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## **GENERAL RESEARCH AND REFERENCE MATERIALS SUPPORTING THE MULTI-JURISDICTIONAL RECALL AUTHORITY FOR CONSUMER PRODUCTS**

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*In 2009, Averture prepared a one-page Limited Guide to Recall Authority existing in Australia, Canada, China, the European Union, and the United States. Presented below is the research supporting that Limited Guide as of January 2010. A copy of the one-page Limited Guide is attached.*

### **I. UNITED STATES**

#### **A. Authority, Regulator, and Guidelines.**

In the United States, the independent federal regulatory agency responsible for consumer product safety policy and enforcement, including recalls of consumer products, is the Consumer Product Safety Commission (CPSC), established by the Consumer Product Safety Act (CPSA) and amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA). 15 U.S.C. § 2064 (b)-(c), 16 C.F.R. § 1115.12-13. Manufacturers, distributors, importers, or retailers who require information about comprehensive recall guidelines under the CPSA should consult the *CPSC Recall Handbook*, 1999. Jurisdiction over other products may rest with other federal agencies, for example, motorcycles and cars (NHTSA); boats (U.S. Coast Guard); drugs and medical devices (FDA); pesticides (EPA); and food (FDA).

**B. Reporting - Compulsory and Voluntary Mechanisms.** Section 15 of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product who obtains information which reasonably supports the conclusion that the product contains a defect that creates a substantial product hazard to inform the Commission of such defect.

A “substantial product hazard” is defined by the CPSA as either:

- (1) A failure to comply with an applicable consumer product safety rule under this Act or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission which creates a substantial risk of injury to the public, or
- (2) A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

*See 16 C.F.R. § 1115.4, Defect; 16 C.F.R. § 1115.2, Scope and Finding.*

The obligation to report a defect under Section 15(b) of the CPSA may arise upon receipt by a subject entity of the “first information regarding a noncompliance, or a potential hazard presented by a product defect, or an unreasonable risk.” 16 C.F.R. § 1115.14(c), *Time when Obligation to Report Arises*; 16 C.F.R. § 1115.12, *Information which Should be Reported; Evaluating Substantial*



*Product Hazard.* Information giving rise to a reporting obligation may include complaints, injury reports, quality control, and engineering data. A subject entity should not await complete or accurate risk estimates before reporting under Section 15(b). 16 C.F.R. §1115.14(c), *Time when Obligation to Report Arises*. However, if information is not clearly reportable, a firm may spend a reasonable time for investigation, not to exceed a period of 10 days, unless the firm can demonstrate that a longer period is reasonable. See, 16 C.F.R. § 1115.14(d), *Time for Investigation and Evaluation*.

In addition to the Section 15(b) compulsory reporting requirement, a voluntary fast-track recall program is available to manufacturers which identify defects in products that could create substantial hazards. 15 U.S.C. § 2064.

A full report as set forth at 16 C.F.R. § 1115.13(d), including copies of all complaints and injury information and a proposed corrective action plan (CAP) to address the problem within 20 working days are necessary components of the voluntary reporting mechanism. See, 15 U.S.C. §2064 (a); see also 16 C.F.R. § 115.12 (a), *General*, 16 C.F.R. §1115.20, *Voluntary Remedial Actions*.

**C. Cooperative Agreements.** The United States has entered into cooperative agreements with sixteen (16) foreign entities, namely Brazil, Canada, Chile, China, Colombia, Costa Rica, Egypt, European Union, India, Israel, Japan, Korea, Mexico, Peru, Taiwan, and Vietnam.

The agreements are entered as Memoranda of Understanding (MOU) generally establishing the intent of the United States and the other parties to cooperate within the scope of the authority of the respective entity toward furthering the goal of consumer product safety. These agreements establish a formal working relationship between the entities'

consumer product mechanisms by creating voluntary exchanges of information.

**D. Upcoming Changes to Recall Program.** Section 214 of the CPSIA amends Section 15 of the CPSC to add a new subsection 15(i), which establishes rules for mandatory recall notices. On January 21, 2010, the CPSC provided its Final Rules establishing guidelines and requirements for mandatory recall notices, which designates specific content that must appear in a mandatory recall notice. See 75 FR 3355-3371. Examples of such required information includes helping consumers identify the product, understand the hazard identified, and know how to act on the manufacturer's remedy. *Id.* Also, Section 15(i)(2) sets forth requirements that must be included in a mandatory recall notice "except to the extent that the Commission determines with respect to a particular product that one or more of the following items is unnecessary or inappropriate under the circumstances..." See, 74 FR 11883-11888 and CPSC website at <http://www.cpsc.gov/library/foia/foia10/brief/notices.pdf>.

## II. EUROPEAN UNION (EU)

### A. Authority, Regulator, and Guidelines.

The Directorate General for Health and Consumers (DG SANCO) is the primary EU regulatory agency responsible for consumer product safety. EU member states are individually responsible for implementation and enforcement of EU legislation, including the General Product Safety Directive (GPSD) which sets out the basic requirements on consumer product safety, including consumer product recalls. 2001/95/EC. Manufacturers or other entities that require information about comprehensive recall guidelines should consult the manual *Product Safety in Europe: A Guide to Corrective Action Including Recalls*, June 2004.

**B. Reporting- Compulsory and Voluntary Mechanisms.** If a product that is already on the market poses a serious threat calling for



quick action, the member state involved shall immediately inform the European Commission (Commission) on the measures taken via the Community Rapid Information System (RAPEX), a system for the rapid exchange of information between the EU member states and the Commission and individual member states where the product was marketed or otherwise supplied to consumers. Article 8(1)(f), 2001/95/EC; Annex I to 2001/95/EC. New rules and reporting guidelines were given to EU Member States in a new directive for the management of RAPEX. See General Product Safety Directive, amended, C(2009) (9843) (2010/15/EU). The new guidelines include, among others, notification timing, risk assessment method, disclosure of standard information, validation and distribution of notifications, and temporary removal of the RAPEX notification from the RAPEX website. *Id.*

A provision providing for voluntary recall is also found in Article 5(1) of the GPSD. This Article provides that producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Article 5(1) 2001/95/EC. One of the ways in which producers may choose to protect against risks is “withdrawal from the market, adequately and effectively warning consumers or recall from consumers.” Article 5(1)(b) 2001/95/EC. Article 5 also makes clear that recalls should be a last resort, where other measures would not suffice to prevent the risks involved, in instances where the producers consider it necessary, or where they are obligated to do so pursuant to the Article 8 mandatory reporting requirements. Article 5(1) 2001/95/EC.

**C. Cooperative Agreements.** The European Commission has entered into agreements with China, Japan, and the United States in order to exchange information on risks identified and measures taken to products originating out of their respective territories.

Unique to the Commission is the fact that some consumer product safety laws and responsibilities reside with individual member states and/or are shared between the member states and the Commission. See, e.g. EC Agreement, Sections 5-6. Notwithstanding this fact, the agreements make clear the intent of the Directorate General to act as liaison with member states and other relevant bodies toward implementing the consumer safety initiatives. See, e.g., EC Agreement, Sections 5-6.

#### **D. Upcoming Changes to Recall Program.**

Recent EU initiatives aim to improve consistency of enforcement of initiatives and legislation across the member states. The new RAPEX Guidelines seek to clarify the scope of the program from an operational point of view, including operations involving voluntary and compulsory recall programs. See, Revised RAPEX Guidelines at [http://www.epha.org/IMG/pdf/Commission\\_Guidelines\\_on\\_RAPEX.pdf](http://www.epha.org/IMG/pdf/Commission_Guidelines_on_RAPEX.pdf).

Other EU initiatives seek to improve market surveillance of non-food consumer products in Europe. This will be achieved through the practical application of best practices developed under the current Enhancing Market Surveillance through Best Practices (EMARS) project and the development of additional best practices. The project also seeks to further capitalize on the improved climate for collaboration amongst national market surveillance authorities that the current EMARS project has contributed to. See, New EMARS Handbook on Market Surveillance at [http://www.emars.eu/uploads/EMARS\\_Best\\_Practice\\_Book.pdf](http://www.emars.eu/uploads/EMARS_Best_Practice_Book.pdf).

### **III. CANADA**

#### **Authority, Regulator, and Guidelines.**

Currently, under Canadian law, there is no Act specifically that has jurisdiction over consumer product recalls. However, in 2009, the Canadian Parliament began to consider a new Consumer Product Safety Act, Bill C-6 (Safety



Act), which gives authority to Health Canada to require the recall of a consumer product by the manufacturer, importer, or seller. The proposed Safety Act is designed to repeal and replace Part I of the Hazardous Products Act (HPA), which currently is the authority that addresses consumer products that are either restricted through regulation or are prohibited from being advertised, sold, or imported into Canada. R.S. 1985, C.H-3.

The proposed Safety Act gives authority to Health Canada to require the recall of a consumer product by the manufacturer, importer, or seller. The Safety Act provides that if an inspector believes that a consumer product is a danger to human health or safety, they may order a person who manufactures, imports, or sells the product for commercial purposes to recall it. *Safety Act* at s. 32(1). As of this writing, the bill is awaiting passage in the Senate of Canada.

The regulatory agency responsible for existing voluntary and proposed compulsory recall action is Health Canada. Manufacturers or other entities wanting information about voluntary recall guidelines under the current Hazardous Products Act should consult *Recalling Consumer Products, A Guide for Industry*, April 2005.

**A. Reporting- Voluntary Mechanism Only.** No formal recall procedure exists under the HPA. R.S., c. H-3, s. 1-31. In Canada, consumer product recalls are company actions to correct or remove noncompliant or defective products from the market. Occasionally, Health Canada may request that an importer, manufacturer, distributor, or retailer initiate a recall, but ultimately that company must implement the recall. Additionally, Health Canada may monitor recall effectiveness, issue public warnings, and prosecute regulatory violations after a recall if unsafe products remain on the market. R.S. c. H-3, s. 22(1).

It should be noted that the absence of compulsory recall provisions does not remove a manufacturer's duty to recall noncompliant or defective products. If a company decides to recall a product that presents a health or safety hazard or violates existing regulations, they must notify Health Canada in writing. After notification, a company must take more detailed steps that are unique to the product and company.

**B. Cooperative Agreements.** Canada has executed MOUs or other agreements concerning consumer product safety with ten (10) entities, namely Australia, China, the EU, France, India, Mexico, New Zealand, Singapore, South Africa, and the United States.

**C. Upcoming Changes to Recall Program.** As discussed *supra*, Bill C-6, if passed by the Senate of Canada, will invoke a mandatory recall program, giving authority to Health Canada to require the recall of a consumer product by a manufacturer, importer, or seller in certain circumstances. *Safety Act* at s. 32(1). Further, in the event of a potentially dangerous product, Health Canada will have authority to stop certain business functions of the entity, such as product manufacturing, advertising, selling, labeling, testing, and transporting. Other regulations, including additional classifications of hazardous products, such as lead reductions, are also controlled by the proposed Safety Act. *Safety Act* at s. 33 (2) (a).

#### **IV. AUSTRALIA**

**A. Authority, Regulator, and Guidelines.** In Australia, the authority for recall of consumer products is found in ss. 65R and 65F of the Trade Practices Act of 1974 (TPA). Separate authority at the State and Territory levels exist, while some States deem that product recalls under s. 65R of the TPA satisfy their respective statutory requirements for voluntary recalls in those States.



The Australia Competition and Consumer Commission (ACCC) is the national regulator of recalls of consumer products. Upon notification, it advertises the recall on the Recalls Australia website and provides oversight to ensure that the proposed recall strategy is effective. Additionally, other regulators can be found at the State and Territory levels. Manufacturers or other entities needed specific information about recall guidelines should consult the manual *Product Safety Recall- A Guide for Suppliers*.

**B. Reporting- Compulsory and Voluntary Mechanisms.** In Australia, there is both a compulsory and voluntary recall mechanism for consumer goods. Under s.65A of the TPA, a compulsory recall can be ordered when an unsafe consumer good comes to the attention of the ACCC or the Minister and the supplier is unwilling to take action. The power can also be used in situations where the supplier has not taken satisfactory action with respect to a voluntary recall. As for the States and Territories, most also have the legislative power to order a compulsory recall. Currently, s.65(1)(f) of the TPA and the respective compulsory recall provisions of the State and Territory legislation, states that the supplier undertaking the recall may determine the appropriate consumer redress after a recall, such as replacement, repair, or refund.

A supplier may notify their intent to conduct a voluntary recall of an unsafe consumer good pursuant to s.65R of the TPA. Upon notification of a voluntary recall, the ACC will advertise the recall on the Recalls Australia website. Similarly, voluntary recalls negotiated by the State and Territory regulators are also advertised on their respective websites. The recall notice should contain, at minimum, details of the product's problem(s), details of the product, including name, description, and serial number(s), and risk assessment and proposed action. This information enables the regulator to effectively assess the risk posed by the good, the number of affected goods, and

the distribution of the goods to determine whether the recall strategy proposed by the supplier will be effective in eliminating the hazard to consumers.

**C. Cooperative Agreements.** Australia has executed MOUs or other agreements concerning consumer product safety with seven entities, namely the EU, Fiji, South Korea, New Zealand, Papua New Guinea, Taiwan, and the United Kingdom.

**D. Upcoming Changes to Recall Program.** Recently, the Productivity Commission recommended that all Australian governments should implement a new national generic consumer law to apply to all jurisdictions. As such, in October 2008, the implementation of the Australian Consumer Law (ACL) was endorsed as part of the new TPA, which provides for a single national consumer law for Australia based on the consumer protection provisions of the TPA and a uniform, streamlined regulatory system for consumer product safety.

The ACL would be implemented nationally and in all States and Territories in three stages. Stage One encompasses new provisions for the TPA involving new penalties and enforcement powers, and will likely be operative at the beginning of 2010. Stage Two covers the best practice reforms with the proposed legislation to be introduced to the Australian Parliament in 2010. Stage Three of the implementation process will require the States and Territories to introduce and pass the laws by December 2010, with the ACL to be fully implemented by January 2011.

## **V. CHINA**

**A. Authority and Regulator.** China's consumer products are not fully regulated by any one authority within China's borders, although many changes for regulation of all consumer products are currently being proposed. The Management Regulations on Recall of Children's Toys allows for recalls



expressly limited to children's toys. The Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) is the responsible body for administering children's toys recalls for defective toys and for providing a unified system of informing the public of those defective toys.

**B. Reporting- Compulsory and Voluntary Recall Mechanisms.** There is both a compulsory and voluntary reporting mechanism for initiating recalls of defective children's toys. Articles XXVII-XXXIV of the Management Regulations require a compulsory recall when a producer is informed that a defect exists in a toy. Producers must promptly provide the relevant information about the toy to the AQSIQ and to the provincial level. Article XVII, Management Regulations. Then, the AQSIQ can mandate a compulsory recall of the toy and further order the producer to immediately stop production and sales of the defective product.

Articles XXI-XXVI of the Management Regulations provide for a voluntary recall mechanism for defective children's toys. If a producer becomes aware of the defective product, it should cease production and sales of the defective toy. They may also implement a voluntary recall pursuant to the regulations and relevant provisions of the AQSIQ. Articles XXI-XXVI, Management Regulations.

**C. Cooperative Agreements.** China has executed cooperative agreements concerning exchange of children's toy safety information, including recalls, with Canada, the EU, and the United States.

**D. Upcoming Changes.** The Legislative Office of the State Council of the People's Republic of China recently announced a rulemaking entitled "Management Regulation on Defective Product Recall." Public comments were due by May 2009. This draft law emanates from China's State Council, which is China's highest-level executive body. It comes

during a time of increased product quality scrutiny and crises management in China. The establishment of the Leading Group helped coordinate government efforts addressing product quality, and likely highlighted the need for comprehensive legal measures on product recalls. Until issuance of this Regulation, Chinese laws governing product recalls focused on specific product areas, such as children's toys, food, medicine, and medical devices.

The Regulation defines defective products means products as those that due to design, production, directions, or other factors, pose or may pose consistent and unreasonable harm to the safety of human physical health and life. Specifically, Article 8 states that upon information that a product is defective, the producer must organize and undertake product defect studies. Depending on the results of the defect study, the producers must warn, amend or correct consumer directions, or retrieve, return, exchange, repair, or destroy products to prevent, control and eliminate the damage or harm that may be caused by the defective product. The recall procedures outlined in the Regulation address both voluntary and mandatory recalls.

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*For informational purposes only. Always consult an attorney and an engineer before responding to these regulations or when seeking compliance.*

**Limited Guide to Multi-Jurisdictional Recall Authority for Consumer Products**

	<b>AUSTRALIA</b>	<b>CANADA</b>	<b>CHINA</b>	<b>EUROPEAN UNION</b>	<b>UNITED STATES</b>
<b>AUTHORITY</b>	Trade Practices Act 1974 s.65R, others at State and Territory Level	None, but see Hazardous Products Act, R.S., 1985, C.H-3	Management Regulations on Recall of Children’s Toys	General Product Safety Directive, 2001/95/EC	Consumer Product Safety Act, 15 U.S.C. §2064(b)-(c), 16 C.F.R. §1115.12-13
<b>REGULATOR</b>	Australia Competition and Consumer Commission – ACCC, others at State and Territory Level	Health Canada	Administration of Quality Supervision, Inspection, and Quarantine - AQSIQ	Directorate General-SANCO, and EU Member States	Consumer Product Safety Commission - CPSC
<b>REPORTING</b>	To Minister for Competition Policy and Consumer Affairs within 2 days, s.65R	To Health Canada, Consumer Product Safety Program	“Producer shall promptly report” to provincial level and to AQSIQ. Article XVII	Immediately to RAPEX and individual Member States where marketed Article 5(3) 2001/95/EC and 2004/95/EC	To CPSC upon “first information” of substantial product hazard, noncompliance, or risk 16 C.F.R. §1115.12
<b>VOLUNTARY</b>	Yes. s.65R	Yes.	Yes. Articles XXI-XXVI	Yes. Article 5(1) 2001/95/EC	Yes. 15 U.S.C. §2064(b)
<b>COMPULSORY</b>	Yes. s.65F	No.	Yes. Articles XXVII-XXXIV	Yes. Article 8(1)(f) 2001/95/EC	Yes. 15 U.S.C. §2064(c)
<b>COOPERATIVE AGREEMENTS</b>	MOUs or Agreements with 7 countries <sup>a</sup>	MOUs or Agreements with 10 countries <sup>b</sup>	Canada, European Union, and United States	3 bilateral agreements, 1 trilateral agreement <sup>c</sup>	MOUs with 16 countries <sup>d</sup>
<b>GUIDELINE</b>	<i>Product Safety Recall—A Guide for Suppliers</i>	<i>Recalling Consumer Products, A Guide for Industry</i> (April 2005)	None	<i>Product Safety in Europe: A Guide to Corrective Action Including Recalls</i> (June 2004)	<i>CPSC Recall Handbook</i> , 1999
<b>UPCOMING CHANGES</b>	2010 – New Trade Practices Act, implement ACL Recall Authority for Australian Commonwealth	Bill C-6, CCPA-Health Canada may invoke a mandatory recall.	proposed “Management Regulation on Defective Product Recall” – public comments were due May 2009	Revised RAPEX Guidelines, New EMARS Handbook on Market Surveillance	CPSIA, Rules for Mandatory Recall Notices 74 FR 11883-11888

<sup>a</sup> EU, Fiji, South Korea, New Zealand, Papua New Guinea, Taiwan, and United Kingdom

<sup>b</sup> Australia, China, EU, France, India, Mexico, New Zealand, Singapore, South Africa, and United States

<sup>c</sup> China, Japan, and United States

<sup>d</sup> Brazil, Canada, Chile, China, Columbia, Costa Rica, Egypt, EU, India, Israel, Japan, Korea, Mexico, Peru, Taiwan, and Vietnam