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In This Issue

Welcome to the first issue of International News for 2008. In this edition, we focus on China products in response to the growing concern expressed by businesses and the media in relation to this increasingly important supply and manufacturing centre. We also review a number of other subjects relevant to our clients and colleagues.

We start in China with a look at how companies with operations in China should expect continued attention from both the U.S. Government and Chinese law enforcement authorities as they bolster their anti-corruption efforts. Jocelyn Francoeur and David Rosenbloom explain the ways in which, in recent years, both civil and criminal enforcement actions under the Foreign Corrupt Practices Act (FCPA) have grown significantly.

Ken Huang gives an overview of how redress against Chinese exporters or suppliers might be pursued through the Chinese courts. Ryan Smethurst looks at insurance that could protect U.S.-based businesses from having to pursue such a course of action.

Frank Schoneveld then reviews the European Union standpoint on Chinese imports and outlines a number of new initiatives introduced to strengthen the enforcement of EU product safety controls. We stay with this theme as Eric Hargan looks at safety issues in relation to pharmaceuticals and dietary supplements, while Peter Resnik and Emily Smith-Lee examine the situation in relation to food.

Finally, Stephen Ryan and Neil Quinter explain why companies doing business in and with China must be increasingly aware of U.S. congressional involvement.

If you have any comments on this issue or would like to contribute to International News, please contact me at dryder@mwe.com.

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Compliance with FCPA and Anti-Bribery Statutes in China

By Jocelyn Francoeur and David Rosenbloom

In recent years, both civil and criminal enforcement actions under the Foreign Corrupt Practices Act (FCPA) have grown significantly. In 2008, as Beijing prepares to host the Olympic Games and international interest is focused on China, companies with China operations should expect continued attention from both the U.S. Government and Chinese law enforcement authorities bolstering anti-corruption efforts.

These enforcement actions show no signs of slowing.

The FCPA prohibits issuers of securities (including foreign issuers listing their stock on a U.S. securities exchange) and domestic concerns (including entities with their principal place of business in the United States) from corruptly making an offer, payment, promise to pay or authorisation of the payment of any money or thing of value to a foreign official for the purpose of influencing any act or decision by the foreign official in his or her official capacity. It is illegal to induce a foreign official to perform or omit to perform any act in violation of his or her lawful duty, or secure any improper advantage, for the purpose of obtaining or retaining business. In addition, the FCPA requires issuers to make and keep books, records and accounts that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of its assets. Issuers are also required to maintain a system of adequate internal accounting controls.

The challenges involved in FCPA compliance in China include the state ownership or control of many Chinese companies and the fact that various payments susceptible to being characterised as kickbacks remain accepted in certain business sectors. Therefore it is not surprising that, in recent years, the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC) have stepped up enforcement efforts in relation to companies operating in China. Since 2005, at least five companies have entered into plea or deferred prosecution agreements related to FCPA violations in China, and these enforcement actions show no signs of slowing. In December 2007, a telecommunications company settled parallel DOJ and SEC enforcement actions by agreeing to pay U.S.$2.5 million in fines and penalties for providing travel and other things of value to Chinese government officials, and improperly recording those expenses.

Although FCPA regulations and Chinese anti-bribery laws generally regulate the same conduct, there are some important differences. For example, although Chinese laws apply only when a bribe is delivered, the FCPA covers both offers and promises to pay. Conversely, the Chinese definition of bribery covers certain payments to units as well as individuals, and anti-bribery laws focus heavily on whether the activity involved “improper interest”. In light of these distinctions, companies operating in China should take particular care to ensure that they have implemented and are maintaining adequate training, record keeping and internal controls regarding their business activities under both local and international laws. Failure to do so could lead to significantly increased liability risk.

A recent communiqué from the Communist Party of China warned that China’s fight against bribery will intensified in the coming year. Companies operating in China should also be aware of the country’s own anti-bribery laws. These laws, which apply to domestic and foreign entities, cover both criminal offences and commercial bribery, which typically result in administrative penalties or civil fines. Although enforcement of Chinese anti-bribery laws traditionally been inconsistent, that may change during 2008. In addition to being the year that Beijing will host the Olympic Games, 2008 marks the 30th anniversary of a number of China’s reform and disciplinary efforts. A recent communiqué from the Communist Party of China warned that China’s fight against bribery will be intensified in the coming year and that corrupt officials will be “severely punished”.

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4 International News
Climate Change: From Bali to Copenhagen

By Prajkt Samant

The post-2012 period, after the Kyoto Protocol’s first commitment period expires, was the major focus of the United Nations Climate Change Conference in December 2007 in Bali, Indonesia. Delegates sought to agree on a negotiation process to finalise a post-2012 regime to cut greenhouse gas emissions.

The negotiation process agreed upon, the so-called “Bali Roadmap”, commits all 192 countries that are members of the United Nations Framework Convention on Climate Change (UNFCCC) to reach an agreement on a successor framework to the Kyoto Protocol by the end of 2009 in Copenhagen, Denmark.

The key to success in Bali was the participation of the United States—the world’s biggest emitter of greenhouse gas emissions and the only major industrialised country not to have ratified the Kyoto Protocol. The United States was in the spotlight following Australia’s ratification of the Kyoto Protocol, which came after Australia’s change of government, in December 2007.

The European Union (EU) conceded on one of the most contentious points: the inclusion in the Bali Roadmap of a reference to 25 per cent to 40 per cent emissions reductions being made by developed countries by 2020. The EU insisted the figures should be included, while the United States demanded (and won) the removal of any figures. In turn, the United States conceded on the issue of how much developing countries should do to curb their emissions. The Roadmap states that countries recognise the need for “deep cuts in emissions”, and calls for a “long-term global goal for emissions reductions”.

The journey to Copenhagen will include a series of meetings and conferences, including the Fourteenth Conference of the Parties to the UNFCCC and the Fourth Meeting of the Parties to the Kyoto Protocol meeting in Poznan, Poland, later in 2008.

In addition to requiring industrialised countries to make concessions, there are repeated calls from developed countries for developing countries, namely China and India, to take positive steps in order to tackle the problem of climate change. In the Bali Roadmap, developing countries agreed to take “measurable, reportable and verifiable” mitigation actions, supported by technology and finance from industrialised countries. This seemed to be a breakthrough of sorts, but it remains to be seen whether this is enough for industrialised players to continue making the concessions needed, and to bring all parties to the table to agree upon an internationally binding successor framework.

The Roadmap states that countries recognise the need for “deep cuts in emissions”, and calls for a “long-term global goal for emissions reductions”.

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Italy Introduces Class Actions

For the first time, Italy has introduced class actions into its civil procedure system; the new law will enter into force on 29 June 2008. Associations will now be entitled to file collective damages claims on behalf of an indefinite number of consumers or users (the class) who have suffered the same damage as result of the same violation of consumer rights. The judgment is enforceable by any person who can establish membership of the class, but it does not preclude individual claims.

Consumer goods producers are now reviewing their quality control systems, service providers are reviewing their marketing practices, and insurance companies are reviewing their product liability policies, but also preparing for new business opportunities. The leading consumer association, Adusbev, has already announced class actions against retail banks and telephone service providers for abusive commercial practices.

Scope of Application: Legal Standing

Under the new provisions, a class action can be brought by the associations of consumers and users registered in the official list held by the Ministry of Productive Activities, and by associations and committees that “adequately represent the collective interest”. This vague definition suggests that associations and committees can be formed ad hoc for the purpose of filing a class action. The judge will have to assess whether such groups represent the collective interest.

This vague definition suggests that associations and committees can be formed ad hoc for the purpose of filing a class action.

The purpose of the class action must be reimbursement or compensation for damages, provided that several consumers and users have been harmed within the framework of standard form contracts, or as a consequence of torts or of unfair commercial practices or anticompetitive behaviour.
Individual consumers or users intending to benefit from the class action must declare in writing their adhesion to the lawsuit (the opt-in system). Only by formally opting in to the class will consumers be able to benefit from the judge’s final decision on the merits. Declarations must be made by the time of the deposit of the conclusion before the court of appeal.

**Trial Phase**

At the first hearing, the judge will assess the admissibility of the claim. In particular, the judge will assess whether the interests underlying the claim can be considered collective and, thus, whether the group of consumers and users on whose behalf the association is acting can be regarded as a class.

If the claim is admissible, the judge will ascertain the liability of the defendant for a violation of consumers’ rights. However, the judgment will not establish the amounts to be awarded to the consumers and users, but only the criteria on the basis of which the amount should be determined. The company itself shall then, within 60 days, propose an amount to each consumer and user that has adhered to the class. Acceptance of the proposal by the consumer constitutes an enforcement title.

As far as the judge’s decision on the merits is concerned, it should be highlighted that an Italian class action, unlike those in other countries, does not provide for punitive damages. Under Italian law, punitive damages are not allowed.

**Settlement Phase**

Should the company not make a payment proposal to the consumers, or should the consumers reject the proposal, a settlement team must be formed to come to an out-of-court agreement on the amounts to be awarded. The settlement team is composed of three lawyers: one designated by the consumer association, one by the company and one by the chairman of the court. Alternatively, the plaintiff and defendant may agree to defer the dispute to the local alternative dispute resolution (ADR) body.

The settlement team or ADR body then establishes the modalities, terms and amounts of payments to the individual consumers and users. The minutes of the meeting constitute the enforcement title.

**Outlook**

The new Italian legal provisions on class actions were inserted—as kind of a last-minute amendment—into the 2008 budget and consisted of only six paragraphs. They broadly regulate the procedural issues, but actually provoke more questions than they resolve. These questions include the identification of the categories of consumers that can access the new form of protection, the lack of enforceability of the decision rendered by the judge at the end of the trial phase, the absence of procedural rules for the settlement phase and the absence of a remedy in case the parties do not reach an agreement.

In fact, it is not currently clear if private investors may fall within the category of consumers or users who are entitled to bring a class action. The new law allows scope for interpreting that they might form a class in situations of market abuse, deceptive prospectuses or other forms of securities fraud.

Furthermore, the law does not state how the settlement team should reach a decision, whether by majority vote or unanimity.

As for now, the defects of the new law are in favour of the defendant companies. But consumer associations are pushing hard to give their new weapon a real edge. It may be expected that the legislature will soon make the necessary amendments and corrections to render the new class action a practicable instrument of Italian civil procedure.

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**An Italian class action, unlike those in other countries, does not provide for punitive damages.**

Unlike in traditional civil proceedings, the judge’s decision on the merits at the end of the trial phase is not enforceable, because it does not state an amount but instead leaves it up to the parties to agree on one. Consequently, if the defendant company refuses to award damages voluntarily, consumers will not be able to enforce their rights but will have to pin their hopes on the settlement phase. There is another problem: the new law does not provide any procedural rules on the settlement phase, and if the parties are not prepared to compromise, the procedure may last for months or years.
German Co-Determination at Board Level

By Gudrun Germakowski and Sandra Urban-Crell

In Germany, employee co-determination at the supervisory board level has various legal sources, but the most important ones are the One-Third Participation Act (Drittelbeteiligungsgesetz) and the Co-Determination Act of 1976 (Mitbestimmungsgesetz).

The management board is subject to comprehensive reporting obligations.

The One-Third Participation Act, *inter alia*, applies to publicly held German companies (AG), partnerships limited by shares (KGaA) and limited liability companies (GmbH) employing between 500 and 2,001 employees. In contrast, co-determination as provided by the Co-Determination Act applies to companies (AG, KGaA, GmbH and limited partnerships) with more than 2,001 employees. Under the One-Third Participation Act, one-third of the members of the supervisory board must be employee representatives; under the Co-Determination Act, the company’s supervisory board must consist of an equal number of shareholders and employee representatives. In large companies, the chair represents the shareholders and has a double vote in case of critical decisions.

Responsibilities and Duties of the Boards

Co-determination under these acts means direct participation by the employee representatives in the actions of the supervisory board. This particularly applies where the management board is appointed by the supervisory board. In the case of a GmbH, the appointment of the management board is transferred from the shareholders’ meeting to the supervisory board. The supervisory board may inspect and audit the company accounts or commission one of its members or experts to do so, and board members may attend shareholder meetings. The scope of the responsibilities of the co-determined supervisory board is mandatory, which means that the articles of associations may not restrict or extend the board’s jurisdiction.

The management board is subject to comprehensive reporting obligations. It must provide the supervisory board with reports on a regular basis, particularly in relation to corporate policy and corporate planning, the profitability of the company and the progress of business.

Strategies to Circumvent a Co-Determined Supervisory Board

In order to avoid a co-determined supervisory board, a German company may be transformed into another legal entity, one that does not require employees’ participation. Two options are available:

*European Company (Societas Europaea)*

The *Societas Europaea* (SE) was created on the basis of EU regulations enabling the cross-border establishment of an SE through the merger of stock corporations from various EU Member States. In an SE, a supervisory board is not mandatory. Co-determination within an SE depends on the outcome of the compulsory negotiations between the management and a special negotiating body (SNB) that represents the employees. Should those negotiations fail, the standard rules apply, meaning that the employees’ rights that were in force before the foundation of the SE should form the basis for employee involvement going forward.

*Transformation of a German Company into a Foreign European Company*

By defining the application of German co-determination laws in terms of the specific company types provided for by German company law, it is generally held that foreign companies organised under the company laws of other jurisdictions are not subject to German co-determination laws. This rule is true when the foreign company maintains its administrative centre outside Germany. Differences of opinion exist where the foreign company has its actual centre of business within Germany. Limited partnerships with foreign companies serving as a general partner have given rise to this issue (*i.e.*, Air Berlin Plc & Co. and Luftverkehrs KG). The predominant opinion is that foreign companies are excluded from the scope of the Acts.
The Relationship Between Doctors and the Commercial Health Care Industry in Germany

By Stephan Rau and Andreas Bauer

The scientific and medical communities overlap, and cooperative medical research is constantly growing in size and importance. Scientists, doctors, hospitals, academic medical centres and health care service providers are in regular contact with each other for many reasons. As in most countries, in Germany the relationship between the commercial health care industry and health care service providers is highly regulated.

The Basics

There are two basic legal requirements that govern cooperation between the health care industry and health care service providers (doctors). First, a doctor cannot receive or make any payment for the referral of patients or samples for laboratory analysis. This is intended to protect patient privacy and the integrity of a physician’s decision in relation to a recommendation, a referral or a test. Second, a doctor cannot receive or request payment for the prescription of drugs, medical devices or laboratory testing. Correspondingly, no company is allowed to offer or make such a payment.

The legal framework applicable to relationships between industry and doctors consists of (1) the professional code of conduct for doctors and the relevant codices relating to the associations of German drug and medical device manufacturers, (2) some regulations governing the public health care system and (3) the German penal code, which criminalises the granting of undue advantage and bribery in hospitals.

There are a number of principles that characterise the legal framework:

- **Segregation.** Procurement of goods and services for a hospital or facility must be strictly segregated from the doctors’ remuneration package as provided by industry.
- **Transparency.** The entire content of any contract between a doctor and industry must be made transparent to the doctor’s employer, i.e., a hospital or medical centre.
- **Adequate remuneration.** The remuneration must be appropriate to the services rendered. As to what remuneration is adequate very much depends on the seniority of the contracting doctor. Related guidelines exist. Also, the services rendered must be appropriate to the doctor involved; to state the obvious, it would be inappropriate to use a cardiologist for a dermatological study.
- **Documentation.** All agreements must be in writing, and all payments must be paid into bank accounts that are preferably based in Germany. Furthermore, the parties must be able to prove that the services were actually rendered.

These principles apply to every type of commercial contract with doctors. There are slight differences between contracts with doctors working in the public sector (e.g., in academic medical centres) and with doctors working in their own practices. Whereas the rules in the public area used to be stricter than those in the private sector, the latter is coming under increasing scrutiny by regulators and lawmakers. Various notorious cases have drawn attention to the issue of undue influence, and corruption has become a major concern.

As a result, 2008 will probably see a tightening of Section 299 of the German penal code, which will increase regulation of cooperation between industry and doctors in the private sector.

Finally, in a manner similar to the relationship between doctors and commerce, any relationship amongst doctors in a shared practice or larger institution is also subject to strict anti-bribery regulation. Any agreement between doctors for kickbacks in return for the referral of patients or samples is illegal.

The bottom line is that research projects, joint ventures, and mergers and acquisitions in the German medical sector are more than feasible. All parties must be aware of the dos and don’ts in this highly regulated market, but if they comply with the principles of segregation, transparency, adequate remuneration and documentation, they should be—generally speaking—on the safe side.

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McDermott partner Raquel Rodriguez interviews former Florida Governor Jeb Bush on strategies for crisis management and avoidance.

Q. What was your most challenging crisis during your two terms as Governor?
A. Our greatest challenge was the 2004-2005 hurricane seasons. In a 16-month period, we had eight hurricanes and four tropical storms, and planned for a few more that didn’t hit our shoreline. It was an exhausting experience for residents, our team in Tallahassee and the emergency operation centres around the state.

Q. What did you learn from this experience?
A. We learned two key things. First, after the crisis you should reflect on what happened and determine ways to improve your response. Second, expect the unexpected: you must hone your ability to anticipate problems before they occur. After a while, we became very good at anticipating and avoiding problems before they happened. Obviously you can’t avoid a hurricane, but you can anticipate policy challenges and deal with them before they become impossible to solve.

Q. You also responded to several other crises as Governor, for example the events of 11 September 2001, and the disappearance of a young girl from foster care. Did these crises require different skills?
A. The lessons of those experiences were that you must stand on principle and you must communicate directly and be transparent. Don’t, even in the most political circumstances, be political—just do what’s right. In a leadership position, doing what’s right and fixing the problem are what matters. Don’t just try to skirt the problem to avoid the hit politically.

Q. Should business follow these principles when dealing with corporate crises?
A. Absolutely. Take two very talented CEOs, for example. One of them realises there’s a problem and gets out in front of the problem, explains it and communicates a solution. This is important, because many times there is gross exaggeration—a lot of misinformation—a lot of fear internally and externally in any organisation. Leaders drive through the crisis and lead the organisation to a

That culture of preparedness for individuals, for business and for government can apply in any circumstance.
The lessons in Florida taught me that if local government doesn’t consider disaster preparedness and training, as well as the needed resources, then no amount of relief from the state or national government will fill that void. When General Powell and I visited Thailand and Indonesia and saw the devastation there, it was clear that, particularly in the remote areas, there wasn’t local preparedness or capability. So I think it’s incumbent upon nations to build a degree of capability that doesn’t yet exist. When I was Governor, we worked with our colleagues in the Caribbean to help them be prepared. The private sector played a very important role in developing relief supply strategies, so that now, when a hurricane comes to the Caribbean, the local infrastructure is better prepared for it, and companies are already organised to provide relief and support. That culture of preparedness for individuals, for business and for government can apply in any circumstance. The lesson I learned from the Florida experience was that the ability to get back on your feet as quickly as possible is hugely important. Making this a higher priority through multi-lateral organisations internationally and training would be an important objective.

In short, you can’t just do it from a standing start. People need to plan, prepare and train ... and to make this a year-long effort—whether it’s in businesses, large and small, or whether it’s in the United States or around the world.

Q. What are the top three priorities for business in preparing for disaster?

A. Clearly, training is the number one priority. As we began to prepare for new threats, it was clear that the whole needed to be greater than the sum of its parts. In a federal system, we had to cross government boundaries to prepare. How do you coordinate or communicate among all these governmental jurisdictions? How do you communicate after a storm when the power is out? You must plan for the worst and train to be able to overcome it—without training, you’re making mistakes when you should be running smoothly. Second, training cannot be delegated away; the CEO of the business should be very obviously taking part in the training programme in order to send a signal that it’s a high priority. The hundreds of millions of dollars lost after a disaster is enough for people to realise that risk mitigation and disaster management are really an essential part of business. Finally, the third priority is investment in preparedness and risk mitigation. No amount of training and leadership will work without resources invested up front. Preparing for disaster might not generate profits directly, but the avoidance of loss is as important as the creation of profit. What we’ve tried to do in government, which I think applies in the private sector as well, is to align people’s interest towards preparedness and avoidance of disaster. It’s that simple.

Jeb Bush was Governor of Florida from 1999 to 2007.

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Since the summer of 2007, there has been an alarming outpouring of news stories concerning the importation of defective or unsafe products from China into the United States and Europe. From toothpaste poisoned with antifreeze to pet food laced with dangerous chemicals to toys decorated with toxic lead paint, the theme of these stories has been the same: Chinese products are potentially dangerous, if not life-threatening, and consumers should be on guard.

Plaintiffs’ lawyers have been eyeing this hysteria with considerable interest, and throughout the second half of 2007 and into 2008, a number of well-known importers of Chinese products have been subjected to class action lawsuits, including the Canada-based pet food maker whose Chinese-sourced product allegedly tainted dozens of brands of American pet food, the U.S. distributor of Thomas & Friends wooden railway toys and a major U.S. toy manufacturer that was forced to recall thousands of toys covered in lead paint. More class actions suits are certain to follow.

The attention from the western press has no doubt led some consumers and legal advocates to exaggerate the danger of Chinese goods. Nonetheless, for class actions, the plaintiff’s lawyer’s perception is often more important than the reality. Thus, it is prudent for companies that regularly import goods from China to assess whether they have meaningful exposure to future lawsuits and, if they do, to take measures now to protect themselves against, or at least limit, any future liability.

In addition to the prospect of class action and personal injury lawsuits, importers of defective goods face a variety of other threats, including the following:

- **Product recalls.** Under the U.S. Consumer Product Safety Act, a company that distributes products in the United States has an obligation to report and to recall potentially hazardous products. On the one hand, product recalls can be enormously expensive and damaging to a brand image. On the other hand, failure to notify the U.S. Consumer Product Safety Commission of a potentially defective imported product will subject an importer to huge fines and penalties, and even worse negative publicity.
Minimising Future Liability

The best approach to minimise future liability is for importers to constructively review and revise their current import contracts. Importers should insist upon a number of revisions to their contracts.

First, contracts with Chinese exporters should be revised to provide for mandatory quality control procedures, including the appointment of a third-party laboratory or other such inspector to review and approve the quality and safety of Chinese goods before they are exported from China. Many contracts with Chinese exporters do not address the subject of quality control, much less provide for the mandatory third-party inspection of goods. Failure to include quality control procedures in an import contract may open the U.S. importer of Chinese goods to claims of negligence, or worse.

Second, contracts with Chinese exporters should be amended to include specific indemnities in favour of the importer on product safety and quality issues. That is, the Chinese exporter should agree to fully indemnify and defend the importer against all claims, liabilities and other costs arising out of allegations that the imported products are defective or unsafe, including, but not limited to, litigation costs and product recall costs. If the importer has sufficient bargaining leverage, these indemnities may even be secured by a “hold-back” of part of the purchase price.

Third, contracts with Chinese exporters should be amended to include a provision requiring the Chinese seller to obtain and maintain product and general liability insurance, preferably with a reputable U.S. or international insurance carrier, to provide sufficient protection to the U.S. importer in the event of a defective or unsafe product. If at all possible, the U.S. importer should be named as an “Additional Name Insured” on such insurance policies.

The unfortunate case of Foreign Tire Sales (FTS) is a case in point. FTS, a family-owned tire import business, was forced to recall 450,000 Chinese-made tires at a projected cost of U.S.$90 million. This product recall, coming on top of a lawsuit brought by victims of a fatal car accident, is threatening to bankrupt the company. Adding insult to injury, at the time of going to press, the Chinese tire manufacturer, which apparently has no recoverable assets in the United States, has simply refused to respond to FTS’s U.S. lawsuit seeking compensation.

Clearly, the potential liabilities for importers of Chinese goods are huge, so importers must take steps to minimise the risks.
How to Claim Damages Under the Chinese Court System

By Ken Huang

Disputes involving products made in China have recently gained much attention in the global media. In U.S. courts, many U.S. companies that outsource production to China or purchase Chinese goods for resale in the United States have been held liable for damages caused by defective Chinese products.

Being the recipient of a favourable judgment in a U.S. court is not always sufficient for a plaintiff to successfully collect damages against Chinese manufacturers in a product liability suit. At present, there is no treaty between the United States and China in relation to the mutual recognition and enforcement of court judgments. Therefore, a plaintiff may not be able to collect any compensation against a Chinese manufacturer when the manufacturer is unwilling to honour the U.S. court judgment and has no attachable assets in the United States that could be liquidated to satisfy the judgment.

The alternative for an importer (not an end user) is to seek damages against the Chinese manufacturer in a product liability suit in Chinese courts. It is advisable to choose arbitration to avoid the Chinese court system, but if the Chinese manufacturer is unwilling to agree to arbitration, there are ways to navigate the system.

Major Features of the Chinese Legal System

The Chinese legal system has three major differences to the U.S. legal system:

- *It is a civil law system.* The Chinese legal system is based on civil law, which is mainly based on codification and starts its analysis from abstract rules, rather than relying on precedents. As such, the logic implied in the Chinese legal system is deductive, not inductive, which to some extent is the basis of the U.S. legal system.

- *There are no juries.* Typically, a Chinese court is constituted by
only three judges, although one of the judges usually has the title “the Jury of People”. The judges play a much more active role during the trial than their peers in U.S. courts. These three judges can literally decide everything in a case.

• There is very limited discovery. The U.S. discovery procedure is one of, if not the, most time-consuming procedures in the U.S. legal system. In contrast, under the Chinese legal system, parties exchange evidence only once or twice during the whole trial. Only on very rare occasions does exchange take place more than three times. Only in very limited situations can a party apply to a court for an order that requests that the other party disclose the evidence its opponent needs.

**How to Sue Manufacturers in China**

**End Users Versus Chinese Manufacturers**

It is not advisable for U.S. end users to file a lawsuit in relation to defective Chinese products, simply because it’s not worth doing so.

The Chinese legal system is based on civil law, which is mainly based on codification and starts its analysis from abstract rules, rather than relying on precedents.

Chinese law does not allow for punitive damages. The only clause that could be considered punitive is Article 49 of the Law of the People’s Republic of China on Protection of Consumer Rights and Interests. This clause states that a business operator engaged in fraudulent activities in supplying items shall, in response to a consumer’s demand, increase the compensation for loss to twice the cost that the consumer paid for the item. In addition, there is no provision for class actions in China. Each end user must file a separate case against the same manufacturer.

The most efficient redress for the U.S. end user is to sue the importer and the seller of the Chinese goods in the U.S. courts. The defendant could then decide whether to seek compensation from the Chinese manufacturers.

Compared to the entitlement of end users, the compensation for losses that an importer can get is relatively large. Under Chinese Contract Law, where a party fails to perform its obligations under the contract, or its performance fails to conform to the agreement and causes losses to the other party, the amount of compensation for losses is equal to the losses caused by the breach of contract. These include the interest receivable after the performance of the contract, but this is applicable only if the total amount doesn’t exceed the probable losses caused by the breach of contract foreseen (or which ought to have been foreseen) when the party in breach agreed to the contract.

**Conclusion**

The best offence is a watertight defence. Contracts and agreements should only be drawn up with the assistance of local knowledge and a thorough understanding of the Chinese legal system. To ensure full protection, importers should consult corporate and disputes lawyers before reaching any agreement. Navigating the Chinese court system is only possible with a highly experienced local guide.

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Recalls of Chinese goods and litigation concerning defective products erode importers’ profits, threaten market share and damage established brands. Importers of Chinese goods can mitigate these risks by procuring appropriate insurance and by negotiating favourable insurance-related terms in their contracts with Chinese suppliers.

Overview of Insurance Products Available to Importers

Most sophisticated importers purchase liability insurance with products coverage. Such policies typically cover claims arising out of product-related damage to third-party property or injuries to consumers. The policies may also cover the costs of defending a product liability lawsuit. Consequently, product liability coverage is essential front-line protection for any importer of Chinese goods.

In light of recent revelations concerning manufacturing defects and quality control issues in China, importers should re-evaluate their existing product liability coverage to assess its scope, the sufficiency of its limits, the effect of defence costs on limits and who has the right to control the importer’s defence and settlement decisions in litigation. Importers should also assess the financial strength of their product liability underwriters and their claims handling reputation, as well as any endorsements or other policy provisions specific to an importer’s business.

Traditional products liability coverage, however, may not offer complete protection. Such policies do not cover product recall and other costs in addition to, or in the absence of, actual or alleged injury to third parties. Product liability coverage will also not apply to the extent that property damage or bodily injury was caused by the sale of products that the importer had recalled or otherwise knew were defective.

Many importers therefore should consider adding product recall coverage to their insurance portfolios. This coverage applies in the event that a product on the market is likely to cause damage or injury to third parties; no actual or alleged damage or injury is required for the policy to respond. Coverage is triggered when an importer incurs costs proactively to prevent injury or damage. Product recall policies also typically cover the costs of communicating a recall to consumers, replacing unsaleable inventory, and mitigating damage to the corporate brand through public relations and crisis management initiatives.

Product recall policies also may cover lost profits occasioned by the negative publicity and lost sales that often
result from a recall. Product recall coverage, however, often comes at a hefty price. Importers should confer with their insurance brokers to discuss pricing and the effect of the recent Chinese products scandal on the breadth of product recall policies on the market. Because U.S. and European authorities are investigating the importation of defective drugs, toys, foodstuffs and other products from China, certain importers should also consider a form of political risk insurance known as trade disruption insurance. Trade disruption insurance is designed to cover lost revenues should an overseas supplier fold for political reasons or encounter trade restrictions affecting or eliminating supply. Trade disruption policies often also cover the costs of securing a replacement supplier, including retooling costs.

In addition, an importer’s first-party property coverage may be responsive to, for example, the destruction of inventories of defective goods. First-party property policies differ in scope and application, but typically cover an importer’s lost income from a covered loss and expenses incurred to restore damaged or destroyed property. Furthermore, if an importer’s management was aware of product defects but negligently failed to act, directors’ and officers’ coverage could be implicated.

Given the breadth of coverages potentially at play and the prospect of costly product recalls, government investigations and litigation, importers should undertake a comprehensive review of their potentially applicable insurance. The increasing costs of product recalls and defending product litigation in the United States and in the EU jurisdictions that now permit class actions and mass tort proceedings warrant such a review as a preventative measure.

**Chinese Suppliers’ Liability Insurance**

Although most U.S. and European importers likely have at least some insurance potentially responsive to claims arising out of defective Chinese goods, importers also should evaluate whether their Chinese suppliers maintain liability insurance and, if so, whether it is adequate and accessible from the importer’s perspective. An importer faced with a product liability lawsuit, for example, may be entitled to make a claim against a Chinese manufacturer’s liability insurer if that insurer has conferred additional insured or similar status to the importer, or has included in its policy a provision extending coverage to entities contracting with the named insured. An importer must carefully negotiate these terms and ensure their conscientious implementation by the supplier and its insurers.

Many importers, therefore, should consider adding product recall coverage to their insurance portfolios. Market restrictions and cultural norms also may limit an importer’s ability to secure meaningful rights against its Chinese supplier’s insurers. Chinese manufacturing firms have been slow to embrace the concept of, and the need for, product liability insurance. Moreover, the insurance markets in China only recently opened to foreign underwriters. As a result, if a Chinese firm has any product liability insurance, it is likely underwritten by a Chinese insurer or a Chinese subsidiary of a foreign insurer, making it difficult, if not practically impossible, for an importer to enforce any rights it has against the supplier’s insurer. In addition, liability policies issued by Chinese insurers often exclude the equivalent of “serious mistakes”—an exclusion that the insurer likely will contend applies when injury or damage is caused by a manufacturing defect or a quality control problem. Chinese firms are also unlikely to carry sufficient liability limits to protect an importer faced with litigation in the United States or European markets, where damages and defence costs often far exceed Chinese standards.

- Request policy endorsements naming the importer as an additional insured or otherwise conferring it rights under the supplier’s liability policies.
- Obligate the supplier and its liability insurers to notify the importer in writing if any of the supplier’s pertinent insurance policies are cancelled, not renewed or materially changed.
- Request access to the supplier’s product liability claims history and losses to evaluate its track record and to assess any erosion of its in-force policies’ aggregate limits.
- Confirm that the supplier has assets in the importer’s domicile and is subject to suit there. For Chinese suppliers that do not meet these criteria—and most will not—importers should require their suppliers to arbitrate any disputes and to agree to do so in the importer’s domicile or a neutral location. Arbitration awards are more readily enforceable in China than foreign judgments.
- Specify that the supplier’s liability, including any duty to indemnify the importer, is not limited to the extent of its potentially applicable insurance.

In sum, given the risks now widely associated with defective or contaminated Chinese food, drugs, toys and other consumer goods, importers’ risk managers and legal departments should work internally before a problem arises to ensure that their organisations have appropriate insurance coverage and insurance-related contractual protections in place.

**Insurance-Related Contractual Solutions**

These products- and recall-related risks can be mitigated contractually. When negotiating insurance aspects of contracts with Chinese suppliers, importers should do the following:

- Require their Chinese suppliers to maintain product liability insurance, at the supplier’s expense, with an underwriter and occurrence and aggregate limits acceptable to the importer. Importers should request certificates of insurance confirming compliance with these terms.

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Product Safety and the EU—
A Problem with “Made in China”?

By Frank Schoneveld

As a result of recent Chinese product recalls, the European Commission has brought in a number of new initiatives to strengthen the enforcement of European Union product safety controls. It is the responsibility of EU Member States to enforce the EU safety requirements imposed on producers and distributors.

The Role of the EU

Many types of products have specific safety criteria under EU law. For example, the safety criteria for toys cover general risks (health hazards or physical injury) and particular risks (physical and mechanical, flammability, chemical properties, electrical properties, hygiene and radioactivity). In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply.

EU law lays down essential health and safety requirements that products must meet during the manufacturing process and before being placed on the market. The European standards bodies draw up technical specifications that correspond to the essential requirements. These are known as harmonised standards and typically have an EN (European Norm) reference number. Unlike compliance with the essential requirements, compliance with harmonised standards is voluntary, and manufacturers are free to apply any technical solution that makes the product compliant with the essential requirements. However, compliance with the EN standard gives rise to a presumption of conformity with the corresponding essential requirements of EU law.

Virtually all industrial and consumer products marketed in the European Union must have the conformity marking (CE mark) attached by the manufacturer. The CE mark is, in effect, a statement by the manufacturer that the product complies with essential EU safety requirements. Responsibility for ensuring that essential safety requirements are satisfied and that the CE mark is properly attached rests with the manufacturer or its authorised representative.

In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply.

In general, EU Member States may not in any way restrict the marketing of foreign products bearing the CE mark unless the CE mark has been improperly applied.

The Role of EU Member States

Member States are responsible for enforcing EU safety requirements and making sample checks on the market. If a Chinese product is not in compliance, a national authority must take corrective action. It can issue warnings and prohibit the marketing of a product, require a recall and withdraw it from the market. If such action is taken, the European Commission will usually be notified, and there may be product recalls across Europe.

Liability of Importers for Defective Products

Recall or prohibition of a defective product can give rise to serious consequences. Should an importer of Chinese goods be sued in a Member State court, it may be impractical to obtain redress from the Chinese manufacturer because of the potential for the Chinese manufacturer to avoid enforcement of an EU court judgment. EU rules on product liability are drafted in such broad terms that the importer of goods from China into the EU will, in effect, be strictly liable for any damage caused by a defect in those goods. Thus, importers of products from China would be well advised to ensure that they have adequate liability insurance to cover the often significant cost of recalling product from the market and disposing of it, as well as large-scale liability to consumers.

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With thanks to Niamh O'Reilly for her contribution to this article.
Chinese Pharmaceutical and Dietary Supplement Safety Issues

By Eric Hargan

Wu Zhen, a deputy director of China’s State Food and Drug Administration (SFDA) has noted that “serious incidents related to drug safety have been happening non-stop in China since 2006”. Exacerbating the issue from a U.S. perspective is the fact that as much as 80 per cent of active pharmaceutical ingredients (APIs) in drugs in the United States are imported, and a majority of these imports are from China. Besides APIs, huge quantities of excipients, as well as botanicals and herbals used in dietary supplements, are exported to the United States from China.

Manufacturers, distributors and sellers of pharmaceuticals and dietary supplements should be watching this space very carefully, as the largest market for pharmaceuticals and dietary supplements (the United States) and one of its main suppliers of product (China) work to address the reality and the perception of the safety of Chinese ingredients.

There are, however, some hopeful signs. In July 2007, China released a new Statute on Drug Registration and Management, one day after the execution of the former SFDA head for corruption in relation to drug licensing, among other things. In December 2007, the U.S. Department of Health and Human Services (HHS) signed agreements with SFDA and AQSIQ providing, among other things, that Chinese exporters would register with the SFDA if they were exporting to the United States certain antibiotics and dietary supplements, human growth hormone, glycerin, glucose test strips and condoms. SFDA and AQSIQ also promised to work towards a process by which they can certify that firms and products meet FDA standards.

The FDA does not have enough resources to conduct routine inspections of every import into the United States. The magnitude of the problem is exemplified by the fact that the FDA inspected 30 foreign drug manufacturing facilities last year, but the number of exporting facilities is estimated to be between 3,000 and 7,000. Over and above resource limitations, the FDA does not have jurisdiction in a sovereign country, such as China, to conduct inspections. It is clear that regulators alone will not be able to cope with these issues fully.

Both the relevant regulatory bodies, the SFDA and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), struggle to cope with an incredible number of product safety issues. By some estimates, there are more than 4,000 pharmaceutical manufacturers in China and an even greater number of excipient manufacturers; these are numbers that can overwhelm even the most diligent regulators.

The real regulators of these issues initially will be the U.S. importers and manufacturers of drugs and dietary supplements in the United States. They must make themselves aware of crucial distinctions in regulation by China: China may be inspecting “drugs” but not “chemicals”, which may be the very category of goods that is being imported. In addition, the SFDA warned in late February 2008 that “safeguarding the legality, safety and quality of raw materials imported for use in pharmaceuticals is the responsibility of the importing country”. It therefore makes sense to develop enhanced programmes that watch regulatory developments in China, ensure the documentation of supply chains and educate Chinese partners on U.S. expectations.

Companies looking to avoid liability in the U.S. marketplace must educate themselves about their suppliers and the supply chains, and understand what Chinese regulations mean for them. U.S. importers and manufacturers should, for their own sake, work to introduce their Chinese partners to U.S. regulations and public expectations, and encourage their Chinese partners to do so on their own initiative. Until the private sector has internalised these imperatives, no governmental agreements, initiatives, budget increases or speeches are going to solve this continuing crisis.
Food Safety Litigation: International Implications

By Peter Resnik and Emily Smith-Lee

A series of events over the past few years has increased attention on food safety issues. These events include the discovery in 2007 of contaminated wheat gluten from China in pet foods, a recent report of contaminated ginger from China entering the United States food supply and the February 2008 recall of more than 140 million pounds of U.S. beef following an investigation that revealed non-compliance with the required procedures for examining crippled or “downer” cattle that might carry Bovine Spongiform Encephalopathy (mad cow disease).

Where there is documented harm to consumers, litigation is virtually certain to follow. The contaminated pet food incident alone, which caused illness and fatalities in pets, has resulted in more than 59 class action lawsuits. Moreover, substantial litigation can result even in the absence of any demonstrated harm attributable to the product if consumer concern about the safety of certain food products causes economic harm throughout the distribution chain. For example, in the first case involving genetically modified (GM) corn, plaintiffs pressed claims for hundreds of millions of dollars despite any evidence of negative health effects associated with the StarLink corn. Under strict product liability principles, liability can attach even in the absence of fault.

These examples are indicative of the increasingly complex task of protecting against and limiting food product liability exposure in the face of widespread use of commodity crops whose origins are far flung and far from certain. There are a number of challenges associated with addressing incidents of widespread food contamination, but there are measures that domestic and overseas producers can take to minimise and mitigate their liability exposure.

Challenges Associated with International Food Safety Crises

In many cases involving contamination of the food supply, whether the source is domestic or international, it can be difficult, if not impossible, to identify the actual source of the contamination. Ingredients are commingled at many stages in the food distribution system before they find their way into a consumer product. Further, product recalls and extensive publicity surrounding food safety crises result in a ripple effect of economic harm throughout the food distribution system. This increases the number of claimants and defendants, and further complicates the resulting litigation.

Food crises with international origins present their own unique challenges. Ingredients often come from countries with vastly different food and agricultural regulations than those in the United States, and country of origin
The best policy is to contain the litigation, but the reputation of recall affect not only subsequent aftermath of a crisis. Develop a Crisis Management Strategy

Recent efforts in the United States to address food safety have some international implications, chiefly country of origin labelling requirements and incentives for foreign suppliers to voluntarily comply with inspection and safety standards. Some or all of these measures also call for vigilant participation by the domestic food industry in developing best practices to ensure the safety of the food supply. Self-evidently, successful prevention of a food crisis also protects against liability. Assuming, however, that these efforts will prove imperfect, it is important to recognise that none of the proposals address the difficulties associated with identifying and reaching a foreign supplier of an unsafe food ingredient.

In short, there is a range of situations that can result in potentially crippling litigation when an unsafe product, or a product merely perceived to be unsafe, enters the food supply.

Recommendations for Managing and Minimising Exposure

Develop a Crisis Management Strategy

The decisions made in the immediate aftermath of a crisis (i.e., a product recall) affect not only subsequent litigation, but the reputation of the company and its brands. Often the best policy is to contain the problem through immediate, publicly announced, proactive and carefully articulated action. Having a strategy in place before the crisis that is informed by business needs and litigation management will help position a company to take immediate steps that serve both interests. The strategy should be developed in connection with legal and public relations counsel and relevant business leaders, and should include: (i) an assessment of the likely reputational impact and litigation exposure, (ii) an immediate plan of mitigation and public relations, (iii) clear lines of authority and communications, and (iv) timelines for implementing crisis response steps.

Audit Current Practices

Failure to implement best practices could increase the possibility of fault-based liability. Producers based in the United States should take care to review new regulatory developments and industry-sponsored best practices, and assess their own practices to make sure they are consistent with evolving industry standards. Continued dealings with suppliers that are known or suspected to have poor quality control practices could also increase the risk of introducing an unsafe food product or a finding of fault. To this end, companies would be well advised to make efforts to identify any entities in the supply chain that may be of concern.

Review Supplier and Customer Contracts

Supplier contracts should be reviewed for appropriate indemnification language, and revised or renegotiated if necessary. In addition, although contractual limitations on liability in customer contracts would not prevent personal injury claims, it may be possible to limit liability for certain economic damages. This is particularly true in a recall situation where retailers might look to their suppliers for recovery of recall costs and consequential damages.

Review Insurance Contracts

Policies should be reviewed to ensure that they cover the types of liability envisioned and do not contain relevant exclusions. Companies should also consider requiring suppliers to maintain appropriate coverage, and potentially listing the company as an additional named insured on the relevant policy.

Conclusion

Food safety crises are no longer a matter of an episode of contamination in a particular restaurant chain, or specific processing errors that result in adulterated food. They increasingly involve the spread of an unacceptable ingredient throughout the food supply, a chain that relies on varied, diffuse and global sources. This makes the liability implications, particularly for food products that include overseas ingredients, ever more complex. To the extent that contamination and resulting litigation cannot be avoided, its consequences can be managed proactively. Companies should develop a protocol for crisis management ahead of time, take a careful look at their practices and those of their suppliers, ensure adequate insurance coverage, and structure commercial relationships and contracts to give the broadest possible protection.

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Congressional Involvement Increases in U.S.-China Business Relationships

By Stephen Ryan and Neil Quinter

Recent scandals involving potentially dangerous products imported from China have heightened congressional activity, potentially affecting U.S.-China business relationships. Companies doing business in and with China must be increasingly aware of congressional involvement, and be prepared to take advantage of potential governmental action or to ameliorate the harm that could be caused.

**Consumer Product Safety**
The 2007 revelations of the use of lead paint on children’s toys manufactured in China helped to spur the U.S. Congress to advance legislation addressing consumer product safety. Both houses have passed different bills. Both bills impose new requirements for manufacturers, importers, distributors and even retailers of imported products. The House bill requires the U.S. Consumer Product Safety Commission (CPSC) to develop a plan for risk assessment and inspection of imported products. The Senate bill also would impose requirements for independent testing of imported children’s products. It would also require the CPSC to develop a risk assessment methodology for imported products, and would empower the CPSC to ban all toy imports from a manufacturer if the manufacturer has a persistent pattern of defective products. Both bills also require studies on the effectiveness of the CPSC’s authority regarding imported products, by different entities. In addition, the Senate bill calls for legislative recommendations regarding inspection of foreign manufacturing plants by the CPSC. Civil and criminal penalties for violations are increased substantially in both bills. The Bush administration opposes several provisions of the Senate bill, including the independent testing requirement.

**Food and Drug Safety**
The U.S. Congress is responding to the numerous instances of safety problems with food imported from China. Recent revelations that blood thinner products from unregulated and unreviewed Chinese factories may have caused numerous deaths in the United States are likely to increase calls for greater congressional action and increased U.S. Food and Drug Administration (FDA) authority. House Energy and Commerce Committee Chairman John Dingell (D-MI) has introduced the Food and Drug Import Safety Act, a substantial expansion of food import regulation, including user fees, country of origin labelling, increased penalties and limitation on ports of entry. Senate Majority Leader Harry Reid (D-NV) has stated his intention to pass food safety legislation in the spring of 2008.

**Chinese Currency Value**
Critics have long argued that China undervalues its currency, the yuan, to artificially boost its trade value. Two Senate committees passed competing bills in 2007 to address the yuan’s value. The Senate Banking, Housing and Urban Affairs Committee passed legislation to restrict the U.S. Treasury Department’s discretion in labelling countries as currency manipulators. The Senate Finance Committee passed legislation providing for a variety of enhanced sanctions in response to “fundamentally misaligned” currencies. In the House, Representative Timothy Ryan (D-OH) has introduced legislation with 70 co-sponsors that would define currency manipulation as an illegal trade subsidy, triggering the possible imposition of countervailing duties.

The Bush administration has criticised these bills as undermining the effort to move China to a market-based currency and some groups are opposing them as well. The Chairman of the House Ways and Means Committee, Representative Charles Rangel (D-NY), and the Chairman of its Trade Subcommittee, Representative Sander Levin (D-MI), have prepared draft legislation, although they have not yet committed to introduce it.

None of these congressional actions is complete. They all likely will be changed substantially as they advance—or don’t—through the legislative process.
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