

NEWSLETTER

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EDITOR'S MESSAGE

Safety matters

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This first newsletter of the year is dedicated to the series of worldwide product recalls by Mattel in 2007 and the impact they had. While the reasons for the recalls were the same in every country concerned, it is fascinating to observe how differently the matter was handled by the national authorities and perceived by the customers. It is a fact which cannot be explained alone by the different number of toys which were affected by the recall in each country. Evidently globalisation does not happen in every case.

I would like to thank all the contributors for providing us with these interesting insights into a case, which I am certain concerned all of us or will do so due to changes in national product safety laws. In the EU Member States such changes will take place at the latest with the transposition of the new Toys Directive, which should have already been introduced at the end of 2007.

As you can see from the information provided in this newsletter our committee has broadened its officers' base. We invite all of you to begin an officer's career in our committee as a national correspondent for our newsletter. In case of interest please contact our Publications Officer, Gabriela Mancero, or me.

Also I would like to use this occasion to advise our members of this year's Annual Conference, which will take place in Buenos Aires from 12–17 October.

I wish you all a successful year and hope to see many of you in Buenos Aires.

Contributions to this newsletter are always welcome and should be sent to the Publications Officer, Gabriela Mancero-Bucheli, at the address below:

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Product recall under Argentinian law: aftermath of the 'Mattel case' in Argentina

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The way in which many jurisdictions worldwide dealt with the recall of Mattel products last year prompted Argentina to review its product recall legislation. We will briefly analyse that law and the aftermath of the Mattel case in Argentina.

Overview

The Argentinian Consumers' Defence Act and Fair Trade Act establish that goods providers who know that an article is dangerous after it has been sold and distributed must inform government authorities and consumers of that fact through advertisements. However, except for cases of medical and food products described below there are no specific legal proceedings for the recall of such defective articles.

Medical product recall

By the adoption of a MERCOSUR regulation, the Argentinian Federal Office for Food and Drug Control (ANMAT) recently enacted measures setting out guidelines for recall of medicines. ANMAT may order recall as a consequence of an *ex parte* investigation or claims of consumers or medicine manufacturers, importers or distributors. In cases of medical products that actually or potentially may harm consumers, the manufacturers, importers and/or distributors of those products shall immediately recall them pursuant to the following criteria:

- In case of product recall ordered by ANMAT, it shall be communicated to all distributors, drugstores, hospitals and any other entity entitled to deliver medicine to consumers in order to prevent its consumption. That communication shall be advertised in official newspapers.
- A person shall be appointed to coordinate and perform the recall. That person shall be responsible for the recall and shall be provided with appropriate personnel as required by the urgency of the recall.
- Distribution registers of the defective (or potentially defective) products with information about wholesalers and distributors to whom the products were delivered shall be immediately available to the person appointed to perform the recall.
- Regulations about recall proceedings shall be regularly updated.
- In the order for the recall proper instructions shall be included for storing the defective (or potentially

defective) products until their final destination is decided.

- The competent authorities of the countries to which the defective (or potentially defective) products were delivered shall be informed of their recall.
- The products recall proceedings shall be controlled and duly registered, and shall include a final report describing the location (ie warehouse, depot) where the product is stored.
- When the recall is voluntarily decided by the product manufacturer, distributor or importer, it is mandatory to inform ANMAT about this. The report shall specify the product batches held by distributors, drugstores, hospitals and any other entity entitled to deliver that medicine to consumers. ANMAT is entitled to participate in the recall proceedings.

Food product recall

ANMAT has also issued a handbook regulating the proceedings for the recall of foodstuffs, based on which it has ordered the recall of several food products (milk, flour, snacks, salt etc) during the last two years, mainly because they infringe the Argentinian Food Code. The provisions of the handbook are largely similar to the guidelines for medical products. However, this handbook distinguishes three kinds of proceedings depending on the sanitary risk of the defective food product, which shall be assessed both by ANMAT and by the product manufacturer, importer or distributor.

- Class I cases: when the defective product represents a substantial risk for consumers' health, such as irreversible damage or death. The products shall be recalled even when they have been acquired by end consumers and notice of the defect and recall shall be widely advertised. Involvement of the manufacturers, importers and/or distributors is required in the recall proceedings.
- Class II cases: when the defective product may cause reversible damage and/or temporary adverse consequences to consumers' health.
- Class III cases: when the defective products do not represent major risks to consumers' health but infringe legal rules.

In Class II and Class III cases the recall proceedings shall depend on the circumstances of each case.

Aftermath of the Mattel case in Argentina

Despite extensive reporting in the media, Mattel did not perform a massive product recall in Argentina as compared with other jurisdictions. Only 47 units of one specific potentially toxic article (a Barbie accessory sold in Argentina between July and August 2007) were voluntarily recalled by Mattel.

Initially, due to worldwide reporting of the Mattel case, the Consumers' Defence Secretariat ordered investigation of a large number of Mattel toys to check on high levels of lead; and – as a preliminary measure – requested Mattel's local subsidiary to stop their sale. Eventually, after the studies concluded that the toys were harmless, the Secretariat authorised their sale.

It must be pointed out, however, that during 2007 Mattel performed a voluntary product recall in Latin America. This was not because of toys containing excessive lead but because the articles in question

contained small magnets that might come off the toys and harm children. In Argentina this recall involved 50,000 articles and was reported to the Consumers' Defence Secretariat in August 2007. To date, we do not know of any litigation against Mattel in Argentina as a consequence of this recall.

Conclusion

Food and medical products are the only goods whose recall is specifically regulated in Argentina. Despite this, national authorities have recalled other products (including toys) regulating these proceedings on a case-by-case basis.

Although the 'Mattel' case was widely covered in the media, Mattel's voluntary recall in Argentina had no major legal consequences for the company.

ARGENTINA

Mattel's toy recall

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There were no major problems in Argentina regarding Mattel's toys. The company voluntarily withdrew from the market some units as a preventive measure.

In order to meet the customers' demands, the company operates a toll-free helpline number and published notices in all major newspapers of the country that contained information about the products marketed locally.

National and provincial consumer protection agencies conducted several studies in order to determine the existence of toxic components in the toys sold by the company locally. The results obtained in specialised laboratories came back negative.

The Law 24.240 of Consumer Protection establishes that any goods or services marketed in the country cannot – under normal conditions of usage – pose a threat to the health or physical integrity of the consumers.

National, provincial and municipal governments are obliged by this law to enforce it in order to protect consumers. This is the reason why they acted rapidly in order to prevent any harm to the population.

In 2006, our office intervened – acting as attorneys for Nestlé – in the withdrawal of a product because of an alleged contamination. At that time, the ANMAT (National Administration of Drugs, Foods and Technology) and the General Administration of Food Safety and Health of the city of Buenos Aires ordered the withdrawal of a batch of powder milk because it was allegedly in bad condition. The government of the city of Buenos Aires had conducted a test that confirmed the alleged presence of a bacterium dangerous for health. Nestlé did not accept this test since the lab in which it was performed did not meet the health and safety requirements. At the same time, the company sent a batch to the Pasteur Institute in France, where it was determined that the product was not contaminated and that it was suitable for consumption.

The Nestlé case shows that the control agencies do not have the necessary tools to enforce the law. In this case, they had the product analysed in a lab which did not meet the required standards, which led to preventive measures against the company, since they had to withdraw from the market a product which was, in fact, in good condition.

It is worth mentioning that as Nestlé's attorneys, we had intervened in several cases in which consumers

denounced that they had health problems for consuming products in bad condition. The charges were dismissed since there was no evidence that the health

of any consumer was affected, which shows that the powdered milk was in good condition.

AUSTRIA

Product safety and the Mattel recall in Austria

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Introduction

Mattel's product recalls of 2007 have been the largest recalls in Austria, receiving extensive media coverage and sharp criticism by the Austrian consumer protection agency. Hence it came as a surprise that their actual general impact in Austria was minor.

Product safety law in Austria

Austrian product safety law in general is regulated in the Produktsicherheitsgesetz (Austrian Product Safety Act, PSG) which is based on EU Directive 2001/95/EC. In essence, producers/importers have to adopt adequate measures to inform and warn consumers and the competent authority of any risks their products may pose, take products off the market or eventually stage a recall. The authority in turn may take precautionary measures, ranging from ordering an amendment of the products manual to a recall, using official notifications, or regulations.

In general, the Federal Minister for Social Affairs and Consumer Protection is the competent authority for product safety, offering on the Ministry's website a public database of product notifications in Austria. However, responsibility for product safety may vary as Article 32 paragraph 2 PSG stipulates that if a statute contains product safety provisions, the Federal Minister responsible for the execution of that statute shall be competent to oversee product safety. In the case of toys, this exception applies since the Spielzeugverordnung (Toy Regulation) contains product safety provisions whose enforcement falls under the authority of the Federal Minister for Health, Family and Minors.

Mattel's recalls in Austria

In Austria, Mattel initiated the recall of toys and notified the authorities. Retailers were contacted directly, while consumers were informed through newspaper advertisements and Mattel's safety bulletins

published on its website and the website of the Federal Ministry for Social Affairs and Consumer Protection. During the first recall on 2 August 2007, mass media showed little interest. This changed dramatically with Mattel's second recall on 14 August 2007 which was covered in the Austrian press, TV and radio. The ensuing discussion, however, fuelled by Mattel's third recall on 5 September 2007, focused more on the potential dangers of Chinese products than on Mattel as a company. Media interest finally waned in late October, though Austrian newspapers now regularly publish articles on Chinese products and safety.

Judging by the number of products actually returned by consumers, public interest was unenthusiastic. Retailers, who had initially prepared for a rush, were surprised to find that even weeks after the recall only a small number of toys had been returned. Officials assume that this may be related to the fact that the first two recalls were announced during the holiday season. According to them, another possibility is that consumers discarded the unsafe toys, instead of going to the trouble to return them.

Due to the limited public interest in the recalls themselves and since no injuries have been reported, there was little political incentive to take legislative action. Although it has been debated whether the Federal Ministry for Social Affairs and Consumer Protection should in future assume responsibility for toy security, this idea has been dropped because of lack of personnel therein. Hence, it was generally agreed that any necessary changes would have to await the implementation of the new EU Toy Directive. At the same time, in order to gather more information on the subject, the Federal Ministry for Social Affairs and Consumer Protection has adapted its regularly conducted survey and has added a new question: 'What do you do, when you have been notified of a recall?'

Conclusion

In Austria, Mattel's recalls have proved to be a short-lived scandal without any impact except maybe a general awareness of product security and China. The government left it largely to Mattel to handle the case and although official responsibility for future 'toy crises'

was debated, no action was taken. What is probably more important, the consumer seemed either uninterested in exercising his rights and/or was unaware of them. So far no legal action initiated by consumers has been reported.

COLOMBIA

The impact in Colombia of Mattel's product recall

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On 14 August 2007 the world's largest toymaker Mattel announced the recall of almost 4,000 toys that were for sale in the Colombian market.¹ Only two weeks before there had been a great commotion in the US media when Mattel's headquarters announced the recall of more than 1.5 million toys from the market, since they contained about 200 times the maximum lead content authorised by US law.²

The apparent cause was that Early Light Industrial, Mattel's subsidiary in China, subcontracted to the manufacturer Hong Li Da HLD, an unauthorised supplier, who used paints with a high content of this metal.³ It has been found that the ingestion of lead in children can cause lethargy and vomiting. When ingested in large quantities it can precipitate neurological problems, hearing loss, stunted growth, reduced IQ and, in most severe cases, can even result in death.⁴

Additionally, the company recalled other toys that did not pass quality standards since they contained wrongly-placed magnets that could puncture children's intestines if swallowed. Those affected were Barbie and her dog Tanner, Polly Pocket, Batman dolls, Dora the Explorer and the characters from Sesame Street, among others.⁵

China products under a magnifying glass

The company promptly made the announcement after the episode acquired a global reach (Mattel recalled more than 18 million toys worldwide in August) and stated that it had reinforced all quality control during production and increased the number of toys' random inspections, to ensure that quality standards were acceptable before the items reached the hands of end consumers.

This scandal triggered a frantic search for lead in toys and other items used by children (such as watercolours, glue caps and backpacks that had been manufactured in

China which proved they also had very high contents of lead paint) in countries such as Peru and New Zealand. The European Union also announced a two-month conscientious research into toys' safety after Mattel's announcement was made.

Colombia's butterfly effect

By the time Mattel CEO Robert Eckert was giving his testimony to the US Consumer Product Safety Commission on the matter,⁶ Colombia's counterpart Mauricio Stellabatti (Mattel Colombia's marketing director) announced that the company wished to recall 2,800 toys as a precautionary measure, although it had detected only one toy that matched with those initially reported to have high lead levels.⁷

The official also said there were about 4,000 toys from the references being recalled in the country, but 1,200 of these were still in the company's warehouses. Allegedly, many of the remaining toys were already in the hands of Colombian consumers. Stellabatti added that the company would exchange the toys that caused concern for customers who specifically requested it. He also clarified that it did not necessarily mean the toys were dangerous for children.⁸

Alyda Romero, Mattel's marketing manager for Latin America's northern region, warned that the news had enough media coverage, which created enough consumer awareness on this subject. She added that until then there had not been any recorded cases sufficient to create a medical alert and that the investigation undertaken by the company was taking into account the health of the factory operators who handled lead paint.⁹

Colombia imported in the first eight months of 2007 nearly 106 million dollars in toys. Of these, more than half (60 million) came from China, the United States took a distant second place with 16 million, and Spain, the third, with 3.3 million. It is impossible to determine

what percentage of the number of Chinese toys offered guarantees for children's health and what percentage corresponded to toys painted with toxic substances.

Zero control at points of entry

Mattel finally collected 18.2 million toys that were considered dangerous for children. Many of the recalled toys returned to the Chinese market. But the tracks of informal trade in Colombia, without excluding others, may have allowed diversion of such goods to poorer or less aware consumers.

Most of the Colombian officials consulted on this matter said that Invima, the Colombian Institute for the Surveillance of Medicines and Foodstuffs, was in charge of the regulation for imports' quality and safety. But spokesmen from that entity reminded the public that they were only in charge of controlling medicine, food, health supplies, pesticides, anatomic components (such as tissues and bones) and toiletries.

While the Ministry of Foreign Trade Regulation Directorate approved the technical specifications that this type of merchandise should have when entering the country, these items are not checked at customs because officials rely on the international certificates on quality that the goods have from their countries of origin.¹⁰

In the aftermath of Mattel's announcement, Consumer Protection Delegate from the Superintendence of Industry and Commerce, Maria Teresa Pineda, acknowledged that there were not any technical regulations that would allow the Colombian Government to check on this type of product. 'There is only one standard technique to do so, but it is not mandatory. Therefore, this body does not have the legal instruments to collect toys or punish the company who introduced them,' she warned.¹¹

At the same time, DIAN, the Colombian Taxes and Customs Directorate, said that while they have laboratories to verify such products, they do not carry it out unless they receive an instruction from the Colombian health authorities. Additionally, DIAN only implements such verifications on seized smuggled merchandise and not on authentic goods.¹²

New regulation released

In reaction to the lack of regulation and practice by government agencies regarding toy safety, in late August, the Colombian Social Protection Ministry launched an alert on the Mattel case. Its Public Health general director, Gilberto Alvarez, announced that this entity was developing a technical standard for regulating toy quality, taking into account their characteristics, so that they do not affect the health of Colombian consumers.¹³

The Ministry also issued a new regulation that sets standards (in micrograms) allowed in toys from metals such as antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium and other substances. It also

orders manufacturers and importers to have a certificate of quality control that would allow the competent authorities to verify the checks made to each toy, before its marketing and placing on the market.

Between 21 August and 10 October, the Ministry issued three sets of rules regulating the manufacture, importation and commercialisation of toys, their accessories and components.¹⁴ Prior to these, Law 9 of 1979 contained the only provision regarding the manufacture, importation and sale of household articles,¹⁵ setting broad standards, such that no household article should contain higher concentration levels of toxic substances than technically allowed.

In addition to the new ruling toys must carry warnings to reduce risks in use, such as the age of the user, whether adult supervision is required, and care recommendations. It also includes technical standards¹⁶ regarding flammability of toys and their materials; tests which the toys must pass in order to be imported and sold in Colombia; physical and technical properties and characteristics of the toys. Many of the standards set are based on EU directives and rules on similar articles.¹⁷

Finally, the rules impose inspection and control duties regarding the manufacture and importation of articles and toys on the Industry and Commerce Superintendence, before which importers and manufacturers of the toys must certify that articles' and toys' labels are accurate regarding the articles' contents.

Notes

- 1 '2.800 juguetes pintados con dosis de plomo busca recuperar Mattel en Colombia' (Mattel is planning to recall 2,800 toys with high lead level paint in Colombia) *El Tiempo*, Bogotá, 9 August 2007.
- 2 'Recalled Mattel Toys Topped U.S. Legal Lead Limits'. Reuters, 19 September 2007.
- 3 'What went wrong at Mattel'. NBC news (www.msnbc.msn.com) 15 August 2007.
- 4 'Health Effects on Lead'. US Lead information Center (www.epa.gov) 2 August 2007.
- 5 'Fisher-Price Recalls Licensed Character Toys Due To Lead Poisoning Hazard'. US Consumer Product Safety Commission (www.cpsc.com) 2 August 2007.
- 6 See n2 *supra*.
- 7 See n1 *supra*.
- 8 *Ibid*.
- 9 'Mattel retirará juguetes del mercado colombiano' (Mattel will recall toys from the Colombian market) *El País*, Cali, Colombia, 9 August 2007.
- 10 'Se buscan 2.800 juguetes por posible riesgo tóxico' (2,800 toys are being searched due to a possible health risk) Red de Gestores Sociales, Republic of Colombia's Presidency Office, Bogotá, 9 August 2007.
- 11 *Ibid*.
- 12 'Mattel busca en Colombia 41 mil juguetes de alto riesgo que ingresaron al país desde hace cinco años' (Mattel is searching in Colombia 41,000 high risk toys that have entered the country in the last five years). *El Tiempo*, Bogotá, 15 August 2007.
- 13 *Ibid*.
- 14 Resolución 2816 del 21 de Agosto de 2007; Resolución 3158 de 10 de Septiembre de 2007 (which repeals the latter); Resolución 3669 del 10 de Octubre de 2007 (which modifies few articles of Resolución 3158).
- 15 Article 551.
- 16 Annexes 1, 2 and 3 to the Technical Standard NTC71-2.
- 17 Such as 'European Standard. Safety of Toys' 1994.

Portugal's overview of Mattel's product recall

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This article presents a broad overview of how the media addressed the recent incident concerning Mattel's toy production from China, which resulted in a massive product recall. It includes information which we have gathered in respect of Portugal from various searches and enquiries undertaken on the matter. The information was obtained, inter alia, from news reports in the Portuguese media channels, such as radio, newspapers and specialist publications:

- The European Commission issued a warning to EU Member States to recall from their respective national markets certain toys considered to be 'dangerous' two days after Mattel announced that it was going to voluntarily proceed with the recall of 27 items since these contained certain magnets and a potentially toxic ink (published in © 2007 'LUSA – Agência de Notícias de Portugal, SA', 16 August 2007).
- The Portuguese National Consumer Institute (Instituto do Consumidor) issued an alert, on 1 March 2007, to recall a toy rabbit manufactured by Fisher-Price/Mattel, since it presented a risk of suffocation to children. According to the Consumer Institute the toy, which was manufactured in China, had been distributed in Portugal and consumers who acquired it were advised to contact the respective point of sale. This information was denied by Mattel Portugal's marketing director (published in 'Jornal de Notícias' 1 March 2007; 'Diário Digital/Lusa' 1 March 2007).
- One of the 83 types of toys which contained high quantities of lead, which the producer Fisher-Price was to recall from the market, was being sold in Portugal. Mattel Portugal, the company which owns Fisher-Price, issued a statement that the toy 'Dora, a Exploradora' (Dora, the Explorer), due to a suspicion that it contained ink mixed with lead, was recalled from the North American market stating also that in Portugal 352 items were sold at several outlets. The company took measures to identify the products, proceeded with their recall from the market and warned parents to return those toys where these had been acquired and to exchange them for other toys of an equivalent value. A telephone helpline and an e-mail address for customer support in order to clarify any possible doubts which consumers might have were also made available (published in 'Radio TSF' 2 August 2007, 'DN online' 2 August 2007 and 'Pais & Filhos' 3 August 2007).
- Toys R Us has recalled 27 toys considered to be dangerous since these contained certain magnets which became loose, and a potentially toxic ink. Included in this recall were specific items of the toy 'Sargento' (Sergeant) from the series 'Cars', 22 Polly Pocket toys, three Doggie Day Care toys and a Barbie doll accessory. In Portugal, only items which were manufactured between the dates of 19 April and 6 July 2007 and placed on sale as from 1 June 2007 onwards were included in the recall action (published in 'Jornal de Notícias', 'Correio da Manhã', 'Rádio Renascença' 2 August 2007, 'SAPO', 'Diário dos Açores', www.portugaldiario.iol.pt, 14 August 2007).
- A toy manufactured in China and sold in major supermarkets contained a chemical substance capable of causing death. This was the subject of a global alert and had already been recalled from markets including Portugal. The toy under consideration was referred to as Bindeez and it allowed children to form certain objects (drawings) by assembling colourful balls. In Portugal, the toy was distributed by 'Concentra', which claimed that it had asked its customers to return the product. Concentra's director Miguel Feist made statements to the newspaper 'Expresso' that from the 10,000 Bindeez toys which were sent to Portugal only 1,000 were being traded (published in www.aeiou.pt, 10 November 2007).
- The consumer protection association 'DECO' advised on 24 August 2007 that, during the course of the preceding week, it had visited ten retail outlets in the greater Lisbon area and discovered that the Telheiras Carrefour supermarket continued to sell 'one of the toys which was supposed to not be on sale any longer': the 'Roda da Moda Polly' (Polly's Fashion Wheel). This was denied by the supermarket in question which said that the item being sold had a different reference number to the one which was recalled from the market. DECO also stated that it had warned the supermarket of the situation during an enquiry which it undertook of several shops in Lisbon, having also alerted Mattel and ASAE on the same occasion. However, the supermarket also denied this information (published in © 2007 'LUSA – Agência de Notícias de Portugal, SA' 24 August 2007; 'Deco Proteste' updated in September 2007).
- The summer of 2007 was marked by three recalls of Mattel's toys. Since August, Mattel has undertaken three further voluntary recalls of toys which presented problems. First, in August 2007, it announced a recall of certain products which were being manufactured by one of its subcontractors in China and which had

a pigment of ink containing lead; these products included the doll 'Dora, a Exploradora' (Dora, the Explorer), the Tube with Three Figures, 352 units of which were sold. Less than two weeks later, Mattel announced a new recall. This time, a toy belonging to the series of metal vehicles 'Cars' was involved, the character 'Sargento' (Sergeant), which was manufactured between May and July 2007 containing high levels of lead. In addition, Mattel announced that it was to proceed with a voluntary recall of some magnetic toys manufactured between January 2002 and 31 January 2007, which included some dolls, figures, groups of playing items and respective accessories, in respect of which small but powerful magnets were at risk of falling off/becoming loose. In Portugal, this action included 22 Polly Pocket toys, three Doggie Day Care toys and a Barbie doll

accessory. The third recall, undertaken in September, included seven Barbie doll accessories (such as a dog, a cat and some toy food) and three products of Fisher-Price GeoTrax (two trains and one musical instrument). None of these items were for sale in Portugal. In Portugal, as elsewhere, the procedure was quite straightforward: Mattel informed the media about the various recalls and placed information in a section on its international website regarding the recalls. A telephone helpline number was available for parents to call if they had any worries and to find out what they should do in order to obtain a toy replacement. Sara Marçal, the company's marketing director, reported that many calls, letters and e-mails were received at the time (published in 'Meios e Publicidade' 28 September 2007).

SWITZERLAND

Mattel and the coffee pot

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Mattel's extensive product recalls last autumn did not spare the Swiss market. Around 100,000 toys produced by Mattel had to be withdrawn due to their health hazards for children. However, although the safety hazards of toys produced in China were first widely publicised through the Mattel recalls, a number of other products had to be withdrawn from the market subsequently. In November 2007, the so called 'Bindeez Magic Pearls' also had to be removed from the shelves. The beads that children used for designs and handicrafts were coated with a chemical substance which, when swallowed, converts into a powerful sedative putting the children's health at risk.

The Swiss authorities have been working on a revision of the product safety law for a number of years already. The first and foremost criticism raised with regard to the present legislation is the fact that there is no obligation for companies in Switzerland to recall dangerous non-food products and that the authorities have no possibility to intervene as is the case in the EU. One main request in this respect is that Switzerland joins RAPEX, the European rapid alert system for dangerous non-food consumer products. In spring 2007, the Federal Council of Switzerland announced a revision of the Federal Statute on the Safety of Technical Equipment and Installations of 19 March 1967, which will now be developed into a new general Statute on Product Safety. In Switzerland product safety is presently

regulated by a multitude of sectoral or product specific laws and regulations. In the case of a large number of consumer goods, Swiss law corresponds to that of the EU, and a lot of products are covered by the Bilateral Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment which entered into force on 1 June 2002. There is also a regular exchange of information between the EU and the Swiss authorities regarding non-compliant products and the measures taken in each case. With the new directive on general product safety, the EU also harmonised the safety requirements for consumer goods. It is the Swiss legislator's aim to eliminate all existing divergences with the European directive in the new law on product safety in order to allow Switzerland to adhere to RAPEX at a later stage. Each RAPEX member country has a National Contact Point through which it receives and distributes all reports of hazardous consumer goods issued by other national authorities.

It is to be assumed that the numerous product recalls of toys produced in China have exerted a catalysing effect on the efforts to improve product safety legislation. As a direct consequence of the recalls, the Swiss Ministry of Health ordered a testing campaign to be carried out at the Swiss borders by the customs authorities in summer/autumn 2007 with a view to obtaining an overview of the safety of the toys imported

to Switzerland. The toys arriving at the customs were examined thoroughly (ie, checked for flammability, physical characteristics, lead content, diluents and other chemical substances). The tests concentrated mainly on plastic toys originating from China. All the toys complied with the guidelines regarding lead content; some contained forbidden diluents, which however did not constitute a serious health hazard. Several toys did not carry all the necessary warnings. Despite this unexpectedly positive result, the Ministry announced that it would submit toys in future to further random checks. The present Swiss legislation lays the bulk of the responsibility on manufacturers, importers and dealers. They have to assume the responsibilities foreseen by the law and ensure that the products that they market are safe. The producers and importers of goods have to be in a position to produce a declaration of conformity at any time confirming that the products comply with the prevailing sectoral and product specific regulations. It is likely that more inspections will take place in future to verify the compliance with this self-control and to ask for the declaration of conformity.

When a hazardous product causes an accident, the Swiss Product Liability Act of June 18 1993 (PLA), regulates the rights of the injured party as well as the liability of the manufacturer, importer and dealer. The PLA largely adheres to the principles of the European directive on product liability. In a groundbreaking decision taken recently by the Swiss Federal Court (BGE 133 III 81, the 'Coffee pot decision'), the definition of a product defect was clarified. The case involved a glass coffee pot manufactured in China which burst in the hands of the user causing serious injuries. According to Art. 4 of the Swiss Product Liability Act, a product must show the safety features that the general public would rightfully assume it to possess, and that under any circumstances. This includes the presentation of the product as well as the use that one can reasonably assume it will be put to. If a product does not fulfil these expectations, it is defective and therefore unsafe in the sense of the PLA. The manufacturer as well as, to the same extent, the person or company who puts the product in circulation are strictly liable to

pay compensation for damage caused by this defect irrespective of any fault, ie, they cannot absolve themselves from liability by saying they applied the necessary care when developing and manufacturing the good. The victim of an unsafe product does not have to prove the exact origin of the defect in order to establish liability. This confirms the newly adopted standpoint that the concept of defect and safety is no longer defined by the design and manufacturing but by the use of a good. This new development has already had consequences in contract law as well. In another decision arrived at recently (Case 4C 321/2006, 1 May 2007), the Swiss Supreme Court stated that absence of the safety which one may legitimately expect from a product entitles a buyer to challenge the sales contract based on the concept of fundamental error. The decision dealt with the purchase of an auto-hoist which collapsed sixteen months after purchase without any external reason. Ulterior tests showed that the auto-hoist collapsed repeatedly without any external reasons, which led the Court to rule, based on the definition of defect provided in Art 4 of the Product Liability Act, that the assumed safety of the product constitutes a fundamental element of the sales contract, absence of which entitles the buyer to cancel the contract and reverse all transactions. The question is whether this decision will pave the way for producers of consumer goods such as Mattel to cancel and reverse their agreements with third party suppliers based on the concept of fundamental error, if the supplied products reveal to be unsafe.

Along with the mentioned developments in legislation, the recent recalls of toys produced in China show that companies that manufacture consumer goods abroad, especially in so called low wage countries, and put them in circulation in Switzerland, have to reckon increasingly with being made liable for the safety of these products beyond their non-contractual liability. As a result of the new developments in legislation and case-law referred to earlier, the legal hurdles the injured parties face when trying to claim their rights from product liability have diminished noticeably.

The Mattel toy recalls: the aftermath in the United States

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In August and September 2007, Mattel announced several recalls of toys that either contained excessive lead in paint or magnets that could be ingested. Over ten million units were recalled which makes this one of the largest recalls ever to be announced in the United States. The effects in the United States were immediate and profound. Beyond the hysterical saturation coverage given to them by the media, the recalls significantly impacted the pending CPSC reauthorisation legislation as well as state legislation. It created a wave of class action lawsuits and raised shareholder litigation issues for the company.

The US Consumer Product Safety Commission (CPSC) had not been reauthorised by Congress in over 15 years. In 2007, the newly elected democratic majority began to hold oversight hearings on the CPSC with the goal of drafting reauthorisation legislation in 2008. After the announcements of the RC2 and Mattel recalls, the drafting process accelerated and the hearings took on a harsh tone. Both the Senate and House Committees berated CPSC and the top management of these companies for failing to protect children from 'unsafe imports'. That became the battle cry for various consumer groups, plaintiff lawyers, and labour unions to demand a drastic overhaul of the Commission's statutory authority.

While final legislation will not be passed for another month or so, it is clear that it will contain a number of far-reaching changes. All children's products will have to be tested and certified by a third party testing laboratory as compliant with the various CPSC standards and regulations. Trace levels of lead in any children's product cannot exceed 100 ppm. Lead in paint is reduced to 90 ppm. The current requirement that the lead in a children's product be bio-available has been struck. To facilitate easy identification of recalled products, manufacturers of children's products must mark each product so the purchaser can ascertain the manufacturer, production time period and batch or run number. Durable children's products must be sold with a consumer product registration form so that the manufacturer can create a database of purchasers to notify in the event of a recall. The database must be maintained for a minimum of six years from the date of manufacture of the product.

Manufacturers, distributors and retailers of consumer products have been affected by a number of other provisions. The number of prohibited acts subject to civil and criminal penalties has been increased as well

as the cap on civil penalties – from US\$1.85 million to US\$20 million. Criminal penalties have been increased to imprisonment for five years and extended to include directors, officers, and agents (presumably including lawyers) even when they have no knowledge that the company's products fail to comply with a federal safety standard. Federal preemption of state and local requirements has been scaled back, opening the door to multiple government regulation of consumer products. CPSC is directed to create a public database containing all consumer complaints and other third party information on consumer products. Importers, retailers and distributors must be able to identify for CPSC the identities of the foreign manufacturers of the product and any of its component parts, including raw materials. Manufacturers and distributors of consumer products may be required to post an escrow, proof of insurance or other security to cover the cost of an effective recall, including the cost of holding the product and then destroying it.

The most controversial provisions are two that would expose manufacturers, importers, distributors, and retailers to more litigation. One would allow the State Attorneys General to enforce all of the rules, regulations, standards, and requirements of the CPSC and recover costs and attorney fees from the manufacturers, distributors and retailers. The other would create protection for whistleblowers from discharge and allow recovery of compensatory and consequential damages, attorneys' fees and expert witness fees, court costs and punitive damages.

Taking their cue from Congress, various state legislators jumped into the battle to protect children from unsafe imports. Illinois passed a statute that banned lead in excess of 600 ppm in children's products and enforced that measure against a number of toy manufacturers whose products were found to have vinyl or other plastic parts that contained lead in excess of that amount. CPSC took the position that the law was valid and not preempted because no federal standard existed that established a lead level for vinyl toys. Michigan enacted several laws that prohibit the sale of toys with lead exceeding 600 ppm, and vinyl lunchboxes containing lead, and require labelling for lead in some consumer products. This is the beginning of the 'balkanisation' of product safety laws which will only make it more difficult for manufacturers to sell goods in a global marketplace.

Federal and state government actions aside, Mattel

faced a plethora of litigation after the announcement of these recalls. Almost immediately a class action suit was brought by a mother who sought a medical monitoring programme for all children who played with the recalled toys made with lead paint. Hundreds of other personal injury suits followed. Several shareholder suits were also filed by pension funds against the Mattel board of directors alleging that the board intentionally failed to report the defective toys to CPSC in a timely manner so that the chairman of the board and CEO and other insiders could unload large blocks of stock valued at US\$33 million. The suits asked the court, among other things, to require the defendants to disgorge any profits

made on their insider sales and return those funds to the company coffers. The Mattel litigation is pending but RC2 that recalled its Thomas the Tank product for paint with high lead levels recently settled a number of class actions for US\$30 million.

The fallout from the Mattel recalls is not complete. The Toy Industry of America in conjunction with the American National Standards Institute just announced a new improved conformity assessment programme to ensure the safety of toys. Because this is being done under the auspices of ISO/IEC 17011, it could impact manufacturers, distributors and retailers in countries other than the United States.

AUSTRIA

Decision on keyword advertising

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In a recently published decision, the Oberster Gerichtshof (Austrian Supreme Court, OGH) has dealt with the permissibility of keyword advertising (17 Ob 1/07 g). The claimant was an Austrian wine retailer, operating establishments under the name 'Wein & Co' (Wine & Co), which name is protected as a national and international word-device trademark. The claimant also operates an online shop under www.weinco.at. The respondent was a supermarket chain which had booked 'Wein & Co' as search keyword on Google. Therefore, the link to the respondent's online shop was shown on top of any search results containing this keyword and also shown before the link to the claimant's website. Furthermore, the respondent's advertisement was titled 'Wein & Co'.

The claimant demanded omission on grounds of trademark infringement and unfair competition. He challenged both the respondent's use of 'Wein & Co' as title of the advertisement and as search keyword for the respondent's own webshop.

The OGH granted both claims and stated that confusion due to the respondent's use of the claimant's trademark as title for his advertisement was obvious. Furthermore, the court decided that even using 'Wein & Co' as a keyword, which led to the respondent's website being displayed above the claimant's website, was confusing. The small print automatically added by Google above the results, stating that the respondent's top-ranked page was an advertisement, was not regarded as sufficient to remedy the confusion and the trademark infringement.

The consumer credit jurisdiction of the Financial Ombudsman Service

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With effect from 6 April 2007, the jurisdiction of the Financial Ombudsman Service ('FOS') was extended to apply to holders of consumer credit licences. FOS now has compulsory jurisdiction over approximately 100,000 such businesses, in comparison with the 8,000 when they were set up. FOS is a dispute resolution body with the aim of resolving disputes between consumers and financial services firms. FOS is not a regulator nor is it a consumer champion. Each year FOS deals with half a million enquiries and settles around 100,000 disputes. It aims to settle eight out of ten disputes within six months. Whether it will be able to meet this objective with its increased jurisdiction remains to be seen.

FOS will not deal with complaints about events that happened before 6 April 2007 but may need to refer, during their investigations, to pre-April 2007 events in order to determine a complaint about something that happened after 6 April 2007.

The territorial scope of the jurisdiction of FOS covers complaints about the activities of a business carried on from an establishment in the United Kingdom but a complaint can be dealt with irrespective of whether the complainant lives in, or is based in, the United Kingdom.

FOS's key role is to resolve complaints in a way that is impartial, fair, accessible and free to customers and to award redress where appropriate.

FOS will not examine a complaint until the business itself has had an opportunity to deal with it. Businesses must, therefore, with effect from 6 April 2007, have in place an effective in-house complaints-handling procedure, which must be in writing. The business must also display a notice in their branches or sales offices showing that the business is covered by the Financial Ombudsman Service.

Once a complaint is made to the firm a prompt written acknowledgment must be issued, the complainant must be kept informed of the progress of the complaint and a final written response to the complaint must be issued to the complainant within eight weeks.

The rules set out what must be covered in the final response letter and this includes the outcome of the investigation carried out by the firm, whether they acknowledge any fault, details of any offer being made and details of FOS.

FOS does not generally deal with complaints where more than six months have passed since the business sent the consumer its final response letter. Also if more than six years have passed since the event the complaint relates to or if later, it is more than three years since the person complaining first became aware of the problem, FOS is unlikely to become involved. However, it does have discretion to waive these time limits in limited circumstances.

The complaint will be determined by reference to what the Ombudsman considers 'fair and reasonable in all the circumstances of the case'. In deciding what is 'fair and reasonable' the Ombudsman can take into account all the circumstances of the case and the complaint need not be a breach of the Consumer Credit Act or the law. FOS will, in considering the complaint, take account of the relevant law, regulator's rules and guidance, relevant codes of practice and good industry practice at the relevant time.

FOS can award compensation up to £100,000 which can include damages for pain and suffering, distress and inconvenience and damage to reputation and their decision can be enforced through the courts. Consumers do not need to accept the Ombudsman's decision but if they choose to then it is binding both on the complainant and on the business.

Consumer credit businesses are having to adapt to this new complaints regime. Whether business considers it a help in resolving disputes or a hindrance, will depend on the FOS being objective and on their dealing with complaints fairly and expeditiously.

Recent developments in Swedish marketing law

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Directive 2005/29/EC and the Swedish Marketing Act

Directive 2005/29/EC on Unfair Commercial Practices ('the Directive') was signed by the European Parliament and the Council on 11 May 2005. The aim of the Directive is to promote the inner market to function correctly and to secure a high level of consumer protection by approximation of laws and other constitutions in the Member States regarding unfair commercial practices that harm the consumer's economic interests.

When comparing the Directive with the current Swedish Marketing Act (1995:450) it first seems there are not that many differences. However, the Marketing Act specifies the commercial practices allowed. The Directive describes what does not constitute correct commercial practice. Another difference is that the Marketing Act includes transactions both from business to business and from business to consumers. The Directive solely includes practices from business to consumers and not commercial practices that can harm other businesses. The Misleading and Comparative Advertising Directive¹ will be applicable on business-to-business misleading advertising and comparative advertising which may harm a competitor but where there is no direct consumer detriment. The Misleading and Comparative Advertising Directive has previously been implemented in the Swedish Marketing Act. The Directive, in distinction to the Swedish Marketing Act, also comprises measures taken by businessmen after entering an agreement, eg information regarding the statutory time limit for complaints.

The Directive will be applicable where there are no specific regulations regarding unfair commercial practices in sector specific legislation. Where such specific provisions do exist they will have precedence over the Directive, for example EU regulation concerning provisions on pharmaceutical products.

Even though the Directive in most parts corresponds with current Swedish legislation, the implementation entails some necessary changes and amendments. In consequence, a new Marketing Act will be necessary. The new Act is expected to enter into force on 1 July 2008.

Forthcoming legislation on gender discriminating advertising

Neither the current nor the new Swedish Marketing Act comprises rules regarding gender discriminating

advertising. Therefore a commission was appointed by the Swedish Government in 2006 to survey the development and extension of such advertising in Sweden. The commission has recently handed over a proposal to the government, reaching the conclusion that legislation is necessary. The proposal aims at promoting equality between men and women by banning discriminating marketing practices. The proposed Act shall ban marketing presenting gender characteristics or gender roles in a way that generally is considered discriminatory for women or men. The concept of 'generally' shall correspond with the common view among the receivers of the marketing message. In such cases the typical reaction such a message creates shall serve as guidance.

The proposal has started a debate in Sweden as to whether a specific law is necessary or if market forces can take care of the problem if there is one. The new Act on gender discriminating advertising is proposed to enter into force 1 January 2009. The discussion will carry on.

Comments

The main purpose of the Directive is to enable more uniform regulation within the European Union. This is of course a sound purpose since it would lead to a simplified process for traders when marketing their products and services throughout Europe. However, there are still some obstacles to overcome before harmonisation is fully achieved.

The Directive solely treats unfair commercial practices that harm consumers' economic interests. Thus, legislation that protects other non-economic consumer interests, which can be affected by the use of commercial practices, is not covered by the Directive. This means that commercial practices regarding eg taste, decency and social responsibility fall outside the scope of the Directive. Regarding such commercial practices the Member States are free to enact legislation that diverges from the provisions of the Directive, however, only providing that the legislation is in accordance with other EU regulations. As mentioned a proposal for gender discriminating advertising, which is a sector that the Directive does not treat, has been presented in Sweden. However, these kinds of commercial practices are assessed in widely divergent ways throughout the European Union. Marketing legislation will therefore still diverge among the European countries and this consequently will lead to continued problems with cross-

border transactions. In a market that often demands quick decisions and where time is of the essence when marketing a new product it is an obstacle for businesses when they cannot, without extensive legal consultancy, market their products throughout Europe and be sure that they will be assessed uniformly in all countries. The idea of having a harmonised set of rules throughout

Europe, or at least within Scandinavia, is a very good one. But we are not there yet.

Notes

- 1 Council Directive of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (84/450/EEC).

TURKEY

Healthy food trend; now in Turkey as all over the world

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Obesity, a worldwide hot topic and one of today's most debated health problems, has already preoccupied many governments, and now Turkey has joined the club. Obesity, determined as 'a condition in which the natural energy reserve, stored in the fatty tissue of humans and other mammals, is increased to a point where it is associated with certain health conditions or increased mortality',¹ is an individual clinical condition, now considered a serious public health problem which is rapidly growing. Many countries eg the United States, United Kingdom and Canada, have already taken action limiting access to junk food in school cafeterias, stopping junk food advertisements, forbidding the use of cartoon characters in junk food packaging, regulating online junk food advertisements etc. To ensure compliance with these measures, committees such as Canada's Children's Clearance Committee have been established, with powers to examine and ban junk food advertisements for children.

In Turkey, following research conducted by the Ministry of Health in 2004, the obesity rate was revealed to be 30 per cent. The Minister made a declaration requesting that advertisements for confectionery, chocolate, chips, wafers and coke were to be aired after 2130 and requested the Advertising Board to take the necessary precautions on the issue. However, lack of legislation prevented the Ministry from pressing further with the matter.

Nevertheless, three years later, in early 2007, regulations aimed at decreasing and preventing the obesity problem were enacted in relation to school cafeterias and food packaging labelling. According to a circular recently issued by the Turkish Ministry of Education (TME) an article deterring the vending of energy drinks, fizzy drinks, cokes, flavoured drinks, fried foods (eg fried potatoes) and chips while encouraging

the selling of milk, ayran (drink made of yoghurt and water), yoghurt, fruit juice, vegetable juice, fruit and vegetables must be added to every school cafeteria lease agreement. The circular also bans advertisements, announcements, promotions, presentations, posters and brochures of unhealthy foods in the cafeterias, and requires the school management's consent for display of any material as to what is acceptable as a healthy diet.

According to the School Cafeterias Chamber chairman's speech assessing the outcome of the circular's impact, progress of 75 per cent on reducing the consumption of chips, cokes and fizzy drinks was achieved due to the food education programme in conjunction with the parent-teacher associations and students. However, the chairman also stressed the insufficiency of these prohibitions in solving or alleviating the obesity problem.

Another regulation was made by the Ministry of Agriculture concerning trans fats and packaging labels. According to the Ministry's newly released communiqué, the 'no trans fat' phrase could only be used on packaging for products with a trans fat proportion not exceeding one per cent.

As a result of these new regulations and the increased trend for healthy food worldwide, producers in Turkey started to explain the healthy character of their products. This has led to the emergence of new marketing strategies eg nowadays advertisements also emphasise whether the product was 'baked' or 'fried'. Moreover blatant changes in consumer preferences are observed; parents look for healthier foods for their children, and seem to buy fewer foods containing excessive amounts of fat, salt or sugar which have minimal nutritional values.

Finally, considering Turkey's harmonisation to EU legislation, enactments on the matter and changes on

consumer reactions will continue especially with the entry into force of the new EU Directive on Television Without Frontier including new provisions on junk food.

Notes

1 <http://en.wikipedia.org/wiki/Obesity>

UNITED STATES

Global trade and regulatory oversight: are uniform product safety standards on the horizon?

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Introduction

While consumer product recalls made headlines internationally in 2007 and generated considerable congressional and administrative attention in the United States, US product safety agencies have for some time systematically entered into agreements with their counterparts in other nations to create mutual obligations related to sharing information about product risks. For example, under such agreements, if a consumer product fails in Greece, information about that failure will, in theory, be rapidly transmitted from country to country until Mexican or Chinese regulators learn about the problem and presumably take some corrective action.

These agreements also impose obligations to exchange information and expertise as a means to further the development of compatible product safety standards. Thus, product safety standards adopted in one nation are likely to spread throughout this network and may subsequently be applied to products wherever they are manufactured and sold. In fact, among the initiatives undertaken by the US Consumer Product Safety Commission (CPSC) in 2007 was to translate nearly 300 US safety standards into Chinese to familiarise Chinese manufacturers with US product safety requirements.

The US Department of Health and Human Services took an even more aggressive step in December 2007, entering agreements with the People's Republic of China regarding drugs, medical devices, food, and animal feed that go beyond mere information sharing to the establishment of registration, certification and inspection programmes. While such developments present new challenges to consumer product manufacturing interests, they also provide new opportunities. And more recently, the Food and Drug Administration commissioner indicated that his agency,

with jurisdiction over the safety of foods, drugs, medical devices, and cosmetics, is considering establishing a presence in US embassies in targeted regions (China/Asia, India, Europe, Central and South America and the Middle East) to ensure the quality and safety of exporting countries' products.

This article describes how the CPSC functions in the US market and explores the lead this independent federal agency has taken by forging agreements with the European Union and individual countries across the globe. In 2006, the agency established a programme office dedicated to such initiatives and to 'exportation' of CPSC regulatory policies, technologies and methodologies into other jurisdictions. The potential impact of this globalisation of regulatory oversight is further analysed from the perspective of product liability.

Some recommend shifting liability up the supply chain via contract provisions with indemnification, buy back, insurance, and arbitration provisions, and these can provide effective protections when the courts in other countries recognise their validity. It is suggested, however, that manufacturers can potentially benefit when their products must comply with a uniform set of standards to gain entry into any international port. Thus, this article concludes with recommendations designed to help product manufacturers successfully engage in and benefit from this emerging regulatory paradigm.

US product regulation

The CPSC is an independent federal agency with authority to regulate the safety of more than 15,000 consumer products, excluding automobiles, alcohol, boats, cosmetics, drugs, food, pesticides, firearms, and tobacco.¹ Its mission is to protect the American public

authority to regulate the safety of more than 15,000 consumer products, excluding automobiles, alcohol, boats, cosmetics, drugs, food, pesticides, firearms, and tobacco.¹ Its mission is to protect the American public from unreasonable risks of injury and death from products within its purview.

The agency is headed by a three-member commission appointed by the President with the advice and consent of the Senate. It accomplishes its mission by identifying product hazards and taking steps to reduce those hazards. The agency develops and enforces mandatory and voluntary standards, conducts consumer outreach and education, and employs enforcement mechanisms that include product recalls and litigation. Under the Consumer Product Safety Act (CPSA), consumer product manufacturers, importers, distributors, and retailers are required to report to the CPSC product defects that could create a substantial product hazard. The CPSC also researches potential safety hazards.

With recent annual budgets around US\$66 million and with nearly 400 full-time employees, the CPSC is charged with reducing the 28,000 deaths and 33.6 million injuries related to products within its jurisdiction that occur each year in the United States at a cost of more than US\$800 billion.²

Concerns about the safety of consumer product imports and a desire to help US businesses compete in a global marketplace led the CPSC to begin a sustained campaign of reaching out to counterparts in other nations by means of agreements that obligate the parties to cooperate in improving product safety by:

- exchanging scientific, technical and regulatory information to help ensure the quality, safety and proper labelling of consumer products;
- exchanging information about emerging issues of significant public health and safety;
- addressing safety problems of consumer products manufactured in either the United States or the other country and sold in the other participating country; and
- participating in the training of laboratory and inspection personnel of both countries.

Nations entering agreements of this nature with the CPSC since 2004³ include China, Taiwan, Japan and Korea (Pacific Rim); Mexico and Canada (North America); Chile and Peru (South America); Costa Rica (Central America); India (Asia); Israel (Middle East); and the European Union (Europe) – major trading partners representing nearly all global regions. These agreements are intended to ‘establish closer working relationships between the signatories [and] provide for a greater and more significant exchange of information regarding consumer product safety . . .’⁴ The CPSC intends to make active use of these existing agreements and to enter into similar agreements with additional countries in the future.⁵

The CPSC underscored its commitment to this initiative when it created its Office of International

Programs and Intergovernmental Affairs in February 2006.⁶ With a stated goal of harmonising ‘the use of standards worldwide’, the office is charged with coordinating ‘efforts with other countries regarding safety standards development and harmonization, and inspection and enforcement coordination’.⁷ The office also works to ensure greater import compliance with recognised American safety standards and to promote CPSC regulatory policies, technologies and methodologies in other jurisdictions.

Regarding the standards development prong of the CPSC’s regulatory approach, Congress has mandated that the agency adopt the voluntary product standards developed by Standards Development Organizations (SDOs) rather than develop its own mandatory standards, if the agency determines that the voluntary standard will eliminate or adequately reduce an injury risk and substantial compliance is likely.⁸ According to Congress, the voluntary approach can provide ‘significant advantages over adversarial rulemaking’.⁹ And the agency has complied by working with industry and others to develop or revise 390 voluntary standards and issuing only 38 mandatory rules between 1990 and 2007.¹⁰ Experience demonstrates that the regulated are more likely to comply with regulations they have had a hand in developing, which thereby results in more effective and efficient regulation.

In July 2006, the agency published a final rule that continues and expands a pilot programme through which the public is notified and given an opportunity to comment on CPSC staff positions relating to the agency’s voluntary standards activities.¹¹ The CPSC also issued a final interpretative rule that, among other matters, indicates that compliance with voluntary product safety standards ‘may be relevant to the Commission staff’s preliminary determination of whether that product presents a substantial product hazard under section 15 of the CPSA’.¹²

In light of the CPSC’s increasing reliance on the voluntary standards developed by private SDOs and its incursions into the international regulatory environment, the trend toward uniformity in product safety regulation is only likely to continue. But it remains to be seen whether this outcome is desirable. For some manufacturing interests, this is a welcome development because it will mean that one reasonably uniform product along with its labelling (ie warnings and instructions for use) will be acceptable in multiple markets and, therefore, costs of cross-border compliance will be correspondingly reduced. Others are more sceptical, with concerns about the possible export of stringent liability standards along with regulatory requirements that favour local (ie competitive) interests.

Either way, consumer product manufacturers would be well-advised to monitor the activities of SDOs that develop product safety standards with the potential to be appropriated by regulatory authorities in other countries and established as applicable industry

from unreasonable risks of injury and death from products within its purview.

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safety standards development and harmonization, and inspection and enforcement coordination’.⁷ The office also works to ensure greater import compliance with recognised American safety standards and to promote CPSC regulatory policies, technologies and methodologies in other jurisdictions.

Regarding the standards development prong of the CPSC’s regulatory approach, Congress has mandated that the agency adopt the voluntary product standards developed by Standards Development Organizations (SDOs) rather than develop its own mandatory standards, if the agency determines that the voluntary standard will eliminate or adequately reduce an injury risk and substantial compliance is likely.⁸ According to Congress, the voluntary approach can provide ‘significant advantages over adversarial rulemaking’.⁹ And the agency has complied by working with industry and others to develop or revise 390 voluntary standards and issuing only 38 mandatory rules between 1990 and 2007.¹⁰ Experience demonstrates that the regulated are more likely to comply with regulations they have had a hand in developing, which thereby results in more effective and efficient regulation.

In July 2006, the agency published a final rule that continues and expands a pilot programme through which the public is notified and given an opportunity to comment on CPSC staff positions relating to the agency’s voluntary standards activities.¹¹ The CPSC also issued a final interpretative rule that, among other matters, indicates that compliance with voluntary product safety standards ‘may be relevant to the Commission staff’s preliminary determination of whether that product presents a substantial product hazard under section 15 of the CPSA’.¹²

In light of the CPSC’s increasing reliance on the voluntary standards developed by private SDOs and its incursions into the international regulatory environment, the trend toward uniformity in product safety regulation is only likely to continue. But it remains to be seen whether this outcome is desirable. For some manufacturing interests, this is a welcome development because it will mean that one reasonably uniform product along with its labelling (ie warnings and instructions for use) will be acceptable in multiple markets and, therefore, costs of cross-border compliance will be correspondingly reduced. Others are more sceptical, with concerns about the possible export of stringent liability standards along with regulatory requirements that favour local (ie competitive) interests.

Either way, consumer product manufacturers would be well-advised to monitor the activities of SDOs that develop product safety standards with the potential to be appropriated by regulatory authorities in other countries and established as applicable industry standards of care in the world’s marketplace and courtrooms. They should also strongly consider finding more direct ways to participate, by submitting comments to the CPSC or actively joining SDO technical committee

deliberations,¹³ for example.

International regulatory mechanisms – the role of SDOs

The International Organization for Standardization (ISO) is an organisation with the potential to bridge product safety differences between nations. In recent years, ISO has begun to pay more attention to consumer products and has developed a new family of standards on toy safety.¹⁴ ISO established a Consumer Policy Committee that has called for the development of an international standard that would provide guidance on how to identify, assess and eliminate or reduce risks associated with consumer products generally. This committee has proposed the adoption of an international standard on the establishment, implementation and management of a consumer product recall programme.¹⁵

ISO has also formed a technical committee (ISO/TC 229) dedicated to developing standards that will address nanotechnologies used in consumer products, and one of its working groups will focus on health, safety and environmental issues.¹⁶ With more consumer products, like sunscreens, cosmetics, medical devices, cleaning products, dishware, clothing, and food packaging, incorporating nanomaterials, SDOs are likely to be in the vanguard when nanotechnology standards are developed.¹⁷

ISO's focus on the harmonisation of consumer safety standards is important for at least two reasons. First, under World Trade Organization (WTO) rules, national standards must be based on international standards if they exist. ISO is the premier organisation issuing international standards on which national standards are based. Secondly, ISO cooperates with SDOs in the development of national voluntary standards. The American National Standards Institute (ANSI) is the US representative at the ISO table.¹⁸

A case in point – pictograms

Faced with dozens of languages by which to provide product warnings in global markets, product manufacturers have been working with organisations such as ISO to develop universal symbols to convey safety information. A quick glance at a product as commonplace as a laptop computer's AC adapter readily shows how such initiatives are already having cross-border effects. Manufactured in China and sold in the United States, a typical adapter has a label with several pictograms warning of electric shock (a triangle with a jagged vertical line ending in an arrow) and explaining the product's usage (a house silhouette with an arrow pointing to its interior). ISO Technical Committee 145 is actively developing standards to universalise the symbols used in safety signs and warnings. Fifteen nations have actively collaborated in this effort, with another 31 nations participating as observers.¹⁹

As a result, the committee's work product is being implemented worldwide.²⁰ It is worthwhile to note, however, that pictograms cannot be viewed as a panacea for the problem of providing consistent warnings across multiple languages due to inevitable variations in interpretation. Nevertheless, they are emerging as one useful tool in the international provision of warnings information.

Product standards and the duty of care

In addition to the financial and logistical burden of complying with different safety regulations, requirements or standards in different countries, many consumer product manufacturers are concerned that such differing compliance will create ammunition for product liability litigants who could claim that the reasonable alternative design available in another country was not available in their country. The allegation will be that the failure to incorporate the 'foreign' product feature renders the product defective or such failure constitutes negligence on the manufacturer's part. The difference between the United States and foreign product design features may simply be the result of mandatory and competing regulatory regimes. Fortunately, US courts generally do not allow the introduction of international designs, warnings or standards in products liability cases.²¹ Still, this risk may be reduced or eliminated for manufacturers that sell products worldwide through the globalisation of product safety standards.

It should be noted, however, in the interests of being thorough, that evidence of US domestic industry or other voluntary standards is permitted in more than a few US jurisdictions by either plaintiffs or defendants.²² Compliance or non-compliance with standards may provide at least some evidence as to whether the product was defective (in the case of strict liability), or the defendant was negligent.

Conclusion and recommendations

Enhanced international communications about product safety, product safety standards and regulatory schemes are beginning to benefit consumers to the extent that product safety information is becoming more readily available and disseminated globally. Yet, manufacturers, distributors and others in the commercial stream are facing regulatory compliance and product liability concerns that cross borders in ways not previously envisioned.

Without question, the internationalisation and harmonisation of product safety standards will continue, and this trend will have an impact on the development of product liability litigation in the United States and elsewhere around the globe, as courts take compliance with product safety standards into account when making decisions about product defects or manufacturer

of product liability litigation in the United States and elsewhere around the globe, as courts take compliance with product safety standards into account when making decisions about product defects or manufacturer liability. With new challenges, however, come new opportunities. By establishing best manufacturing practices, monitoring applicable standards development activities and taking action to influence standards development in a way that provides a measure of control over the future business environment, a consumer product manufacturer will be well situated to compete in the global marketplace.

Certainly, in one light, consumer product safety harmonisation initiatives can be viewed by manufacturers as a serious threat – one complaint in one country concerning one product can travel the world and have regulatory and, perhaps, liability implications in ‘virtual’ time. To the extent, however, that ‘one world/one product’ is a strategic objective for any manufacturer, the harmonisation of product safety standards may well present substantial opportunity. Clearly, it is not economical to develop products to meet the different regulatory requirements of every country.

As ISO would have it, ‘one standard, one test’ for products can minimise the costs associated with research and development, design, manufacturing, labelling, and sale of products. And thus, the harmonisation of standards would benefit any company exporting products for sale in the global marketplace. The benefits would be more significant for multinational companies that research, develop, manufacture, assemble, and sell products globally. Moreover, manufacturers benefit to the extent that harmonisation results in fewer non-tariff-based impediments to trade and, potentially, reduces litigation and related expenses. Consumers also benefit from such harmonisation through better products which carry better information at a price that reflects the economies introduced by harmonisation.

Based on the foregoing, it is suggested that whether or not manufacturers elect to embrace the globalisation of product safety systems and standards, they should recognise the need to actively participate in the process. Some companies may wish to simply monitor the development of standards and other regulatory developments – this much is essential. More so, it is strongly recommended that manufacturers consider finding more direct ways to participate in the process – by joining or actively working with SDO committees, participating in the ISO technical committees (of which there are more than 225) or otherwise engaging in the standards development and harmonisation process. Doing so can only improve the quality of the regulatory schemes and provisions that will be applied to consumer products. Opportunities for participation can be identified when the CPSC publishes notices in the Federal Register about its meetings and rule-making activities. Similarly, ISO’s website can be reviewed for opportunities to actively participate in initiatives

of the technical committees that develop standards. The same is true for other SDOs such as Underwriters Laboratories, to name just one of the more than 200 SDOs accredited by ANSI.

It will take time and effort to actively participate in these standards development activities or to stake out a position in the international arena. The payoff, however, is the potential for the development of one uniform international standard and, thereby, one uniform product for the global marketplace that furthers a manufacturer’s desire for a level playing field in the marketplace and in the courtroom, both locally and globally.

See *eg* *DiCarlo v Keller Ladders, Inc*, 211 F3d 465, 468 (8th Cir 2000) (allowing defendant to introduce evidence that ladder from which plaintiff fell complied with ANSI standards); *Moulton v Rival Co*, 116 F3d 22, 26 (1st Cir 1997) (allowing admission of evidence that potpourri pot probably did not meet relevant safety standards).

Notes

- * Marc E Shelley, Associate, and Dale E Walker with Shook Hardy & Bacon LL Fall Out Boy P, contributed significantly to this article, and their excellent efforts are gratefully acknowledged.
- 1 Congress created the agency in 1972 with passage of the Consumer Product Safety Act, 15 USCA §§ 2051-2085 (1998 and Supp 2006). The agency also administers the Flammable Fabrics Act, 15 USCA §§ 1191-1204 (1998), the Poison Prevention Packaging Act, 15 USCA §§ 1471-1476 (1998), the Federal Hazardous Substances Act, 15 USCA §§ 1261-1278 (1998), and the Refrigerator Safety Act, 15 USCA §§ 1211-1214 (1998). The excluded product categories are within the bailiwick of other federal agencies.
- 2 CPSC, 2007 Performance and Accountability Report i, 3, 13 (2007).
- 3 These CPSC agreements are variously referred to as a ‘Memorandum of Understanding’, an ‘Information Sharing Agreement’ or a ‘Statement of Intent’.
- 4 CPSC, 2007 Performance Budget Request 44 (2006).
- 5 *Ibid*. According to CPSC, the agency was unable to finalise additional MOUs for lack of a commission quorum for six months in 2007; the agency is currently negotiating MOUs with Brazil, Colombia, Egypt, and Vietnam. CPSC, 2007 Performance and Accountability Report 64 (2007).
- 6 Statement of Organization and Functions, 71 Fed Reg 5165 (1 February 2006) (to be codified at 17 CFR pt 1000).
- 7 CPSC, 2007 Performance Budget Request 43 (2006).
- 8 15 USCA § 2056(b) (1998), 15 USCA § 1262(g)(2) (1998), 15 USCA § 1193(h)(2) (1998). The agency is also required to provide administrative and technical assistance to private standards development organisations, 15 USCA § 2054(a)(3) and (4) (1998).
- 9 5 USCA § 521 note (1998).
- 10 CPSC, 2007 Performance and Accountability Report 3 (2007).
- 11 Commission Involvement in Voluntary Standards, 71 Fed Reg 38,754 (10 July 2006) (to be codified at 16 CFR pt 1031).
- 12 Substantial Product Hazard Reports, 71 Fed Reg 30,350 (proposed 26 May 2006) (to be codified at 16 CFR pt 1115). See also US Consumer Product Safety Commission, www.cpsc.gov/volstd/vslinks.html (last visited 28 Jan 2008) (stating ‘failure to meet a voluntary safety standard could lead to a substantial product hazard determination by the Commission and result in a recall’).
- 13 Private standards development organisations (SDOs) in the United States are accredited by the American National Standards Institute (ANSI), which requires that SDO standards be the product of a consensus process that affords interested parties due process and is open and transparent. ANSI also accredits US technical advisory groups that bring the US position on standards issues to the table in international arenas such as the International Organization for

Standardization (ISO). The technical committees and advisory groups that participate in standards development activities are generally composed of individuals representing consumer, governmental, academic, and private business interests. Some standards can take years to develop or revise, and the public is invited to comment as drafting progresses, thus affording the savvy product manufacturer a number of ways to provide scientific or technical input and help shape a final standard.

- 14 See International Organization for Standardization, *Safe Toys for the Children of the World: A Crucial International Standard for Manufacturers and Authorities in All Countries*, ISO Bulletin, March 2000, at 4, available at www.iso.org/iso/en/commcentre/pdf/Safetoys0003.pdf.
- 15 Press Release, American National Standards Institute, *ISO COPOLCO Calls for Measures to Enhance Consumer Product Safety* (7 June 2006), at www.ansi.org/news_publications/news-story.aspx?menuid=7&articleid=1245.
- 16 ISO/TC 229, *Nanotechnologies*, Business Plan 13 (23 April 2007).
- 17 In 2007, nanotechnology had been incorporated into some US\$50 billion worth of manufactured goods, despite the fact that 'no single nano-specific regulation exists anywhere in the world'. See Project on Emerging Technologies, News, www.nanotechproject.org/ (last visited 29 January 2008).
- 18 ANSI adopted a United States Standards Strategy at the end of 2005 that sets forth several goals with an international focus, including (i) 'actively promote the consistent worldwide application of internationally recognized principles in the development of standards', (ii) 'work to prevent standards and their application from becoming technical trade barriers to US products and services', and (iii) 'strengthen international outreach programs to promote understanding of how voluntary, consensus-based, market-driven sectoral standards can benefit businesses, consumers and society as a whole': ANSI, *United States Standards Strategy* passim (2005).
- 19 Geoffrey Peckham, Chair, US ANSI TAG to ISO/TC 145, *New Signs: The Key to Communicating Safety in Buildings*, ARCHI-TECH, May-June 2006.
- 20 ISO Standard 3864-1 sets rules for the colour and shape of safety signage. Thus, warning signs consisting of a yellow triangle with a black outer band, containing a black graphical symbol, provide hazard warnings. A prohibition, on the other hand, is depicted as a circle surrounded in red with a red slash from top left to bottom right over a black graphical symbol.
- 21 See, eg *Deviner v Electrolux Motor*, AB 844 F2d 769, 773-74 (11th Cir 1988) (affirming district court's exclusion of Swedish safety standards for chainsaws to avoid juror confusion); *Garmon v Cincinnati, Inc*, 1993 WL 190923, *2-3 (Tenn Ct App 4 June 1993) (finding no abuse of discretion to exclude evidence of English product safety standards, because 'rules and standards not having the force and effect of law are not admissible as evidence').



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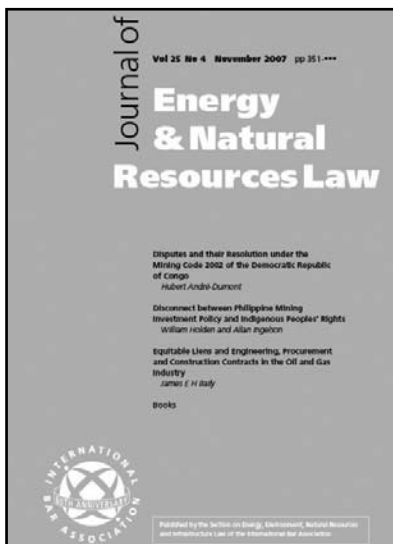
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