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Product Liability & Safety 2021

Japan
Law & Practice

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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 subject to the CPSA generally. 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 to prevent the lives or health of general consumers for the specified products 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 inspected (and kept the inspection record of) the product, 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 to the Secretary General of the Consumer Affairs Agency (CAA), within ten days, certain information related to the product and the accident. 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 the increase of such danger, to consumers. For non-serious product accidents, 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, such as hot

water heaters and bathroom dryers, 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, it must conduct an inspection on 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 shall 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 the occurrence of 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 them, without affixing the PSC mark under the CPSA.

Certain specific products are exclusively regulated by other regulators. For examples, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) regulates automobiles. The Ministry of Health, Labour and Welfare (MHLW) regulates medical products, cosmetics and medical devices. The MHLW also regulates food, food additives and cleaning agents. These regulators have the power to establish technical or other relevant standards. If certain conditions

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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, in cases where product incidents have originated with those consumer products, investigate the cause of these product incidents, and if the person finds doing this necessary to prevent the occurrence and increase of safety hazards, they must endeavour to recall the consumer products or otherwise take measures to prevent the occurrence and increase of safety hazards.

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, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding foreign

manufacturing, must, when they learn of the occurrence or spread of hazards in health and hygiene, suspected to be caused by using the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products that they have manufactured and sold or received a certain approval for, 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 is not, or is likely to not be, in conformity 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 to MLIT certain matters specified in the Act. A recent update to this is that, under the amended Road Trucking Vehicle Act, which came into effect on 1 April 2020, automated driving devices, as defined by Item 2 of Article 41, which are used in autonomous vehicles, have been added to the equipment covered under the necessary safety standards.

Food standards

Under the FSA, if a food business operator find it necessary to prevent food sanitation hazards resulting from the sale of food, etc, it must endeavour to take any necessary measures appropriately and immediately, such as the provision of a certain record to the relevant state or prefectures and the disposal of the food for sale that had 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, quasi-pharmaceutical 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 accident that has originated with a consumer product that it manufactures or imports, it must report to the CAA certain information related to the product and the accident. 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 accident has occurred.

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

The FSA, which was amended on 13 June 2018 and came into force on 1 June 2021, provides a reporting obligation for food recalls. Under the amended FSA, if a business operator recalls the food, additives, apparatus, or containers and packaging which are or are expected to be in violation of the FSA, it must notify the prefectural governor of the initiation of the progress of the recall without delay, except in cases where the MHLW or a prefectural governor order the business operator to recall them 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 make a report to the CAA or has made a false report to the CAA in violation of the obligations explained above, in **1.4 Obligations to Notify Regulatory Authorities**, if the competent minister finds it necessary for securing the safety of the consumer products manufactured or imported by that manufacturer or importer, the competent minister may order the manufacturer or importer to develop a system necessary for collecting information on serious product accidents 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 subject the manufacturer or importer and their representative to 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.

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 demandant's right or legally protected interest by the demandee;
- an intentional or negligent act of the demandee;
- 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 by 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 demandee corresponding to:
 - (a) any person who manufactured, processed, or imported the product as a business;
 - (b) any person who indicates their name, trade name, trademark or other indication (hereinafter referred to as "representation 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 a) and b), 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, (a), (b) and (c) are collectively referred to as "manufacturer, etc").

- Delivery of the product which shall be movable by the demandee.
- Damage being caused by the product which, at the time of delivery by the demandee, was manufactured or processed and shall be movable.
- A defect in the product at the time of delivery by the demandee.
- Infringement of the demandant'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;
- a defect in the product;
- the cause of that defect being attributable to the defendant;
- the occurrence of damage; and
- a causal relationship between the defect and the damage.

Until the end of March 2020, in special cases where the buyer and the seller engaged in a transaction focusing on the individuality of the specific products (eg, a transactions of used products) or where the buyer acknowledged the existence of a defect and permitted the delivery of defective products as the performance of the seller's obligation, a different rule applied (eg, the scope of damages to be compensated became different). However, the Civil Code was amended, which amendment became effective on 1 April 2020, and by this amendment, the rules were unified and the rule for the above special cases was abolished.

2.2 Standing to Bring Product Liability Claims

Individual Standing

Tort – a person whose right or legally protected interest has been violated has the standing to bring the claims for product liability listed in **2.1 Product Liability Causes of Action and Sources of Law**.

Product Liability Act – (i) the person who has been injured because of the defect, or (ii) the person whose property, excluding the defective product itself, has been damaged because of the defect has the standing to bring the above claims for product liability.

Contract law – the buyer has the standing to bring the above claims for product liability.

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:

- 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; and
- a claim for damages based on a tort (limited to a claim based on the provisions of the Civil Code).

However, the action may not be filed when the damage incurred is any of the following:

- (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 dis-

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- position 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.

Since the damage which is 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 shall be extinguished by the completion of prescription if the victim, or their legal representative, does not exercise the right within three years from the time when they realised the damages and the identity of the perpetrator. In addition, the right shall 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 shall 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 shall be extinguished when ten years have elapsed from the time when the manufacturer, etc, delivered the product. However, this ten-year period shall 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 defect within one year from the time the buyer became aware of the defect, the buyer cannot make a claim against the seller unless the seller was aware of the existence of the defect at the time of delivery or was not aware of the existence of the defect through gross negligence. Even if the notice is given within one year, the right to claim shall 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 the claim for damages caused by injuries of life or body, this period shall be extended for 20 years) from the time it becomes exercisable.

2.4 Jurisdictional Requirements for Product Liability Claims

The courts of Japan shall 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 other 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 business office or other office is unknown. In addition, the courts of Japan shall have

jurisdiction in the following cases depending on the grounds of the claim.

Tort

The courts of Japan will have jurisdiction if the place where the wrongful act was committed or the place where the consequences occurred are in Japan (excluding the case in which the consequence of the wrongful act committed in a foreign country have occurred within Japan but it would not ordinarily have been possible to forecast that such consequences could have occurred 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 between a consumer and an enterprise, which is brought by the consumer against that enterprise, the courts of Japan shall 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 commenced formally 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, who has received advance notice, has responded to the said 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 regarding particulars that will clearly be necessary for preparing allegations or proof if the action is filed.

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 (including any other objects prepared for the purpose of indicating information) to send that document when it is found that the petitioner will have difficulty in

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obtaining that document by themselves and where that document will be clearly necessary for proving the facts to be shown in the action intended to be filed. The holder of the document does not need to be the notifying person or the would-be defendant here. However, this petition is not widely used.

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 the person who holds a document to send the document. The holder of the document is not, however, obliged to do so.

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 possessed by a party who has referred to it in the suit;
- the party that requested the court to issue the submission order has the right to request the 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 the foregoing, the holder of the document may refuse to submit the document when the document falls under the categories set forth by Article 220 of the Code of

Civil Procedure, which includes 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.

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 inquired matters, 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 expertise of an expert, who shall be designated by the court. The expert shall state their opinion in writing or orally. When the expert is to state their opinion orally, the court may ask questions to the expert, followed by questions from the parties.

As an exception to the foregoing, 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

Apart from the foregoing, a party may submit an expert report, prepared by an expert that that party appointed, 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 the court to conduct an examination

against the expert, or submit another expert report prepared by their expert.

Technical Advisor

The technical advisor system does not directly relate to expert evidence as this system does not necessarily aim at obtaining expert evidence. However, the technical advisor system is worth noting here because a technical advisor is expected to provide an explanation of technical matters to the court, which may affect the judgement.

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

While the court shall hear the opinion of the parties about the involvement of the technical advisors in advance, the consent of the parties is not required for the court to have a technical advisor participate in the proceedings (the technical advisors may not participate on a date when the court attempts to arrange a settlement without the consent of the parties, however). Having said that, upon the petition of both parties, the court is required to revoke its determination for the participation of a technical advisor (Article 92–4 of the Code of Civil Procedure). Accordingly, it is unlikely that the court will have a technical advisor participate in the proceedings in the first place when it is clear that the both parties are against it.

The court may have a technical advisor give an explanation on the technical matters in writing or orally. When a technical advisor 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 a technical advisor (Article 34-5 of the Rules of Civil Procedure). The explanation of an expert is not treated as an evidence, but it is pointed out that the court may base its judgment on such explanation if both parties so agree. Therefore, a party should carefully examine the content of the explanation given by a technical advisor to see if it contains erroneous or inappropriate descriptions.

In addition, the court may, with the consent of the parties, allow a technical advisor to put questions to witnesses, the parties, or the expert (Article 92–2 (2) of the Code of Civil Procedure). The answers to such questions by a witness, the parties, or the expert will constitute a part of the evidence and a basis for the judgment.

2.9 Burden of Proof in Product Liability Cases

In principle, a party who 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 damage suffered in product liability cases in tort bears the burden of proving the facts that give rise to the plaintiff's right to seek damages in 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 of the defendant;
- the occurrence of damage and the amount of damage 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 give 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 which a plaintiff claims; 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 that 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; or
- where the product of the defendant is used as a component or raw material of another product, the defect occurred primarily because of the compliance with the instructions concerning the design given by the manufacturer of that other product, and that the manufacturer, etc, is not negligent with respect to the occurrence of that defect.

Contractual

A plaintiff who seeks compensation for the 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;
- the cause of that defect being attributable to the defendant;
- the occurrence of damage and the amount of the damage claimed; and
- a causal relationship between the defect and the damage.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases shall be filed with a district court or summary court as a court of first instance. As the summary courts are to handle civil cases that involve claims not exceeding JPY1.4 million, product liability cases which involve more than this amount shall 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 to 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 can be filed with the high courts in response to a final judgment made by a district court as the court of first instance, and with the district courts in response to a final judgment made by a summary court. An appeal to the court of second instance shall 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, an appellee may file an incidental appeal until oral arguments are concluded in the second instance.

Final Appeal

A final appeal can be filed with the Supreme Court in response to a final judgment made by a high court as the court of second instance, and with a high court in response to a final judgment made by a district court as the court of second

instance. A final appeal in response to a high court's judgment shall be filed within two weeks from the day on which the written judgment is served to the parties. As with the first level appeal, an appellee 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.

Petition for Acceptance of Final Appeal

If the Supreme Court is the court with which 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 a 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 because of compliance with the instructions concerning the design given by the manufacturer of that other product, and the manufacturer and other relevant parties 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 differ from the purpose and objective of the Product Liability Act, it is commonly understood that conformity or non-conformity with these regulations will be regarded as nothing more than one of the factors to be taken into account in product liability cases. Furthermore, with respect to voluntary regulations concerning the safety of products, it is also commonly understood that conformity or non-conformity with such regulations will similarly be regarded as merely one of the factors to be taken into account in determining whether a product is defective.

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

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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 party-appointed expert witnesses and such costs are borne by each party, although they may be recovered as part of damages.

Legal Costs

Court costs do not include legal costs and these are borne by each party, in principle. However, in practice, part (generally 10% of damages) of the prevailing party's legal costs can be awarded as part 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 other than an attorney or a legal professional corporation may, for the purpose of obtaining compensation, engage in the business of:

- providing legal advice or representation;
- handling arbitration matters;
- aiding in conciliation;
- providing other legal services in connection with lawsuits, non-contentious cases, or objections;

- requests for re-examination, appeals and other petitions against administrative agencies;
- other general legal services; or
- acting as an intermediary in such matters.

Furthermore, under the Attorney Act, no person may engage in the business of obtaining the rights of others 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 Co-ordinated 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) came into effect on 1 October 2016. It introduced opt-in type 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 business operator 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 is incurred

by considerable number of consumers in 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. On 6 March 2020, the Tokyo District Court rendered a declaratory judgment that a defendant owed monetary obligations to a considerable number of consumers in the first lawsuits seeking a declaratory judgment on common obligations, which became final and binding. On 10 July 2020, the Tokyo District Court made an order of commencement of Simple Determination Proceedings. 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.**

2.17 Summary of Significant Recent Product Liability Claims

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

3. RECENT POLICY CHANGES AND OUTLOOK

3.1 Trends in Product Liability and Product Safety Policy

Product Recall

The METI has been paying close attention to, and collecting information on, product recalls implemented in other jurisdictions. The METI has recently become more active in encouraging business operators to implement product recalls in Japan at the same time as, or closely

co-ordinated with, those implemented in other jurisdictions. Business operators should realise afresh the importance of well-coordinated implementation of worldwide product recalls.

Internet of Things Devices

On 28 April 2021, the METI issued a guideline on how to ensure the safety of internet of things (IoT) devices such as electrical appliances and materials or gas equipment. This guideline was issued in response to the spread of IoT devices and the related increase in the risk of a product incident caused by a cyber-attack or due to inadequate security protocols.

The main points required by the guideline are as follows.

- When designing IoT devices:
 - (a) the safety function and the communication channel of IoT devices should, as much as possible, be separated through physical means such as fuses to ensure safety even in the event of a communication interruption or cyber-attack;
 - (b) functions that can prevent or reduce damage caused by overconfidence or erroneous operation of remote operators and damage to users near remotely operated devices should be incorporated; and
 - (c) cybersecurity measures to download software properly should be incorporated.
- After shipping IoT devices:
 - (a) separation of safety function and communication channel of IoT devices should be maintained;
 - (b) software that can ensure compliance with safety requirements, even during and after installation of software, should be provided;
 - (c) devices whose software cannot be updated should be separated and replaced;

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- (d) the authenticity, integrity, etc, of IoT devices related to safety function when updating software must be ensured; and
- (e) requirements that encourage active action for remote operators and users should be clarified.

Electronic Filing and Abolition of Seal

On 17 February 2020, the METI newly commenced electronic filing for some procedures under 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 to promote operational efficiency. Covered procedures are:

- notification of commencement of business of manufacturing or importing;
- notification of a change of the notified particulars of the business of manufacturing or importing;
- notification of permanent cessation of business; and
- notification of a trademark, which had previously been only on a paper basis.

It is expected that the commencement of electronic filing will reduce costs associated with the correction of paperwork and visits and inquiries from relevant authorities.

In addition, on 28 December 2021, the METI abolished provisions that require a seal in some application procedure forms under 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.

Pharmaceuticals and Medical Devices

Under the amended Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, which

will come into effect on 1 August 2021, an administrative surcharge of an amount equivalent to 4.5% of the sales amount of pharmaceuticals, etc, shall be imposed on a person who advertises, describes or circulates false or exaggerated statements regarding the name, manufacturing process, efficacy and effects or performance of pharmaceuticals, etc.

Furthermore, under the amended Act, precautions and explanations for pharmaceuticals (excluding pharmaceuticals requiring guidance, and over-the-counter pharmaceuticals) shall be provided electronically.

3.2 Future Policy in Product Liability and Product Safety

Artificial Intelligence

On 15 January 2021, the [AI Governance in Japan Ver. 1.0 INTERIM REPORT](#) was disclosed by the Expert Group on Architecture for AI Principles to be Practiced. This interim report discusses the AI governance regime that would be ideal in Japan at the moment, taking the trends in AI governance in Japan and around the world into account.

In this report, AI governance is defined as “design and operation of technological, organizational, and social systems by stakeholders for the purpose of managing risks posed by the use of AI at levels acceptable to stakeholders and maximizing their positive impact.”

Japan has adopted seven principles in “Social Principles of Human-centric AI”, which was disclosed by the Integrated Innovation Strategy Promotion Council in March 2019:

- human-centricity;
- education/literacy;
- privacy protection;
- ensuring security;
- fair competition;

- fairness, accountability, and transparency; and
- innovation.

From the perspective of balancing respect for these AI principles and the promotion of innovation, the interim report concerning AI governance aims to enforce AI governance mainly through soft law. In other words, the interim report suggests setting an intermediate rule such as a guideline, which is not operated in a legally binding manner like regulations.

However, in certain areas, such as the automotive and healthcare sectors, the interim report indicates that it is deemed desirable for the organisations responsible for the specific industry laws to be involved in rule-making, considering the existing regulatory regime and design philosophy rather than the perspective of the information technology.

Internet Transaction

Business operators that provide a market for transactions such as online shopping malls, internet auctions and online flea markets to other business operators and consumers (hereinafter referred to as “mall operators, etc”), are not subject to the regulations of the four laws related to product safety (listed in **3.3 Crisis Management/Situations/Business Disruption and Product Liability and Product Safety Laws**) unless they are manufacturers, importers and retailers. However, with the expansion of the scale of e-commerce, both the number of violations of the four product safety laws by internet sales business operators and the proportion of serious product accidents caused by products purchased via the internet are increasing.

Therefore, in June 2020, the METI compiled a [proposal](#) on product safety in online transactions. This proposal describes efforts, co-oper-

ation and collaboration between the government and mall operators, etc to ensure the safety of products sold at online shopping malls, etc.

In response to the proposal, the METI issued requests to specific mall operators, etc to confirm the presence of labelling as stipulated in the four product safety laws and not to allow internet sales business operators to sell products without labelling, etc. Also, the METI has established a co-operative system with eight mall operators regarding product safety and response to suspected violations.

In addition, to deal with consumer troubles, such as the distribution of harmful products through internet transactions and the difficulty of resolving disputes due to the inability to identify distributors, the CAA is proceeding with the examination of a new bill regarding transactional digital platforms, where transactions are conducted between business operators and consumers (eg, online malls) regardless of the scale or subject of the transaction. Under the new bill, the transactional-digital-platform providers (such as mall operators, etc) are requested to take the necessary measures to prevent regulatory violations by sales-business operators and to remedy consumer damages. For example:

- the CAA may request transactional-digital-platform providers to suspend sales or other necessary measures when there is a problem with labelling regarding safety; and
- consumers who use the transactional digital platform can request disclosure of the necessary information of the sales business operators when making claims for damages.

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3.3 Crisis Management/Situations/ Business Disruption and Product Liability and Product Safety Laws

On 7 April 2020, the Japanese government declared a state of emergency for the COVID-19 pandemic.

In response to this, the METI decided that it would, in principle, refuse to receive in person notification under the four laws related to product safety:

- the CPSA;
- 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.

The notifications under these laws must be submitted by mail, email or on the prescribed website. In addition, the METI does not accept face-to-face inquiries regarding product safety in principal. Therefore, it is recommended that the inquiries be made by e-mail or telephone.

Furthermore, following the declaration of the state of emergency issued by the government on 7 April 2020, some courts limited their services. However, although the Japanese government declared a third state of emergency on 23 April 2021, in principal, courts are operating as usual.

In addition, the Pharmaceuticals and Medical Devices Agency, which conducts scientific reviews of marketing authorisation applications for pharmaceuticals and medical devices, has started priority review for pharmaceuticals, medical devices, in-vitro diagnostics and regenerative medical products targeting COVID-19 infections and related symptoms.

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Nagashima Ohno & Tsunematsu is the first integrated full-service law firm in Japan, and is one of the foremost providers of international and commercial legal services based in Tokyo. The firm's overseas network includes offices in New York, Singapore, Bangkok, Ho Chi Minh City, Hanoi and Shanghai; associated local law firms in Jakarta and Beijing, where its lawyers are on-site; and collaborative relationships with prominent local law firms throughout Asia and the rest of the world. The firm has extensive corporate and litigation capabilities

spanning key commercial areas such as antitrust, intellectual property, product liability and safety, labour, and taxation, and is known for path-breaking domestic and cross-border risk management/corporate governance cases and large-scale corporate reorganisations. The approximately 540 lawyers of the firm, including over 40 experienced foreign attorneys from various jurisdictions, work together in customised teams to provide clients with the expertise and experience specifically tailored to each client matter.

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