



Product Recall

in 28 jurisdictions worldwide

2012

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Contributing editor: Mark Tyler
Shook, Hardy & Bacon
International LLP

Business development managers

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Marketing assistants

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Marketing Manager (subscriptions)

Rachel Nurse
Subscriptions@
GettingTheDealThrough.com

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Jonathan Cowie

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Jonathan Allen

Subeditors

Davet Hyland
Caroline Rawson
Sarah Morgan

Editor-in-chief

Callum Campbell

Publisher

Richard Davey

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Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
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Japan

Naoki Iguchi and Makoto Terazaki

Anderson Mōri & Tomotsune

General product obligations

- 1 What are the basic laws governing the safety requirements that products must meet?

The Consumer Products Safety Act (Act No. 31 of 1973, as amended) (the CPSA) generally applies to all kinds of products sold in Japan and accidents caused by products within Japan. Further to the CPSA, some specific products are also regulated in part by the following laws:

- electrical appliances by the Electrical Appliances and Materials Safety Act (Act No. 234 of 1961, as amended);
- gas appliances by the Gas Business Act (Act No. 51 of 1954, as amended); and
- combustion appliances (eg, gas stoves) by the Act on the Security and Transaction of Liquefied Petroleum Gas (Act No. 149 of 1967, as amended).

Other products, however, are regulated exclusively by the following laws instead of the CPSA:

- automobiles by the Road Tracking Vehicle Act (Act No. 185 of 1951, as amended) (the RTVA);
- medicines, cosmetics, and medical appliances by the Pharmaceutical Affairs Act (Act No. 145 of 1960, as amended) (the PAA); and
- food, additives and the like by the Food Sanitation Act (Act No. 233 of 1947, as amended) (the FSA).

With respect to the outline of the CPSA described in English, please see the document on the website of the Ministry of Economy, Trade and Industry (the METI) (www.meti.go.jp/policy/consumer/seian/shouan/contents/outline_psc_act090331e.pdf)

- 2 What requirements exist for the traceability of products to facilitate recalls?

If the safety level of a consumer product may deteriorate after a period of use, the CPSA requires the manufacturers and importers (hereinafter, ‘manufacturers’) of such product to prepare a list of the product holders based on the information provided by such holders (CPSA article 32-11(1)).

Under the PAA, authorised holders of products composed of biological products should keep the records of their assignees (PAA article 68-9(1)).

The FSA requires that food business operators endeavour to keep records of all necessary information, such as the identities of buyers (FSA article 3(2)). Although the laws do not link such lists and records with the product recall programme, product traceability supported by such systems is seen to be helpful in the actual recall process.

- 3 What penalties may be imposed for non-compliance with these laws?

All laws have penalty provisions applicable to non-compliance with the law. Under the FSA, a person producing food or additives that do not conform to the standards risks imprisonment with (or without) work for a period not exceeding two years or a fine not exceeding ¥2 million, or both (FSA article 72).

Under the CPSA, a person selling ‘designated products’ (see question 19) that do not meet the requirements stipulated by law risks imprisonment with (or without) work for not more than one year or a fine of not more than ¥1 million, or both (CPSA article 58(1)).

In addition, publication of a product recall is in itself a type of ‘penalty’, as such publication usually includes the name of the manufacturer of the product, and such publication can damage the manufacturer’s reputation.

Reporting requirements for defective products

- 4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

If a manufacturer is made aware of any serious accident caused by a product, they are required by the CPSA article 35(1) to report it to the relevant authority. It is assumed, however, that retailers will report such knowledge to the manufacturers or importers of the product. Recently, the METI has provided an online version of the reporting system on its website (www.meti.go.jp/product_safety/form/index.html) (Japanese only). If the accident caused by a product is not serious or it is clear that the accident is caused by something other than a product, it should be reported to the National Institute of Technology and Evaluation (the NITE, one of the independent administrative agencies), an online version of whose reporting system is available on its website (www.nite.go.jp/jiko/nite_yoshiki/nite_yoshiki1.doc) (Japanese only).

Furthermore, under article 63-3(1) of the RTVA, automobile manufacturers must notify the Ministry of Land, Infrastructure and Transportation (the MLIT) of any defects discovered in the design or manufacturing process. This notification must be made before any necessary remedial measures are taken.

The PAA requires manufacturers of medicines, cosmetics and medical devices to notify the Minister of Health, Labour and Welfare (the MHLW) if they initiate a product recall or are made aware of any adverse effects caused by such medical products or devices (PAA articles 77-4-2 to 3).

The FSA requests food business operators to endeavour to prevent public health hazards by taking any necessary measures appropriately and immediately, such as providing central or local government with the records of retailers they have supplied (FSA article 3(3)).

- 5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Under the Ordinance for Enforcement of the CPSA (Joint Ordinance of the Ministry of International Trade and Industry (the MITI, predecessor of the METI) and the Ministry of Agriculture, Fishery and Forestry (the MAFF), No. 1 of 1974 (CPSA Ordinance)), the reporting of a serious accident caused by a product required by the CPSA article 35 should be submitted to the relevant authority, within 10 days of the date when the reporter came to know of such accident, in the prescribed form described in question 7 (CPSA Ordinance article 3).

The Ordinance for Enforcement of the PAA (Ordinance of the Ministry of Welfare (the MOW, predecessor of the MHLW), No.1 of 1961 (the PAA Ordinance)) requires a manufacturer to report to the MHLW as soon as it initiates a product recall programme (PAA Ordinance article 254).

- 6 To which authority should notification be sent? Does this vary according to the product in question?

The relevant authority to which the notification should be sent depends on the product as follows:

- consumer products, electric appliances, gas appliances and combustion appliances to the Consumer Affairs Agency (the CAA);
- medical products, cosmetics and medical devices to the MHLW;
- automobiles to the MLIT; and
- food, additives and the like to the CAA.

In addition to notifying the relevant authority, as required by law, it is highly recommended that other relevant authorities and local governments are notified.

- 7 What product information and other data should be provided in the notification to the competent authority?

Article 3 of the CPSA Ordinance, which refers to the CPSA article 35(1), requests that the notification be made in the prescribed form (Form I) and contain the following information:

- name of the product, brand, number of models and the country of production;
- details of human injury;
- situation of the accident (ie, facts, causes, measures taken to prevent future accidents, contact person or organisation that conducted the investigation and the holder of the products);
- date and reason a supplier reported the accident;
- place of the accident;
- period and total volume of production, imports and distribution;
- company name and address of the product manufacturer or importer; and
- industry association.

RTVA article 63-3(1) and PAA Ordinance article 254 also set forth information to be provided to the relevant authority.

- 8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Under article 51-2 of the Ordinance for Enforcement of the RTVA (Ordinance of the Ministry of Transport, No. 74 of 1951 (RTVA Ordinance)), manufacturers must update information about risks every three months until remedial measures are completed.

The CPSA does not impose an obligation on manufacturers to update information, but manufacturers are expected to keep the relevant authorities updated regarding the status of the product recall programme.

- 9 What are the penalties for failure to comply with reporting obligations?

Manufacturers who fail to report or who submit false reports in violation of the CPSA article 35(1) may be ordered by the relevant authority to establish systems to collect information on serious product accidents, if such is regarded as necessary by the relevant authority (CPSA article 37). Violation of such orders risks imprisonment with (or without) work for less than one year or a penalty of ¥1 million, or both (CPSA article 58(v)).

- 10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

As a general rule, administrative organisations shall disclose ‘administrative documents’ upon request (Act on Access to Information Possessed by Administrative Organs, Act No. 42 of 1999, as amended (the AAI). ‘Administrative documents’ are defined in the AAI; however, the AAI excludes several kinds of information from disclosure (AAI article 5). Such information includes confidential business information which if disclosed could have a harmful effect on the competitive position of a certain business entity. ‘Commercially sensitive information’ is assumed to be generally covered by this category; however, the AAI also sets forth a category for absolute disclosure if disclosure is necessary for the protection of life, health, livelihood and property (AAI article 5(ii)). In the context of a product recall, most of the information provided by manufacturers is likely to fall within the scope of absolute disclosure. It is uncertain whether such commercially sensitive information can be kept undisclosed.

- 11 May information notified to the authorities be used in a criminal prosecution?

As a general rule, information that is acquired through an administrative procedure may not be used in a criminal investigation. The CPSA expressly sets out the rule that on-site inspections conducted by the relevant authority may not be regarded as criminal investigations (CPSA article 41(12)).

Product recall requirements

- 12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The CPSA sets forth a general criterion for determining whether a product recall programme is required: manufacturers must take the necessary measures, including a product recall programme, to prevent hazards or product deterioration (CPSA article 38(1)). Retailers of such products are required to cooperate with the manufacturers’ hazard-preventing measures (CPSA article 38(2)).

Under the RTVA, the applicable criteria are the ‘security standards’ stipulated in articles 40 to 46. The security standards vary in accordance with the type of automobile. Detailed criteria are also provided in the ‘Security Standards for the Road Tracking Vehicle’ (Ordinance of the Ministry of Transport, No. 67 of 1951). Product recall is expected if automobiles are found to violate the security standards; manufacturers and importers shall report to the MLIT once such product recall programme is put into force (RTVA article 63-3(1)).

As explained above, most of the criteria are quite abstract, and manufacturers and importers are not specifically instructed to initiate a product recall programme. However, a product recall programme is generally accepted as one of the most typical ‘hazard-preventing measures,’ and manufacturers and importers are therefore expected to implement such a programme.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Most of the laws and regulations order manufacturers to take the necessary measures to collect information on product accidents caused by their products, to provide such information properly to general consumers and to prevent a hazardous situation being caused by a product (eg CPSA articles 34(1) and 38(1)). Such necessary measures are assumed to include publication of information as well as conducting a product recall programme. In addition, under the PAA, manufacturers and sellers shall dispose, recall, stop selling, inform about defective products and take any other necessary measures (PAA article 77-4(1)).

14 Are there requirements or guidelines for the content of recall notices?

There are requirements for the content of recall notices in several laws and regulations. The Request for Providing Information Regarding the Accident, etc. Caused by Consumer Products, etc. (Notification by Director General for Commerce and Distribution Policy, No.1 of 2007) applies to products regulated by the CPSA. The PAA is also supplemented by the Medicine Recall Notice (Notification by the Medical Safety Bureau, Notification No. 237 of 2000).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The laws and regulations do not stipulate any obligatory media or communication measures that must be taken to announce a recall programme. In practice, since manufacturers must report accident information and the initiation of a product recall programme to the relevant authorities, such information is forwarded to and uploaded on the websites of non-profit consumer information centres, which are affiliates of the authorities. The relevant authorities may also announce the accident at a press conference, when regarded as necessary.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no specified targets or any particular period after which the recall will be deemed satisfactory.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

As previously explained, the laws and regulations do not provide for any mandatory repair programme. In practice, manufacturers choose measures that will best prevent a hazardous situation or the product's deterioration.

18 What are the penalties for failure to undertake a recall or other corrective actions?

When a person violates an order of article 39(1) of the CPSA (as mentioned in question 19), that person shall be punished by imprisonment with (or without) work for no more than one year or a fine of not more than ¥1 million, or both (CPSA article 58(iv)).

Under the RTVA, manufacturers who find that their automobiles do not meet the legally requested requirements must report to the MLIT (RTVA article 63-4(1)). If the manufacturer makes a false report, they shall be charged and punished with imprisonment with (or without) work for no more than one year or a fine less ¥3 million, or both (RTVA article 106-4(iii)). In 1999, a major truck and bus manufacturer was found to have failed to report a product defect

and conduct a product recall. Accordingly, several employees in charge of product security were penalised with one and a half year's imprisonment (with probation for three years) (Yokohama District Court, judgment on 13 December 2007; affirmed by Tokyo High Court, judgment on 2 February 2009). In addition, the representative directors each received a penalty of ¥200,000 due to violation of the RTVA article 63-4(1) (Tokyo High Court, judgement of 15 July 2008, affirmed by the Supreme Court, judgment on 9 March 2010).

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The manufacturers or importers of consumer products may be ordered by the relevant authority (a hazard prevention order under CPSA article 39(1)), and to the extent necessary, to recall products where:

- serious accidents have occurred;
- the lives or wellbeing of general consumers has been placed in serious danger or the occurrence of such danger is considered to be imminent; or
- the relevant authority finds it necessary to prevent the occurrence or increase of any type of danger.

If a recall is carried out in an unsatisfactory way, a hazard prevention order or an on-site inspection order (as described in question 19) would be executed.

The METI can produce a list of 'designated products' that are deemed as being highly likely to cause danger to general consumers as a result of their structure, material or usage, etc. (CPSA article 2(2)). The METI may order the manufacturer to take all necessary measures to improve methods of manufacture, import or inspection of the specified products where it finds that such manufacturers fail to conform to the requirements outlined in the CPSA Ordinance (the Order for Improvement).

The relevant authority may, when necessary, enforce the CPSA by:

- ordering a person engaging in the manufacture, import or sale of the products or a business operator transacting specified maintenance products, to report on the status of its business (CPSA article 40(1)); or
- sending officials (or the NITE on behalf of officials) to enter the offices, factories, workplaces, stores or warehouses of a person engaging in the manufacture, import or sale of the products, or a business operator transacting specified maintenance products and to conduct an inspection of products, books, documents and other items (CPSA article 41(1)).

If the relevant authority has asked its official to conduct an on-site inspection, but some products are found to be extremely difficult for the official to inspect on-site, the authority may order the owner or possessor to submit them for inspection to the relevant authority within a designated period (CPSA article 42(1)).

20 Can the government authorities publish warnings or other information to users or suppliers?

When relevant, the authority can publicly announce its orders and information to users and suppliers (CPSA article 36 (1) and 39(2), RTVA article 63-2(4), etc). Public announcements are made through press releases on the website of the CAA (www.caa.go.jp/), which does not provide a facility for members of the public to post remarks or reports of incidents. Under the CPSA, the definition of information included in such public announcement is specified as 'the name

Update and trends

After the accidents at the Fukushima Daiichi Nuclear Power Station following the Great East Japan Earthquake which occurred on 11 March 2011 in Japan, there has been great concern regarding the safety of foodstuffs (water, vegetables, crops, meats etc) being threatened by radiation leaked from such a damaged nuclear power station. For example, it has been reported that, if a person were to continue to consume vegetables containing the highest levels of radiation recorded thus far for a period of ten days, that person would be exposed to an amount of radiation approximately equal to half the amount he or she would receive over the course of a year

as background radiation. In response to this situation, the CAA has published releases on its website (English site: www.caa.go.jp/en/index.html) providing information regarding food safety. The MHLW has set provisional regulation values for radioactive materials in food (bottled drinking water and food) based on the guidelines drawn up by the Nuclear Safety Commission, and that food with radiation levels exceeding these values should not be consumed. The details of such provisional regulation values are explained in 'Food and Radiation Q&A' (English version: www.kantei.go.jp/foreign/noda/topics/201108/FoodandRadiation_QA.pdf).

and type of the consumer products pertaining to said serious product accidents, the details of the accidents and any other matters that contribute to avoiding the dangers associated with the use of said consumer products' (CPSA article 36 (1)); however, other various information, including but not limited to information regarding the relevant manufacturer, the current status of the accidents, a periodical report from the relevant manufacturer etc, is also described in such public announcement.

- 21** Can the government authority organise a product recall where a producer or other responsible party has not already done so?

Under the PAA article 70(2), the MHLW and prefectural governors, after ordering necessary measures to be taken by the responsible parties under the PAA article 70(1), may dispose or recall or take other necessary measures if it is immediately necessary or if such responsible parties fail to observe the orders imposed upon them. However, there is no provision that allows government authorities to conduct a complete product recall programme.

- 22** Are any costs incurred by the government authority in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

There is no such provision.

- 23** How may decisions of the authorities be challenged?

Even though no decisions have been challenged so far, any administrative disposition imposing an obligation on parties can be challenged under the Administrative Case Litigation Act (Act No. 139 of 1962, as amended).

Implications for product liability claims

- 24** Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Security warnings do not have any legal standing as admission of liability. However, in actuality, such warnings are likely to be seen by the civil court as strong evidence in establishing the liability of defective products.

- 25** Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Even though the Code of Civil Procedure (Act No. 109 of 1996, as amended (the CCP)) does not provide for full-discovery, the court may order that documentary evidence be provided to a party upon the other party's request (CCP article 220). Although the document-holding party may refuse to provide such documents on the grounds that they are irrelevant to the facts of the case, many of the documents are assumed to be relevant to product liability in actual product liability actions. Notwithstanding the above, the document-holding party may still refuse to submit a document prepared exclusively for use by the holder thereof (CCP article 220(iv)(d)).

ANDERSON MŌRI & TOMOTSUNE

Naoki Iguchi
Makoto Terazaki

naoki.iguchi@amt-law.com
makoto.terazaki@amt-law.com

Izumi Garden Tower
6-1 Roppongi 1-chome, Minato-ku
Tokyo 106-6036
Japan

Tel: +81 3 6888 1089
Fax: +81 3 6888 3089
www.amt-law.com/en



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