

CHAMBERS GLOBAL PRACTICE GUIDES

Product Liability & Safety 2024

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Japan: Law & Practice

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JAPAN

Law and Practice

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1. Product Safety

1.1 Product Safety Legal Framework

The Consumer Product Safety Act (CPSA) is the main law for product safety in Japan. Consumer products are generally subject to the CPSA. The term "consumer products", as used in the CPSA, has a very broad scope and means any product supplied mainly for use by general consumers in their everyday lives, excluding certain products listed in the table appended to the CPSA. The excluded products include:

- medical products, cosmetics and medical devices, which are regulated by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices;
- automobiles, which are regulated by the Road Trucking Vehicle Act; and
- food, food additives and cleaning agents, which are regulated by the Food Sanitation Act (FSA).

Consumer products that are found to be highly likely to cause harm, particularly to the lives or health of general consumers, are defined as "specified products" under the CPSA; these include climbing ropes, autoclaves and pressure cookers for household use, riding helmets and portable laser application devices. The relevant competent authority establishes the technical standards necessary for the specified products to prevent the lives or health of general consumers being endangered.

The regulatory framework under the CPSA is as described below.

Product Safety of Consumer Products (PSC) Mark System

The PSC mark system is a pre-marketing method to ensure product safety by regulating the sale and display of specified products, for sale purposes, through labelling requirements. If a manufacturer or an importer of specified products has submitted the required notification, ensured the products conform to certain technical standards set by the competent authority, and has had the products inspected (and kept the inspection record), they can affix the PSC mark on the specified products. The sale or display, for the purpose of selling, of these products is prohibited, unless the PSC mark is placed on the specified products.

Reporting Obligations

A manufacturer or importer of consumer products that becomes aware of a serious product accident that has occurred in relation to a consumer product that it manufactures or imports, must report specific information related to the product and the accident to the Secretary General of the Consumer Affairs Agency (CAA) within ten days. For non-serious product accidents, manufacturers and importers of consumer products, as well as retailers and other parties who are involved with such products, are expected to report the accident to the National Institute of Technology and Evaluation (NITE), an independent administrative agency, by an official notice issued by the Ministry of Economy, Trade and Industry (METI).

For serious product accidents, the Secretary General of the CAA will publish certain information related to the relevant product and accident, if the Secretary General finds this necessary to prevent serious danger, or an increase in danger, to consumers. For non-serious product acci-

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dents, NITE generally publishes limited details of the accident.

Inspection and Labelling Requirements to Prevent Accidents Due to Deterioration

Under the CPSA, consumer products that have a high likelihood of causing a serious accident due to degradation over time; ie, oil water heaters and oil bath boilers, are called "specified maintenance products". For these specified maintenance products, a manufacturer or importer must set:

- a standard period of use during which there will be no safety issue if used under the standard conditions of use, which is called the "design standard use period"; and
- an inspection period to prevent injury due to age-related deterioration once the design standard use period has expired.

The manufacturer or the importer must place labelling which shows, among other information, the design standard use period and the time of commencement and expiration of the inspection period. The manufacturer or the importer must send a notification to the user of the specified maintenance product when the end of the design standard use period is approaching. Furthermore, when requested within the inspection period, the manufacturer or the importer must conduct an inspection of the specified maintenance product. For consumer products that do not have a high likelihood of causing a serious accident but that have a high volume of accident reports due to deterioration over time, such as electric fans and air conditioners, warning labels on deterioration and the design standard period of use must be affixed.

In addition to the CPSA, some consumer products may be subject to other laws, such as the Electrical Appliances and Materials Safety Act, the Gas Business Act and the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas.

1.2 Regulatory Authorities for Product Safety

No regulator has general jurisdiction over product safety issues in Japan. When the CAA was established, jurisdiction over existing legislation involving the safety of the lives and health of people remained with the relevant ministries which then had jurisdiction. Due to this arrangement, the CAA has limited power to regulate business operators with respect to consumer safety matters. However, serious product accidents must be reported by manufacturers and importers to the Secretary General of the CAA under the CPSA.

One of the main regulators for product safety in Japan is the METI. As the METI has jurisdiction over the CPSA, under which most consumer products are regulated, the METI has broad jurisdiction over consumer products.

A ban on the sale of a specific consumer product can be imposed by the competent authority. For example, if certain specified products fail to conform to the technical requirements established by the competent authority and the competent authority finds doing so particularly necessary to prevent harm to the lives or health of general consumers, the competent authority can prohibit the manufacturer and the importer of the products from affixing the PSC mark on the products for a period of not more than one year. This effectively results in a ban on the sale of the specific consumer products, as no person engaged in the manufacture, import or sale of the specific consumer product may sell, or display such products for the purpose of selling

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them, without affixing the PSC mark under the CPSA.

Certain specific products are exclusively regulated by other regulators. For example, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) regulates automobiles; and the Ministry of Health, Labour and Welfare (MHLW) regulates medical products, cosmetics and medical devices, as well as food, food additives and cleaning agents. These regulators have the power to establish technical or other relevant standards. If certain conditions are met, these regulators can order the manufacturer to implement remedial measures, including the implementation of product recalls.

1.3 Obligations to Commence Corrective Action

General

The Basic Consumer Act provides that the Japanese government must take necessary measures to ensure the safety of consumers, such as by:

- requiring that business operators recall goods that may be detrimental to safety; and
- collecting and providing information on goods and services that may be detrimental to safety.

Business operators are expected to implement a product recall if a product that they manufacture, import or sell might be detrimental to the safety of its consumers.

Under the CPSA, any person engaged in the manufacture or import of consumer products must investigate the cause of any product incidents that occur involving these particular consumer products. The manufacturer or importer must endeavour to either recall the consumer products or take measures to improve the safety of these products and prevent the occurrence of further product incidents.

Sector-Specific

Medical

Under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, holders of a marketing authorisation for pharmaceuticals, guasipharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding the foreign manufacturing of these products, must, when they learn of the occurrence or spread of hazards in health and hygiene suspected to be caused by using such products that they have manufactured and sold or for which they have received certain approval, dispose of, recall, discontinue selling and provide information on such products, and take other necessary measures for the prevention of the occurrence or spread of hazards in health and hygiene.

Automotive

Under the Road Trucking Vehicle Act (including a guideline established thereunder), in cases where the structure, mechanism or performance of a certain range of automobiles of the same model does not, or is not likely to, conform with the necessary safety standards, and the cause relates to the design or manufacture of the automobiles, a manufacturer or importer must promptly recall the automobiles and report certain matters specified in the Act to MLIT.

Food standards

Under the FSA, a food business operator must endeavour to take all necessary measures, appropriately and immediately, to prevent food sanitation hazards resulting from the sale of food, etc, such as the provision of a certain

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record to the relevant state or prefectures, and the disposal of the food that caused the food sanitation hazards.

Advertising

There is no mandatory advertising requirement under the CPSA and FSA. However, under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, in cases where holders of marketing authorisations for pharmaceuticals, guasipharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding foreign manufacturing, file for a recall, they must - in addition to promptly providing the information on the recall to each medical institution, etc provide such information using the internet. Furthermore, under the Road Trucking Vehicle Act, if manufacturers of automobiles file for a recall. they must have the filing published in the journal of the Japan Automobile Service Promotion Association to disseminate information on the recall to providers of automobile repair services.

1.4 Obligations to Notify Regulatory Authorities

The CPSA sets out incident-based reporting. If a manufacturer or importer of consumer products comes to know of a serious product incident that has occurred with a consumer product that it manufactures or imports, it must report certain information related to the product and the incident to the CAA. The report must be submitted in the format provided for in the Cabinet Office Order within ten days from the date of knowing that a serious product incident has occurred.

Even if an incident that occurs involving the consumer product is not serious, it is expected by an official notice issued by the METI that business operators involved with such consumer products – eg, manufacturers, importers and retailers, will report the incident to NITE, which is an independent administrative agency, in the format provided for on NITE's website.

The FSA provides a reporting obligation for food recalls. Under the FSA, if a business operator recalls food, additives, apparatus, or containers and packaging which are, or are suspected to be, in violation of the FSA, it must notify the prefectural governor of the initiation of the process of recall without delay, except in cases where the MHLW or a prefectural governor has ordered the business operator to recall the products, or there is no risk of a food hygiene hazard. When the prefectural governor has received the report, it must report it to the MHLW.

1.5 Penalties for Breach of Product Safety Obligations

In cases where a manufacturer or an importer of consumer products fails to send a report to the CAA or sends a false report to the CAA in violation of the obligations explained in 1.4 Obligations to Notify Regulatory Authorities, the competent minister may find it necessary - to secure the safety of the consumer products manufactured or imported by that manufacturer or importer to order the manufacturer or importer to develop a system necessary for collecting information on serious product incidents that occur in relation to the consumer products manufactured or imported by it, and for the proper management or provision of that information. Failure to observe such an order issued by the competent minister may result in the manufacturer or importer and their representative facing imprisonment for up to one year and/or a fine of up to JPY1 million. However, failure to report to the CAA in itself, pursuant to the obligation explained in 1.4 Obligations to Notify Regulatory Authorities, does not trigger criminal penalties.

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2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The main causes of action for product liability are tort and contract.

Tort

The general principle of tort is provided in Article 709 of the Civil Code – namely, that a person who intentionally or negligently infringes another person's right or legally protected interest is liable to compensate them for any loss or damage caused by that infringement. The tort liability under Article 709 of the Civil Code requires the following conditions to be met:

- the violation of the plaintiff's right or legally protected interest by the defendant;
- an intentional or negligent act on the part of the defendant;
- · the occurrence of damage; and
- a causal relationship between the violation and the damage.

In addition, a special rule to the general principle of tort is added by Article 3 of the Product Liability Act. The special rule is that a person who is injured as a result of the defects of a product can demand compensation from the manufacturer and other involved parties without having to prove intent or negligence. Product liability under Article 3 of the Product Liability Act requires the following conditions to be met.

- The defendant corresponding to:
 - (a) any person who manufactured, processed, or imported the product as a business;
 - (b) any person who indicates their name, trade name, trade mark or other indication (hereinafter referred to as "represen-

tation of name, etc") on the product as the manufacturer of the product, or any person who indicates the representation of name, etc, on the product which makes others misunderstand that they are the manufacturer; or

- (c) except for the cases outlined in the two bullet points above, any person who indicates any representation of name, etc, on the product which, in terms of the manufacturing, processing, importing or selling of the product, and other circumstances, is recognised as its substantial manufacturer (hereinafter, any persons corresponding to these three bullet points are collectively referred to as "manufacturer, etc").
- Delivery of the movable product by the defendant.
- Damage being caused by the product which, at the time of delivery by the defendant, was manufactured or processed and was a movable product.
- A defect in the product at the time of delivery by the defendant.
- Infringement of the injured party's right or legally protected interest.
- The occurrence of damage.
- A causal relationship between the defect and the damage.

Contract

Buyers of defective products may, in accordance with contract law under the Civil Code, make a claim against the seller for compensation for damages, the repair of a defect, or the delivery of a substitute for the product.

Contractual liability requires the following conditions to be met:

• the conclusion of the contract;

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- · a defect in the product;
- the cause of that defect being attributable to the defendant (this not being required for a claim for the repair of a defect, or the delivery of a substitute for the product);
- · the occurrence of damage; and
- a causal relationship between the defect and the damage.

2.2 Standing to Bring Product Liability Claims

Individual Standing

The following have the standing to bring claims for product liability, as listed in 2.1 Product Liability Causes of Action and Sources of Law:

- under a tort a person whose right or legally protected interest has been violated;
- under the Product Liability Act -
 - (a) a person who has been injured because of the defect; or
 - (b) a person whose property, excluding the defective product itself, has been damaged because of the defect; or
- under contract law the buyer.

Collective Redress

Furthermore, in Japan, the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers has been enacted. This Act allows a specified qualified consumer organisation to bring lawsuits against a company on behalf of unspecified and multiple individual consumers in certain cases.

This Act establishes two phased proceedings for the collective redress for property damage incurred by consumers. In the first proceeding, a specified qualified consumer organisation files an action for declaratory judgment on common obligations, which is an action seeking a declaratory judgment that a company owes monetary payment obligations to unspecified and multiple consumers based on factual and legal causes common to the consumers, where property damage is incurred by a considerable number of consumers in connection with consumer contracts. In the second proceeding, simplified determination proceedings to determine the presence or absence and the contents of a claim for payment of money are carried out by the district court which made the final judgment in the first instance of the action for declaratory judgment on common obligations.

A specified qualified consumer organisation may file an action with regard to monetary payment obligations which pertain to the following claims in connection with consumer contracts (set forth in Article 3 (1) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers):

- a claim for performance of a contractual obligation;
- a claim pertaining to unjust enrichment;
- a claim for damages based on non-performance of a contractual obligation;
- a claim for damages based on a tort (limited to a claim based on the provisions of the Civil Code); and
- following claims for damages on the grounds that a company's employee has caused damages to a third party in the performance of their duties regarding the consumer contract
 - (a) a claim for damages based on the provisions of Article 715 (1) of the Civil Code against a company that has intentionally or through gross negligence failed to exercise reasonable care in appointing

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the said employee or in supervising the business;

- (b) a claim for damages based on the provisions of Article 715 (2) of the Civil Code against a supervisor of the business who has intentionally or through gross negligence failed to exercise reasonable care in appointing the said employee or in supervising the business; and
- (c) a claim for damages based on a tort (limited to a claim based on the provisions of the Civil Code) against the said employee who has intentionally or through gross negligence caused damage to a third party.

Damage which cannot be compensated through collective redress actions

An action may not be filed when the damage incurred is any of the following (set forth in Article 3 (2) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers):

- (i) damage due to the loss or damage of property other than goods, rights, or any other object of a consumer contract resulting from the non-performance of a contractual obligation or a tort;
- (ii) damage due to the loss of profit which would have been gained through the disposition or use of the object of a consumer contract if that object had been provided;
- (iii) damage due to the loss or damage of property other than goods pertaining to manufacturing, processing, repair, transport, or retention under a consumer contract or any other subject of the service which was the object of a consumer contract, resulting from the non-performance of a contractual obligation or a tort;

- (iv) damage due to the loss of profit which would have been gained through the use of the service that is the object of a consumer contract or through the disposition or use of the subject of the service if the service had been provided;
- (v) damage due to harm done to the life or body of a person; or
- (vi) damage due to mental suffering (excluding the following damages (limited to the cases where the main facts on which the calculation of the amount is based are common to a substantial number of consumers)):
- damages that are claimed in conjunction with the claims listed in Article 3 (1) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers (regarding claims (iii) to (v) set forth in Article 3 (1), limited to those that do not include claims pertaining to damages due to mental suffering) and based on factual causes common to property claims; or
- damages that are caused by a company intentionally.

Since the damages which are subject to the claims described in **2.1 Product Liability Causes** of Action and Sources of Law correspond to (i), (ii), (v) and (vi) above, a specified qualified consumer organisation cannot bring a collective redress action with respect to a claim under the Product Liability Act.

2.3 Time Limits for Product Liability Claims

Tort

The right to seek compensation for damages in tort will be extinguished by the completion of prescription if the victim, or their legal representative, does not exercise the right within

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three years from the time when they realised the damages and the identity of the perpetrator. In addition, the right will be extinguished when 20 years have elapsed from the time of the act of tort.

Product Liability Act

The right to claim damages provided under the Product Liability Act will be extinguished by the completion of prescription if the victim, or their legal representative, does not exercise the right within three years (if death or injury occur, the prescription term is extended to five years) from the time when they realised the damages and the person liable for the damages. In addition, the right will be extinguished when ten years have elapsed from the time when the manufacturer, etc, delivered the product. However, this tenyear period will start from the time of the occurrence of (i) the damage caused by substances which become harmful to human health when they accumulate in the body; or (ii) symptoms that appear after a certain latent period.

Contract Law

If the buyer fails to notify the seller of the nonconformity with the terms of the contract within one year from the time the buyer became aware of the non-conformity, the buyer cannot make a claim against the seller unless the seller was aware of the existence of the non-conformity at the time of delivery, or was not aware of the existence of the non-conformity through gross negligence. Even if the notice is given within one year, the right to claim will be extinguished by prescription if it is not exercised within five years from the time when it becomes known that the right can be exercised or if it is not exercised within ten years (in the case of a claim for damages resulting from the death or injury to persons, this period will be extended to 20 years) from the time it becomes exercisable.

2.4 Jurisdictional Requirements for Product Liability Claims

The courts of Japan have jurisdiction over an action that is brought (i) against a corporation whose principal office or business office is located in Japan; and (ii) against a corporation whose representative or person principally in charge of its business is domiciled in Japan, if the corporation does not have a business office or other office in Japan, or if the location of its business office or other office is unknown. In addition, the courts of Japan have jurisdiction in the following cases depending on the grounds of the claim.

Tort

The courts of Japan have jurisdiction if the place where the wrongful act was committed or the place where the consequences occurred are in Japan (excluding cases where the consequences of a wrongful act committed in a foreign country have occurred within Japan, but it would not ordinarily have been possible to predict that such consequences could occur within Japan).

Product Liability Act

In line with the principle applying to tort above, the courts of Japan will have jurisdiction over the product liability case if the place where the wrongful act was committed or the place where the consequences occurred was within Japan. In relation to the product liability case, "the place where the wrongful act was committed" is interpreted as the place of manufacture.

Contract Law

The courts of Japan will have jurisdiction if the place of performance of the obligation under the contract is within Japan, or if it is determined that the place of performance of the obligation is within Japan in accordance with the law of the place selected under the contract. In the case of an action regarding a contract concluded

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between a consumer and an enterprise, which is brought by the consumer against that enterprise, the courts of Japan will have jurisdiction if the consumer is domiciled in Japan at the time when the action is brought or at the time the consumer contract is concluded.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no mandatory steps that must be taken before proceedings can be formally commenced for product liability cases.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The Code of Civil Procedure provides for the preservation of evidence, under which parties to a lawsuit can file a petition with the court, either prior to or after filing the lawsuit, to conduct an examination of the evidence including documentary evidence, testimony and the product itself.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Enquiry Prior to Filing of Action

If a person has provided notice of an action to the would-be defendant of the action in advance, that notifying person may make an enquiry in writing to the would-be defendant who received the notice, regarding particular matters that are obviously necessary for the preparation of the allegations or proof if the action is filed. When the would-be defendant has responded to the notifying person with a written response to that advance notice, under certain circumstances, such a would-be defendant may themselves make a written enquiry to the notifying person. Under the Act Partially Amending the Code of Civil Procedure, which was passed on 18 May 2022, and will take effect in or before 2026, these procedures (the notice and enquiry by the notifying person and the response and enquiry by the would-be defendant) can be conducted by electronic means.

Furthermore, upon petition by the notifying person or the would-be defendant who received the notice, the court may commission the holder of a document to send that document when it is necessary. However, this petition is not widely used. Under the Act Partially Amending the Code of Civil Procedure, the court may commission the sending of electronic records as well as documents.

Preservation of Evidence

Preservation of evidence (see 2.6 Rules for Preservation of Evidence in Product Liability Claims) is often used for the purpose of collecting documentary and other evidence.

Commissioning Sending of Document

After filing an action, the parties may petition the court to commission a person who holds a document to send the document. The holder of the document is not, however, obliged to do so. Under the Act Partially Amending the Code of Civil Procedure, electronic records may be submitted as evidence and the parties may petition the court to commission the sending of electronic records.

Order to Submit Documents

After filing an action, the parties may request that the court issue an order for the submission of a document against the opposing party or a third party who holds that document. The holder of the document may not refuse to submit the document to the court when:

- the document is in the possession of a party that has referred to it in the suit;
- the party that requested the court to issue the submission order has the right to ask the

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holder of the document to deliver it or allow it to be inspected; or

• the document has been produced in the interest of the party that requested the court to issue the submission order or regarding the legal relationships between that party and the person who holds the document.

If the document does not fall under any of the foregoing, the holder of the document may refuse to submit the document if it falls under the categories set forth by Article 220 of the Code of Civil Procedure, which include the categories of a document concerning confidential information in connection with a public officer's duties, and a document prepared exclusively for use by the holder of the document. Under the Act Partially Amending the Code of Civil Procedure, electronic records may be submitted as evidence and the parties may request that the court issue an order for the submission of an electronic record.

Request for Information Through the Bar Association

An attorney registered in Japan may request the bar association to make enquiries to public offices or public or private organisations for information necessary for their case. It is understood that those who have received such an enquiry should submit a report on the matters under enquiry, unless there are justifiable grounds not to do so.

2.8 Rules for Expert Evidence in Product Liability Cases

Expert Testimony

Upon the request of a party, the court may hear expert testimony to obtain the input of an expert, who will be designated by the court. The expert will state their opinion in writing or orally. Under the Act Partially Amending the Code of Civil Procedure mentioned in **2.7 Rules for Disclosure** of Documents in Product Liability Cases, the expert may state their opinion in an electronic file, etc.

As an exception to this, by its own authority and without the request by a party, the court may commission a government agency or public office, a foreign government agency or public office, or a corporation to give expert testimony.

Expert Report

In addition to this, a party may submit a report – prepared by an expert appointed by the party – to the court as documentary evidence. It is also possible to request the court to conduct a witness examination of the experts. If the opposing party wishes to rebut the content of an expert report, the opposing party may request that the court allows it to conduct an examination of the expert, or to submit a report prepared by their own expert.

Technical Adviser

In product liability cases, highly technical matters often become central issues. In such cases, the court may, after hearing the opinions of the parties, have a technical adviser participate in the proceedings to assist the judge in understanding technical matters (Article 92–2 of the Code of Civil Procedure).

The consent of the parties is not required for the court to have a technical adviser participate in the proceedings, but upon the petition of both parties, the court is required to revoke its determination for the participation of a technical adviser (Article 92–4 of the Code of Civil Procedure). Accordingly, it is unlikely that the court will have a technical adviser participate in the proceedings in the first place when it is clear that both parties are against it.

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The court may have a technical adviser give an explanation of the technical matters in writing or orally. When a technical adviser submits the explanation in writing, that document is sent to both parties (Article 34-3 of the Rules of Civil Procedure), and both parties may state their opinions on the explanation of the technical adviser (Article 34-5 of the Rules of Civil Procedure). The explanation of an expert is not treated as evidence, but it is pointed out that the court may base its judgment on such explanation if both parties so agree. Under the Act Partially Amending the Code of Civil Procedure mentioned in 2.7 Rules for Disclosure of Documents in Product Liability Cases, a technical adviser may give an explanation in an electronic file, etc.

2.9 Burden of Proof in Product Liability Cases

In principle, a party that benefits from the legal consequences bears the burden of proof of the facts which give rise to such legal consequence.

Tort

A plaintiff who claims compensation for damages suffered in product liability cases in a tort bears the burden of proving the facts that gave rise to the plaintiff's right to seek damages in a tort under Article 709 of the Civil Code, including:

- the violation of the plaintiff's right or legally protected interest by the defendant;
- an intentional or negligent act by the defendant;
- the occurrence of damage and the amount of damages claimed; and
- a causal relationship between the violation and the damage.

Product Liability

A plaintiff in product liability cases, who seeks the benefit from the occurrence of the legal effect of the Product Liability Act, bears the burden of proving the facts that gave rise to the plaintiff's right of claim under the Product Safety Act, including:

- the existence of a defect in the product;
- the occurrence of damage and the amount of damages claimed by the plaintiff; and
- a causal relationship between the defect and the damage.

Even if the plaintiff proves the above facts, the defendant may be relieved of liability by proving the following facts, which constitute exemptions of liability under the Product Safety Act:

- 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 (see 2.12 Defences to Product Liability Claims); or
- where the product of the defendant is used as a component or raw material of another product and the defect occurred primarily as a result of compliance with the instructions concerning the design given by the manufacturer of that other product, and where the manufacturer, etc, has not been negligent with respect to the occurrence of that defect.

Contract Law

A plaintiff who seeks compensation for loss or damage suffered in product liability cases, as a contractual liability, bears the burden of proof of the following facts, which constitute the right to claim such compensation:

- the execution of a contract;
- · a defect in the product;

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- the cause of that defect being attributable to the defendant;
- the occurrence of damage and the amount of damages claimed; and
- a causal relationship between the defect and the damage.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases must be filed with a district court or summary court as a court of first instance. As the summary courts handle civil cases that involve claims not exceeding JPY1.4 million, product liability cases which involve more than this amount must be filed with a district court.

The lay-judge system has been introduced to criminal trials in Japan, where citizens selected as judges participate in trials, but not in civil cases. As such, product liability cases are decided without the involvement of a jury and by judges only.

2.11 Appeal Mechanisms for Product Liability Claims

As with ordinary proceedings of civil cases, the proceedings of product liability cases are governed by the Code of Civil Procedure and the Rules of Civil Procedure.

Court of Second Instance

An appeal to the court of second instance must be filed within two weeks from the day on which the written judgment is served to the parties. Even after the right to appeal to the court of second instance is extinguished, a respondent may file an incidental appeal until oral arguments are concluded in the second instance. Under the Act Partially Amending the Code of Civil Procedure mentioned in 2.7 Rules for Disclosure of Documents in Product Liability Cases, the court renders its judgment based on the electronic judgment form.

Final Appeal

A final appeal in response to a high court judgment must be filed within two weeks from the day on which the written judgment is served to the parties. As with the first-level appeal, a respondent may file an incidental final appeal. A final appeal can be filed on the grounds that the judgment reflects an error in the interpretation of the constitution or that it is otherwise unconstitutional. A final appeal can also be filed on the grounds of the existence of a material violation of the proceedings under Article 312(2) of the Code of Civil Procedure. A final appeal to a high court can also be filed on the grounds of a violation of law or regulation that has clearly influenced the judgment. Under the Act Partially Amending the Code of Civil Procedure, the court renders its judgment based on the electronic judgment form.

Petition for Acceptance of Final Appeal

If the Supreme Court is the court where the final appeal should be filed, and the prior judgment contains a decision that is inconsistent with precedents rendered by the Supreme Court or involves other material matters concerning the interpretation of laws and regulations, the Supreme Court can, on petition, accept the case as the final appellate court.

2.12 Defences to Product Liability Claims

The manufacturer and other relevant parties are not liable where the product is used as a component or raw material of another product, and a defect occurred primarily as a result of compliance with the instructions concerning the design given by the manufacturer of that other product, and the manufacturer and other relevant parties

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are not negligent with respect to the occurrence of the defect.

Furthermore, the manufacturer and other relevant parties are not liable where a defect in the product could not have been discovered given the state of scientific or technical knowledge at the time when it was delivered. As the "state of scientific or technical knowledge" is generally interpreted as the highest level of scientific or technical knowledge available when the product was manufactured, it is very difficult to successfully use this defence (there is currently no precedent in which the defence has been successfully applied).

Other general defences, such as comparative negligence and extinguished prescription (time barring), are also available.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to regulatory requirements is a relevant consideration in product liability cases.

Various regulations concerning the safety of products are implemented under a variety of laws such as the CPSA, the Road Trucking Vehicle Act, the FSA, the Pharmaceutical Affairs Act and the Building Standards Act. Since the purpose and objective of these regulations is only to establish minimum safety standards, and this differs from the purpose and objective of the Product Liability Act, it is commonly understood that conformity or non-conformity with these regulations (including voluntary regulations concerning the safety of products) will be regarded as nothing more than one of the factors to be taken into account in product liability cases.

2.14 Rules for Payment of Costs in Product Liability Claims Court Costs

In principle, the court costs are borne by the losing party. In the case of a partial defeat, the court determines, at its own discretion, the burden of the court costs on each party. However, depending on the circumstances, the court can have one of the parties bear all the court costs.

Court costs include, among other things, filing fees, travel expenses, daily allowances, accommodation costs, expenses for the preparation and submission of documents and the fees of any court-designated expert witnesses. Court costs do not include costs relating to partyappointed expert witnesses, which are borne by each party, although they may be recovered as part of the damages.

Legal Costs

Court costs do not include legal costs, which are borne by each party, in principle. However, in practice, part of the prevailing party's legal costs can be awarded as part of the damages (generally 10% of the damages), for claims under the Product Liability Act and tort claims based on the Civil Code. For breach of contract claims, the legal costs cannot be included as part of the damages awarded to the prevailing party.

2.15 Available Funding in Product Liability Claims

There is no explicit provision permitting or prohibiting litigation funding. There are some provisions that relate to the legitimacy of litigation funding. Under the Trust Act, no trust is allowed to be created for the primary purpose of having another person conduct any procedural act.

Under the Attorney Act, no person may engage in the business of obtaining the rights of oth-

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ers by assignment and enforcing those rights through lawsuits, mediation, conciliation or any other method. Whether litigation funding is allowed in light of this prohibition has not been legally tested and it is not clear whether litigation funding is permitted under Japanese law. Contingency fees or "no-win, no-fee" arrangements are not prohibited, although pure contingency fees or "no-win, no-fee" arrangements are rarely used.

2.16 Existence of Class Actions, Representative Proceedings or Coordinated Proceedings in Product Liability Claims

The Act on Special Measures Concerning Civil Proceedings for the Collective Redress for Property Damage Incurred by Consumers (Act No 96 of 2013) introduced opt-in collective action. Under the Act, a collective action can only be brought by a specified qualified consumer organisation, and not by a consumer.

The Act involves a two-phased procedure.

- In the first phase, a special qualified consumer organisation files an action for a declaratory judgment on common obligations. This action seeks a declaratory judgment that a company owes monetary obligations to a considerable number of consumers, based on factual and legal causes common to these consumers (except where an individual consumer has no grounds to claim a payment of money due to circumstances specific to that consumer) where property damage has been incurred by a considerable number of consumer sin connection with consumer contracts.
- In the second phase, simplified proceedings to determine the presence or absence, and the contents, of a claim of each opt-in

consumer for the payment of money (Simple Determination Proceedings) are carried out by the district court that rendered the final judgment at first instance for a declaratory judgment on common obligations. The scope of claims that can be brought under the Act is limited to those listed therein and compensatory claims under the Product Liability Act (Act No 85 of 1994) are out of its scope. For more details, see 2.2 Standing to Bring Product Liability Claims. In addition to company (a corporation or any other association or foundation and an individual when the individual conducts the business), under the Act Partially Amending the Act on Special Measures Concerning Civil Proceedings for the Collective Redress for Property Damage Incurred by Consumers, which took effect on 1 October 2023, individuals other than companies can be named as defendants (the CAA assumes that a business supervisor or employee who was involved in tortious business practices can be a potential defendant).

2.17 Summary of Significant Recent Product Liability Claims

There have been no particularly significant product liability cases in Japan in recent years.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Mandatory Standards for Children's Toys On 19 June 2023, the Order for Enforcement of the Consumer Product Safety Act was amended to prohibit the sales of magnetic amusement products and water-absorbing synthetic resin toys, in order to address reported accidents in which children accidentally swallowed such toy.

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Amendment to the Consumer Product Safety Act and Other Related Acts

On 1 March 2024, a Cabinet Decision was made on the Bill for the Act for Partially Amending the Consumer Product Safety Act and Other Related Acts. The outline of the bill is as follows.

- Responses to the expansion of internet transactions (Consumer Safety Act, Gas Act, Electrical Appliances Act, and Liquefied Gas Act):
 - (a) in a case involving an overseas operator selling products directly to consumers in Japan without going through a domestic importer, the overseas operators should be clarified as an entity allowed to submit a notification under the four Acts related to product safety; and the overseas operator is required to appoint a responsible person (domestic supervisor) in Japan to ensure the enforcement of regulations;
 - (b) in a case in which consumer safety products, etc, sold on any digital platforms for shopping, are considered to cause harm to consumers in Japan and the seller of the products is not expected to take the necessary measures – eg, recall, the business providing the digital platforms for shopping is subject to measures, including a request to remove the consumer safety products, etc, to the digital platform providers; and
 - (c) any business that violates any laws, orders under the laws, or other provisions should have its name and other information publicised, including the names and addresses of the business that has made notification and its domestic supervisor.
- Responses to ensuring the safety of products for children – eg, toys (Consumer Safety Act):
 (a) the manufacturers and importers of spec
 - ified products for children are required

to have the products meet the technical standards stipulated by the government of Japan and indicate a warning about using the products, including the intended age range and precautions for use; and

(b) a business intending to sell used products that are specified products for children is allowed to sell the used products in Japan provided that the business has established a system or other framework for raising public awareness and ensuring the safety of the used products for consumers in Japan.

3.2 Future Policy in Product Liability and Product Safety

Security Conformity Assessment Scheme for IoT Products

On 15 March 2024, METI published the "IoT Product Security Conformity Assessment Scheme Policy Draft". This document describes the draft policy for the IoT Product Security Conformity Assessment Scheme (the "Scheme") to be established. The intent of this Scheme is to improve products' added value by assigning labels to products that have undergone conformity assessment to security requirements. This document suggests that for products procured by organisations such as government agencies, it is recommended that labelled products that meet the security level required by each organisation be selected and procured. By making this mandatory in the future, IoT product vendors will be given incentives to acquire labels. According to this document, the Scheme will initially be operated as a voluntary scheme.

Al Guideline for Businesses

In April 2024, after a call for public comments, the Ministry of Internal Affairs and Communications (MIC) and METI published the "Al Guideline for Businesses Ver. 1.0". This guideline is a non-

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binding soft law for AI business actors. By referring to this guideline, businesses can confirm the guiding principles for the safe and secure use of AI. This guideline has adopted a "risk-based approach" in which the measures shall be taken in proportion to the magnitude and probability of the risk. The government plans to continuously update this living document, taking into account international discussions.

Draft Act for Responsible Utilisation of AI

Considering the restrictions by the above Al Guideline for Businesses, which is a soft law, as insufficient, the ruling Liberal Democratic Party (LDP) is aiming for restrictions by a hard law which is legally binding. In February 2024, the LDP published an outline of a draft Basic Law for the Promotion of Responsible AI. Under the draft legislation, (i) the government shall designate "AI Foundation Model Developers" which meet the criteria of certain sizes and objectives and (ii) the designated developers shall have the obligations of safety verification, investment in cybersecurity, etc. The failure of compliance with these obligations may lead to criminal penalties.

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