

Product regulation, safety and recall Q&A: Japan

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Country Q&A | Law stated as at 30-Jun-2019 | Japan

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Japan-specific information concerning product regulation, safety and recall issues.

This Q&A provides country-specific commentary on [Product regulation, safety and recall: Cross-border overview](#), and forms part of [Cross-border commercial transactions](#).

Industry-specific regulation

1. Is there any industry-specific regulation as regards product safety?

There are several pieces of legislation governing product safety in Japan, including:

- Consumer Product Safety Act (CPSA).
- Electrical Appliances and Materials Safety Act.
- Gas Business Act.
- Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas.

- Household Goods Quality Labelling Act.
- Act on Control of Household Goods Containing Harmful Substances.
- Food Sanitation Act.
- Poisonous and Deleterious Substances Control Act.
- Industrial Standardisation Act (JIS Mark Labelling Act), and so on.

In addition, separate laws apply to:

- Ships.
- Road transport vehicles.
- Cosmetics.
- Quasi-drugs.
- Pharmaceutical products and medical equipment.

These types of product are not included in, or are excluded from, the definition of consumer products regulated by the CPSA. Consumer products are defined as products to be supplied mainly for use by general consumers for their routine everyday activities (*Article 2, paragraph 2, CPSA*).

Consumer product legislation

2. How is general product safety regulated in the national jurisdiction? Does national law impose any product safety obligations over and above those contained in the 2001 General Product Safety Directive?

The 2001 General Product Safety (EU) Directive does not apply in Japan.

Consumer products are further categorised by the CPSA (*Article 2*) based on the potential risk they may present:

- Specified Products are consumer products deemed to be highly likely to cause danger, in particular to the lives or bodies of general consumers, because of these products' structure, material and usage, as detailed by applicable regulations (for example, pressure cookers, helmets for motor vehicles, certain water heaters and bath boilers).
- Special Specified Products are Specified Products for which manufacturers or importers may have insufficiently achieved the quality level necessary to prevent the occurrence of dangers to the lives or bodies of general consumers, as detailed by applicable regulations (for example, cribs, portable laser equipment).

A person engaging in the manufacture or import of Specified Products must notify the relevant Minister of certain matters in accordance with the classification of specified products provided by Ministerial Ordinance (name and address, legal representative, classification of the type of specified product, name and address of the factory or workplace manufacturing the specified product and measures taken to compensate victims in the event the lives or bodies of general consumers are harmed due to a defect in a specified product).

In practice, manufacturers and importers of Specified Products must submit a Notice of Manufacture/Import of Specified Products to the competent Regional Bureau of Economy, Trade and Industry (or the Ministry of Economy, Trade and Industry (METI) in case of multiple business locations). Specified Products must comply with technical requirements established for each product by Ministerial Ordinance (self-confirmation of conformity). The sale of Specified Products without the safety mark showing compliance with the prescribed standards is prohibited. Restrictions apply to the sale display, and labelling of Specified Products.

In addition to the above formalities, Special Specified Products must also undergo a conformity inspection (*Article 12, CPSA*). Testing is carried out by a third-party assessment agency.

A further category defined as Specified Maintenance Products refers to certain consumer products that are deemed highly likely to cause serious danger to the lives or bodies of general consumers because of their lack of reliable safety due to deterioration caused by long-term use (age-related deterioration), and which are specified by Cabinet Order as being in need of improvement through proper maintenance. Specified Maintenance Products are subject to notification requirements roughly similar to those applied to Specified Products.

Specified Maintenance Products include:

- Hot water heaters (petroleum).
- Bathtub water heating units.
- Built-in dishwashers (electric).
- Bathroom dryers.
- Kitchen water heating unit indoor installations (gas), and so on.

Under the CPSA a "specified manufacturer" must determine the following matters in accordance with the requirements provided by Ordinance of the relevant ministry with respect to the Specified Maintenance Products the manufacturer has manufactured or imported (this does not apply to products intended for export):

- The standard period of use without any safety issues, if used under standard conditions of use.
- The period of inspection necessary to prevent the occurrence of injury due to age-related deterioration once the design standard use period expires.

(*Article 32-3, CPSA.*)

Business operators must also provide information on dangers, obsolescence and deterioration, inspection and maintenance to acquirers of Specified Maintenance Products upon delivery of the product.

The Long-term use Consumer Product Safety Indication System covers electrical appliances. Under the Electrical Appliances and Materials Safety Act, manufacturers and importers of electrical appliances must submit a notice to the competent Regional Bureau of Economy, Trade and Industry (listing contact details, product type as per METI classification, information on manufacturing site location and so on).

Certain electric devices prone to accidents due to ageing must bear warning labels. Products covered include fans, air-conditioners, certain TV sets and washing machines.

The SG (Safety Good) mark system administered by the Consumer Product Safety Association (*SeihinAnzenKyoukai*) is a voluntary certification system. To bear the SG-Mark, a company must make sure that its products conform to the safety specifications and requirements promulgated by the Association. The SG-Mark covers a large number of products, including:

- Products for children and for the elderly.
- Furniture.
- Kitchen utensils.
- Sporting and leisure goods.
- A consumer compensation scheme is funded by the Association through (among other things) the sale of SG-Mark stickers which are attached to all products that meet the SG-Mark standard. Adherence to the SG-Mark standards is voluntary, but for many products, commercial pressures compel adherence.

3. How is product safety legislation enforced in the national jurisdiction? What powers do the enforcement authorities have?

When the Minister of Economy, Trade and Industry becomes aware of the fact that Specified Products manufactured or imported by a business operator fail to conform to technical requirements, the Minister may order the notifying business operator (see [Question 2](#) for notification obligations) to take the necessary measures to improve the methods of manufacture, import and inspection of the Specified Products, or any other business methods (*Order for Improvement, Article 14 of CPSA*). In addition, if the Specified Products manufactured or imported by the notifying business operator are likely to cause danger to lives or bodies of general consumers because they fail to conform to the applicable technical requirements, the Minister of Economy may prohibit labelling by such notifying business operator for a period of not more than one year (*Prohibition of Labelling, Article 15 of CPSA*).

The Minister of Economy, Trade and Industry may order necessary measures, such as product recall, in the event that:

- The business operator who manufactures, imports or sells Specified Products sells regulated products without labelling them, or the notifying business operator manufactures, imports or sells Specified Products covered by such notification which do not conform to technical requirements.
- Serious product accidents have occurred due to defects in other consumer products, or the lives or bodies of general consumers have been seriously endangered, or the occurrence of such danger is considered to be imminent.

(*Hazard Prevention Order, Articles 32 and 39, CPSA*.)

If the Minister of Economy, Trade and Industry finds that a business operator who manufactures or imports Specified Maintenance Products is in breach of its obligations with respect of the establishment of an inspection period, the running of an inspection with regard to the Specified Maintenance Products it has manufactured or imported, or the labelling of the products, it may order that all necessary measures be taken to correct such violation (*Order of Improvement, Article 32-16, CPSA*).

If a person engaging in the manufacture or import of Consumer Products fails to submit a report on serious product accidents, or has made a false report, the Prime Minister may order such person to develop an adequate system for the collection of information on serious product accidents and for the proper management or communication of said information (*Order to Develop System, Article 37, CPSA*).

4. What sanctions are imposed under national law for breach of product safety legislation?

In the event of a violation of the prohibition on labelling (see [Question 3](#)), sale of Specified Products with labelling within the prohibition period, or a breach of a Hazard Prevention Order, individuals are liable to imprisonment with work for not more than one year, or a fine of not more than JPY1 million, or both, while legal entities are liable to a fine of not more than JPY100 million (*Article 58, paragraphs 2, 4 and Article 60, paragraph 1, CPSA*).

In the event of a violation of the restrictions on sale and labelling of Specified Products, an Order of Improvement or an Order to Develop the System, individuals in breach are liable to imprisonment with work for not more than one year, or a fine of not more than JPY1 million, or both, while legal entities are liable to a fine of not more than JPY1 million (*Article 58, paragraphs 1, 3 and 5, and Article 60, paragraph 2, CPSA*). Other provisions for the violation of the same Act are provided by Chapter 5 of CPSA.

5. Does national law imply any terms into a contract in relation to product safety? Can they be excluded?

Although more directly connected to tort than breach of contract, reference can be made to the Product Liability Act (PLA).

Under the PLA, a plaintiff may seek compensation for damages caused by a defective product. The plaintiff must prove that the product was defective, and that the defect caused the damage. Defects include:

- A design defect, arising when the design of the product does not adequately consider safety issues relating to use, handling or storage.

- A warning defect, when the manufacturer (broadly defined as including an importer, distributor and so on) fails to properly warn consumers of those dangers associated with the product which are not easily predictable or obvious and does not properly instruct the consumer on how to use, handle or store the product to prevent an accident.
- A manufacturing defect, when a product is improperly manufactured.

Even if manufacturers cannot exclude liability for personal injuries that may result from defective products, they can contractually exclude or limit their liability towards business parties other than consumers.

6. Do product safety regulations apply equally to imported products?

Yes, the CPSA applies regardless of whether the product is domestic or imported.

Packaging

7. Does national law regulate the safety of packaging?

The CPSA does not include provisions on the safety of packaging.

By contrast, there are obligations under the Act on the Promotion of Effective Utilisation of Resources, from the perspective of promoting the use of recycled materials related to certain specified labelled products, such as the obligation to affix an identification mark on containers and packaging (*Article 24, Act on the Promotion of Effective Utilisation of Resources*). The relevant Minister can take measures against a non-compliant business operator (starting progressively from a request to correct the defect, publication of the infringement and so on) (*Article 25, Act on the Promotion of Effective Utilisation of Resources*).

There are also specifications and standards under the Food Sanitation Act for the safety of appliances, containers and packaging used with, or for, food (*Food Sanitation Act, Article 18, "Specifications and Standards for Food, Food Additives" (Notice of the Ministry of Health, Labour and Welfare, No. 370)*).

Product recall

8. What provision does national law make for product recall? Is it mandatory or voluntary?

See [Question 3](#).

The PLA does not contain provisions that would force a manufacturer (including an importer, distributor and so on) to recall or repair a product found to be defective in a product liability lawsuit. However, the CPSA vests powers in the competent Minister (for the majority of consumer products, the minister with regulatory oversight is the Minister of Economy, Trade and Industry) to investigate complaints relating to particular products, compel manufacturers and importers to disclose information relating to allegedly unsafe products, and order product recalls or other remedial actions if the minister finds it necessary to prevent the occurrence or increase of a danger.

Under the CPSA, a person engaging in the manufacture or import of consumer products is legally obliged to investigate the cause of product accidents, and if they find it necessary to prevent the occurrence and increase of a danger, they must endeavor to recall said consumer products or otherwise take preventive action (*Article 38*). In the event of a serious product accident, or where serious danger has occurred to the lives or bodies of general consumers or the danger is considered to be imminent, the competent Minister may order the person engaging in the manufacture or import of said consumer products to recall the consumer products or otherwise take measures to prevent occurrence (*Article 39*).

Separate statutory rules apply to road transport vehicles, pharmaceutical products and other products which are not treated as Consumer Products regulated by the CPSA (see [Question 1](#)), for example, Article 63-2 of the Road Transport Vehicle Act; Article 68-9 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics.

The law amending the Food Sanitation Act (FSA) promulgated in 2018 includes two major amendments relating to product recalls:

- Collection of information on health hazards caused by food containing specific substances (Article 8 of the amended FSA). To prevent health hazards, business operators dealing with food products containing specific substances requiring special precautions must report health problems caused or likely to be caused by such a product to the prefectural authorities. The relevant substances include alkaloid and hormone-like substances.
- Reporting system for food recalls (Article 58 of the amended FSA). When a business operator voluntarily recalls food products in breach of the FSA, it must report such recall to a prefectural governor. Reported recall information will be posted on the MHLW's website.

These amendments will be effective within two and three years respectively (the date will be set by a Cabinet Order).

9. Are there any sanctions for failure to initiate a product recall exercise?

See [Question 4](#) and [Question 8](#).

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