance is about 12 months.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

While the court is entitled to conclude a case whenever it is of the opinion that the suit is ripe for entering judgment (for example, the court is not obliged to examine witnesses before it enters judgment), the CCP does not provide for a procedure by which a court is to specifically address preliminary issues.

4.7 What appeal options are available?

The losing party to a suit filed in the district court, as the court of first instance, may file a *Koso* appeal with a high court. In a *Koso* appeal, the high court will conduct a complete re-examination of the case. The losing party of such *Koso* appeal may file a *Jokoku* appeal with the Supreme Court of Japan, as a right either on the ground that the judgment of *Koso* appeal is in violation of the Constitution or that substantial illegalities occurred during the procedure undertaken in the lower court. In addition, a losing party may file a petition to the Supreme Court for acceptance of a *Jokoku* appeal on the basis that

the case involves an important issue relating to the interpretation of the law. The Supreme Court has discretion to accept or deny such petition.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As stated in the response to question 4.2 above, a court may appoint an expert commissioner to provide the court with explanations based on the commissioner’s technical expertise. In addition, the court may seek an expert opinion at a party’s request, and possibly *sua sponte* as well (although the prevailing view is that courts should not seek expert opinions *sua sponte*). The court can select an eligible expert at its own discretion, and there is no strict restriction on the qualification of an expert. A party may also submit an expert opinion prepared by an expert retained by such party, and may have such expert testify as a witness at a hearing.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no explicit provision in the CCP addressing witness statements. However, in practice, in almost every case the parties will prepare written witness statements and have them exchanged prior to the witnesses’ examinations.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The CCP does not provide for pre-trial discovery procedures pursuant to which each party is required to disclose requested documentary evidence to other party. However, before the filing of a complaint or during the course of an action, a party may ask the court to implement an evidence preservation proceeding. The court will do so only if it believes that circumstances exist which will make use of the subject evidence difficult (such as the likelihood of alteration of documentary evidence) unless such evidence is preserved through prior examination. The CCP imposes a limited obligation to produce relevant documents during the course of an action, and if a motion demanding production of specified documents is brought by a party and granted, the person in possession of the subject documents will be required to produce them or face consequences including, possibly, the court’s adverse inference determination in regard to the unproduced documents.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In addition to litigation, disputes may be resolved through (a) a civil conciliation procedure, which is a mediation type proceeding conducted *in camera* by a conciliation committee composed of one judge and two or more civil conciliation commissioners, (b) arbitration, if agreed by the parties (although arbitration is normally not an option to resolve damages claims under the PL Law or tort claims under the Civil Code as there would not be an arbitration agreement between the relevant parties), and (c) for disputes involving product liability or product safety issues, private dispute resolution service providers, such as the PL Center for Consumer Products, the Chemical Products PL Consulting Center, and the Automotive Dispute Resolution Centre.

4.12 In what factual circumstances can persons that are not domiciled in Japan, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Any claimant, regardless of his/her place of domicile, may file a product liability lawsuit or tort lawsuit with a Japanese court as long as the principal office of the defendant Manufacturer is in Japan. Further, even if a defendant Manufacturer's place of corporate domicile is outside of Japan, a claimant is permitted to file such lawsuit in Japan against said Manufacturer if the relevant tortious act occurred in Japan. This includes not only the place where the tortious act was committed but also the place where results thereof occurred; provided, however, that if the result of a tortious act committed in a foreign country occurred in Japan, and the occurrence of such result in Japan was ordinarily unforeseeable, a Japanese court will not exercise its jurisdiction over such case.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, there are time limitations for asserting claims under the PL Law and the Civil Code.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Please see response to question 3.5 above.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Although it would seem to be a highly exceptional case and thus hard to generalise, a finding of concealment or fraud could affect the running of time limits mentioned in 3.5 above.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In a claim brought under the PL Law and a product-related tort claim under the Civil Code, the claimant's possible relief is limited to monetary compensation.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The PL Law expressly provides that the Manufacturers shall be liable for damages arising from the infringement of life, body or property of others. Mental damages are also recoverable. On the other hand, the PL Law does not apply if only the defective product itself is damaged.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Recoverable damages under product liability suits are limited to those already sustained as a result of the defective product, and thus the cost of medical monitoring in circumstances where injury has not yet been sustained would not be compensated.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable in Japan.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable under the PL Law or the Civil Code.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no such special rules.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product? If so, who has responsibility for the repayment of such sums?

Japanese government authorities are not entitled to make any claim against the amount of damages awarded or the settlement amount paid to a claimant in a product liability suit.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In general, the litigation expenses of both parties, such as court fees paid in the form of revenue stamps, fees paid to witnesses and travel expenses, are borne by the losing party. Attorneys' fees, however, are excluded from the litigation expenses charged to the losing party. Depending on the nature of the case, reasonable attorneys' fees may be recoverable as part of the damages awarded in a judgment rendered in a tort case or breach of contract case.

7.2 Is public funding e.g. legal aid, available?

Yes, claimants suffering economic hardships may receive legal aid from the Japan Legal Support Center (the "JLSC"), a public

corporation established under the Comprehensive Legal Support Act of Japan (Law No. 74 of 2004).

7.3 If so, are there any restrictions on the availability of public funding?

To be eligible to receive support from JLSC, all of the following conditions must be met: (i) the financial resources of the applicant must fall below a certain specified amount; (ii) the possibility of achieving a successful result through a court procedure must exist; and (iii) providing support to the applicant must be consistent with the purpose of such legal aid.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Japanese lawyers are not prohibited from receiving contingency fees. They may agree with their clients on their fee arrangement, although pure contingency fee arrangements are rarely used in Japan.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding is not prohibited. Therefore, a claimant may receive funding from a third party in accordance with their contractual arrangement.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Japan.

Recent product liability cases generally show a trend by courts to lighten the burden of proof for plaintiffs to establish their cases with respect to product defects. One such example is the Sendai High Court product liability case decided on 22 April 2010.

In a recent product related tort case, the Tokyo District Court held, on 21 December, 2012, that the defendant Manufacturer was liable for the death of a family member of the plaintiff, who died from carbon monoxide poisoning caused by the incomplete combustion of a gas-fired water heater even though such incomplete combustion was caused by an illegal modification to such water heater by a co-defendant repair business operator. At issue was whether the Manufacturer was responsible for damages sustained even if the water heater, which was later illegally modified, was not defective at the time of manufacture. The court ruled that under the relevant circumstances: (a) the defendant Manufacturer owed a duty (i) to notify owners and users of the water heater of the risk of the potential accident and to ask them to cease using it, and (ii) to implement an inspection and/or recall thereof; and (b) the defendant Manufacturer had failed to carry out such actions in breach of such duty. This judgment is now final (i.e., not appealable). While the basis for the duty to implement a product recall was not made clear by the court, this judgment is noteworthy for the fact that the court found a Manufacturer to be liable for a tort based on its failure to take proper actions.

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Prior to joining NO&T, he served as a judge of the Tokyo District Court, a Staff Attorney with the Civil Affairs Bureau of the General Secretariat of the Supreme Court of Japan, and a Deputy Director of the Industrial Finance Division, Economic and Industrial Policy Bureau, Ministry of Economy, Trade, and Industry (METI). He has also served as a Coordinator of the Legislative Council of the Ministry of Justice.

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