Product Liability in the People's Republic of China

2nd Edition

BEITEN BURKHARDT

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Introduction

The China-Team of BEITEN BURKHARDT is pleased to present the new edition of this well-received handbook which provides an overview of the PRC legal framework of product liability and it considers legislation and cases up to December 2014.

Companies importing to China or producing goods in China have to keep track of many issues. The following overview may help readers to identify product liability risks and then take steps to address them pro-actively, such as in the course of reviewing agreements, or when preparing procedures for certain scenarios (e.g. product recalls). Companies that are sourcing products in China will be able find out more about their rights towards manufacturers and suppliers in China. This handbook is designed to provide practical advice on a range of legal issues that may affect your business in China, but it cannot replace the in-depth review that is necessary before undertaking a specific project.

With consumption in China on a continuous rise, the topic of product liability has gained further momentum. Consumers hold both domestic and foreign brands to high standards and are increasingly aware of their rights. In addition, high profile cases keep the topic in the public eye and social media and online ratings allow news on sub-standard goods to spread fast. Last but not least, Chinese companies are increasingly interested in building confidence into the quality of their products, both domestically and abroad, in order to compete internationally.

We would be pleased to respond to any questions you may have regarding product liability issues in China and provide contact details of our offices at the back of this handbook.

The China-Team of BEITEN BURKHARDT

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Abbreviations

AIC	Administration of Industry and Commerce
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
CCC	China Compulsory Certification
CFDA	China Food and Drug Administration
FIE	Foreign Invested Enterprise
ISO	International Standardization Organization
PRC	People's Republic of China
RMB	Renminbi
SAIC	State Administration of Industry and Commerce
USD	United States Dollar

Chapter 1: General Product Liability

In the past years, the Chinese government has introduced numerous reforms and regulatory measures related to product liability. Most important among these are the enactment of the Tort Liability Law in 2009 and the first amendment of the Consumer Protection Law in 2013 (after its enactment 20 years ago in 1993). Other important regulatory developments are the enactment of the Law on the Application of Law in Foreign-Related Civil Relations in 2011, a new interpretation of the Supreme People's Court on Disputes over Sales and Purchase Contracts in 2012, the Provisions of the Supreme People's Court on Cases Involving Food and Drug Disputes in 2013 and the Administrative Measures for Online Trading of the SAIC in 2014. The criminal provisions on food safety infringements have been amended as well. These incremental reforms did not lead to a consolidation of existing rules and the rules remain fragmented and complex. Since 2009, there is also a regulatory instrument of the Supreme People's Court, which is the release of "guiding cases". So far, there are 26 guiding cases and two of those are related to product liability.

1. Relevant Laws and Regulations

The following list is an overview of the most important laws, national regulations and opinions and interpretations of the Supreme People's Court relevant to product liability in the PRC. Additional legislation may apply in certain industries or cases.

a) National Laws

- Law of the PRC on Protecting Consumers' Rights and Interests of 25 October 2013 ("Consumer Protection Law")
- Civil Procedure Law of the PRC of 31 August 2012 ("Civil Procedure Law")
- Criminal Law of the PRC of 14 March 2012 ("Criminal Law")
- Law of the PRC on the Application of Laws to Foreign-Related Civil Relations of 28 October 2010 ("Law of Foreign-Related Civil Relations")
- Tort Liability Law of the PRC of 26 December 2009 ("Tort Liability Law")
- Product Quality Law of the PRC of 8 July 2000 ("Product Quality Law")
- Contract Law of the PRC of 15 March 1999 ("Contract Law")

- Standardization Law of the PRC of 29 December 1988 ("Standardization Law")

- General Principles of the Civil Law of the PRC of 12 April 1986 ("Civil Law")

b) National Regulations

- Administrative Measures for Online Trading, released by the SAIC on 26 January 2014 ("Administrative Measures for Online Trading")

- Some Provisions on the Handling of Contraventions of the Rights and Interests of Consumers of 12 March 2004, released by the SAIC ("Consumer Rights Contravention Provisions")

- Provisions Concerning the Repair, Replacement, and Restitution of Certain Goods, released by the State Economic and Trade Commission, the State Technology Supervision Bureau, the SAIC and the Ministry of Finance on 25 August 1995 ("Warranty Provisions")

- Regulations for the Implementation of the Standardization Law of the PRC of 6 April 1990 ("Standardization Regulations")

c) Opinions and Interpretations of the Supreme People's Court

- Provisions of the Supreme People's Court on Certain Issues Concerning the Application of the Statute of Limitations in the Trial of Civil Cases of 21 August 2008 ("Interpretation on the Statutes of Limitation")

- Interpretation of the Supreme People's Court on Compensation for Personal Injury of 26 December 2003 ("Interpretation on Personal Injury")

- Official Reply on Whether the Aggrieved Party in a Product Infringement Case May Bring a Civil Lawsuit Against the Product Trademark Owner of 11 July 2002 ("Official Reply of 11 July 2002")

- Some Provisions of the Supreme People's Court on Evidence in Civil Procedures of 21 December 2001 ("Evidence Provisions")

- Interpretation of the Supreme People's Court on Problems Regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts of 8 March 2001 ("Interpretation on Emotional Damages")

- Opinions of the Supreme People's Court on Several Issues Concerning the Application of the Civil Procedure Law of the PRC of 14 July 1992 ("Opinions on Civil Procedure Law")

d) Important Cases

- Guiding Case No. 23: Sun Yinshan v. Jiangning Store of Nanjing Auchan Supermarket Co., Ltd., (judgment of 26 January 2014, as adopted by the Judicial Committee of the Supreme People's Court after deliberation)

- Guiding Case No. 17: Zhang Li v. Beijing Heli Huatong Auto Service Co., Ltd., (judgment of 8 November 2013, as adopted by the Judicial Committee of the Supreme People's Court after deliberation)

- Jiepao Electronic Technology Co., Ltd. v. Qingdao Hisense Import & Export Co., Ltd, (judgment of 24 August 2012), Qingdao Intermediate People's Court, Shandong Province)

- Shanghai Zhongmei Geophysical Prospecting Measurement Co., Ltd. v. Shanghai Jiangling Motor Sales Co., Ltd. (judgment of 14 April 2008), Shanghai Intermediate People's Court No. 2

- Zhao Jiying et al. v. Ningbo Yinzhou Fuyang Appliance Factory (judgment No.: (2007) Yue Min Yi Chu Zi No. 1756), People's Court of Yuecheng District, Shaoxing City, Zhejiang Province

- Qi Qingmin v. Shanghai Volkswagen Automotive Co., Ltd (judgment of 27 February 2006), Beijing Intermediate People's Court No.1

- Gu Xuefeng v. Shenzhen Pepsi-Cola Beverage Co,.Ltd (judgment of 31 July 2001), People's Court of Luohu District, Shenzhen

- Chen Meijin & Lin Dexin v. Mitsubishi Auto Industry Co., (judgment of August 10, 2000), Beijing Intermediate People's Court No. 2

- Zhou Zhi Qing v. Guangzhou Shi Zhu Jiang Beer Corporation Group (judgment of May 13, 1999), Guangzhou People's Court

2. Product Liability According to Product Quality Law

2.1 Essential Features of Product Liability according to Product Quality Law

According to the Product Quality Law, both the manufacturer and the seller may be liable. Because "manufacturer" and "seller" are not legally defined, the precise meaning of these terms is not clear. The predominant view in the Chinese literature is that the manufacturer for the purposes of the Product Quality Law is only the manufacturer of the final product, and not the parts manufacturer. However, the person who appears from the presentation of the product to be the manufacturer will be considered to be the manufacturer. According to the literature, the wholesaler, retailer and importer are all regarded as the seller.

According to the universally applicable prescriptions of the Product Liability Law, the following prerequisites must be fulfilled for product liability to arise:

(1) the product is placed on the market;

(2) the product exhibits a design or manufacturing defect;

For this prerequisite one may refer to **Zhou Zhi Qing v. Guangzhou Shi Zhu Jiang Beer Corporation Group**. Plaintiff was injured when two beer bottles exploded under the table at which he was sitting. Scientific and technical investigation of the bottles revealed that the explosion was caused by an external force and not by a potential defect in the beer bottle. Because the product did not reveal a defect, the manufacturer was not found liable.

(3) an injury to person or property has occurred;

In the case of **Gu Xuefeng v. Shenzhen Pepsi-Cola Beverage Co., Ltd.**, plaintiff claimed damages after having found a bug inside a bottle of defendant's cola beverage. The product was obviously defective. However, because plaintiff discovered the bug inside his drink before opening and drinking it, therefore no injury occurred and the court dismissed Plaintiff's claim.

(4) the product defect caused the injury.

For instance, in **Zhao Jiying et al. v. Ningbo Yinzhou Fuyang Appliance Factory**, defendant argued that plaintiff modified the circuit of his electrical fan by himself, which should be deemed to have been the main reason for plaintiff's electrocution. However, the court held that the non-conformity of the insulation resistance and electrical current with national quality standards contributed to plaintiff's injury.

2.2 Principles of Liability

a) Manufacturer's Liability

(1) Strict Liability

The manufacturer's liability is a so-called strict (or absolute) liability, i.e., the manufacturer is liable for losses caused by a defective product, regardless how the defect arose. The plaintiff may bring a product liability claim without having to prove the manufacturer's fault.

This is in contrast to the more general rule of Article 106 of the Civil Law, which holds that a person who injures someone or damages another's property (only) bears civil liability, if such injury or damages were caused by negligence or intent.

(2) Product Defectiveness

Article 46 of the Product Quality Law provides two rules for judging if a product is defective. First, a product is defective if it poses an unreasonable danger to personal safety or another's property. This is the case if the level of safety is less than a reasonable person in ordinary circumstances would expect from the product. Second, the product is defective if the product does not meet applicable national or industry standards.

In **Jiepao Electronic Technology Co., Ltd. v. Qingdao Hisense Import & Export Co., Ltd**, the Qingdao Intermediate People's Court held that the fact that a product was recalled in a different jurisdiction does not automatically render the product defective in China. Rather the determination has to be made according to the Chinese laws, regulations and standards.

(3) Defenses

Article 41 of the Product Quality Law provides that a manufacturer is not liable if he can prove any of the following circumstances:

- he did not put the product on the commercial market;
- the defect did not exist at the time the product was put on the market; or
- the defect was not perceptible by existing science or technical knowledge when it was put on the market.

b) Seller's Liability

There is some contention within the Chinese literature about whether the seller is liable for damages only if he acted improperly (tortious liability) or if even where he merely sold a defective product (absolute liability). The basis for this controversy lies in the unclear relationship between Article 42 (1) and Article 43 of the Product Quality Law. While Article 42 (1) states that the seller is only liable if the defects in the product arose from his fault, Article 43 provides that the injured party may claim damages from both the seller and the manufacturer. We believe the preferable interpretation is that the seller is only liable if he acted improperly, since the organization of the law suggests that Article 42 (1) refers not to the internal relationship with the manufacturer, but to the external relationship with the injured party.

However, Article 42 (2) of the Product Quality Law holds the seller liable in the absence of fault when he cannot locate the manufacturer or supplier of the defective product.

The principles of liability compel the manufacturer and seller to establish a well-functioning system for quality management. Article 3 of the Product Quality Law requires them to establish a comprehensive internal system for quality management and strictly maintain standards for quality assurance in the workplace, responsibility for quality and corresponding tests. Consequently, an adjudicator could find the manufacturer and the seller responsible for identifying and remedying any deficiency in this system.

c) Licensor's Liability

Pursuant to the Official Reply of 11 July 2002, a person who allows another to use their name, trademarks or other distinguishing marks for the defective products of a third party is liable along with the actual manufacturer and the seller.

2.3 Joint and Several Liability

According to Article 43 of the Product Quality Law, the manufacturer and seller are jointly and severally liable for the defective product. Thus, the injured party can pursue a claim from either one or both of them. However, if one accepts that the seller is only liable for injuries caused by product defects due to his own fault (tortious liability as mentioned above), then joint and several liability can also only exist on such basis (and not on strict liability). If the seller pays compensation, but the manufacturer is responsible for the product defect, the seller has the right to recover its loss from the manufacturer. Vice versa, the manufacturer has the right of recovery against the seller if the product defect was caused by the seller.

2.4 Burden of Proof

Although the Civil Procedure Law (Art. 64) stipulates that the party claiming damages is obliged to provide proof for its claims, in practice the burden of proof is often placed on the manufacturer. It is then up to the manufacturer to prove that there were no defects in the product.

Further, the Supreme People's Court confirmed in its Evidence Provisions that the manufacturer of the product bears the burden of proof for the defenses as set-out in Art. 41 Product Quality Law, which are mentioned above under 3.2 a) (3).

In the case of **Chen Meijin & Lin Dexin v. Mitsubishi Auto Industry Co.,** the vehicle manufacturer was liable because insufficient evidence was submitted that the shattering of the windscreen in the vehicle in question was not brought about by a defect in the vehicle, or that any other external force caused the death of the driver.

However, in the case of **Shanghai Zhongmei Geophysical Prospecting Measurement Co., Ltd. v. Shanghai Jiangling Motor Sales Co., Ltd.,** plaintiff was unable to present the court sufficient evidence establishing that the car was defective. Therefore, the manufacturer was released from its legal burden of proof for further defense.

The aforementioned two cases show that the plaintiff (i.e. customer or injured person) in product quality proceedings will first have to provide evidence that the product in question is indeed defective. Only then will the burden of proof shift to the defendant (i.e. manufacturer or seller) who will then be responsible to prove any of the defenses set-out in Art. 41 Product Quality Law.

2.5 Conclusiveness of Expert Opinion

The Civil Procedure Law requires experts on certain issues be appointed by the court (Art. 76). Accordingly, under the Product Quality Law, the court may instruct an institution for the testing of product quality to inspect a product in detail, and the resulting inspection report is considered expert evidence (Art. 48).

The plaintiff and the defendant may also supply evidence to prove that the product was or was not defective. In practice, however, the courts ascribe greater weight to the expert evidence of the legally appointed specialist institutions, and this expert evidence is in most cases decisive.

2.6 Limitation of Action

The injured party's claim against the manufacturer or seller for damages is barred if the limitation period has expired.

The limitation period expires two years after the injured party discovered or should have discovered the injury to his rights (Product Quality Law, Art. 45 (1)). The limitation period expires in any case ten years after the defective product is delivered to the first user, except where the period for safe use clearly indicated has not expired, in which case such later period applies (Product Quality Law, Art. 45 (2)).

The limitation period will be stayed by the commencement of an action, and also where one of the parties makes a demand or agrees to settle a claim. The limitation period starts again after the stay expires (Civil Law, Art. 140).

According to Art. 2 of the Supreme People's Court "Interpretation on the Statutes of Limitation", the limitation period cannot be extended or shortened (e.g. by agreement or waiver) in violation of any legal provision.

2.7 Private International Law

PRC product liability laws and regulations also apply to foreign manufacturers who export products to the PRC. This is based, first, on the Civil Law, which declares applicable the law of the place of the tortious conduct to claims for damages (Art. 146). It also flows from the Product Quality Law, which applies not just to production activities in the PRC, but also to products distributed there (Art. 2). The Civil Law (Art. 145 (1)) and the Contract Law (Art. 126 (1)) stipulate that, unless PRC law requires otherwise, the parties to a foreign-related contract may choose the applicable law. However, both foreign and domestic producers and sellers should be aware that the Product Quality Law applies to products that are made or sold in the PRC.

Art. 45 of the Law of Foreign-Related Civil Relations states that product liability shall be governed by laws of the habitual residence of the infringed party. Where the infringed party "chooses" to apply laws of the place of the principal office of the tortfeasor or the law of the place of the tortious conduct, the laws of the place of principal office of the tortfeasor or place of tortious conduct shall apply. These laws also apply if the tortfeasor does not engage in relevant business activities at the habitual residence of the infringed party. This option to choose the applicable law retroactively may pose a particular risk to those manufacturers whose principal office is in jurisdictions that impose high amounts of damages, such as the US.

3. Product Liability According to Tort Law

By and large, the Tort Liability Law compiles various existing rules that are currently found in other laws and regulations. Chapter 5 of the Tort Liability Law is dedicated to product liability but contains only seven articles. Naturally, reference has to be made to the detailed provisions in the Product Quality Law and the Consumer Protection Law, especially for core definitions such as "product" and "defect". However, the Tort Liability Law introduces some new concepts as well.

3.1 Continuous obligation to take remedial action

The Tort Liability Law (Art. 46) requires a manufacturer or seller to take remedial action in a timely manner, such as by issuing a warning or recall, if a product is found defective after it is placed on the market. If damage is caused due to a failure to take remedial action in a timely manner or due to ineffective implementation of such action, the manufacturer or seller will bear tort liability. This is intended to encourage the manufacturer or seller to address defects in a proactive manner.

3.2 Punitive damages

The Tort Liability Law (Art. 47) allows an injured party to seek punitive damages if a manufacturer or seller has clear knowledge that a product contains a defect, but nonetheless continues to produce or sell the same, resulting in death or serious injury.

4. Contractual Product Liability

4.1 Buyer's Warranty Rights

If the condition of a product upon sale does not meet quality standards, the Contract Law grants the buyer the right to claim for repair, replacement, remanufacture, exchange or reduction of the sale price (Art. 155, 111 and 113). The buyer may also make a claim for damages. Similar warranty rights are expressed elsewhere, such as the Warranty Provisions (Art. 1), the Product Quality Law (Art. 40), the Consumer Protection Law (Art. 24) and the Consumer Rights Contravention Provisions (Art. 6). This liability is a strict liability and arises independent of fault – that is, the seller is liable even when not at fault for the quality defect.

Generally, the quality standard of a product is based primarily on the contractual agreement (Contract Law, Art. 154 and 61). Without such agreement judges will apply common usage. They will use national or industry standards or, if these do not exist, the general or particular standards that conform to the purpose of the contract (Contract Law, Art. 154, 61 and 62 (2)).

4.2 Limited Possibility of Exclusion of Liability

In order to protect the legal rights and interests of consumers, the Consumer Protection Law (Art. 16 (3)), the Contract Law (Art. 40) and the Consumer Rights Contravention Provisions (Art. 3 (1)), the Administrative Measures for Online Trading (Art. 17) prohibit merchants from stipulating (through form contracts, circulars, statements and notices in business premises) provisions that are unfair or unreasonable to consumers. These laws also prohibit the exclusion or limitation of the merchant's civil liability for infringement of the legal rights and interests of consumers. Any such purported exclusions or limitations are ineffective.

Thus the exclusion of liability through general business terms is not possible in the sphere of product liability. Though the scope of liability may be to some extent defined in individual contracts, the parties are not allowed to "contract out" of certain liabilities. Although a commercial seller may use contractual language to evade responsibility for damage due to his simple negligence, according to the Contract Law (Art. 53), he cannot exclude liability for damage to life and limb, or for intentional or grossly negligent damage to property.

4.3 Limitation of Claims

The Civil Law governs the limitation period for making a contractual product liability claim. The limitation period for damages claims for personal injury and claims for

defective products is one year (Civil Law, Art. 136 (1)(2)). The period begins when the injured party identified or should have identified the infringement of its rights (Civil Law, Art. 37). The limitation period for an international contract dispute is four years, and likewise starts running at the time when the injured party identified or should have identified the infringement of its rights (Contract Law, Art. 129). The limitation period expires no more than 20 years from when the rights were infringed. However, the People's Court may extend the period in exceptional circumstances (Civil Law, Art. 137).

As with tortious product liability claims, the limitation period is interrupted and begins to run anew if the grounds as mentioned in 2.6 above are met.

According to Art. 2 of the Supreme People's Court "Interpretation on the Statutes of Limitation", the limitation period cannot be extended or shortened (e.g. by agreement or waiver) in violation of any legal provision.

4.4 Choice of Law

The Contract Law (Art. 126 (1)) states that only the parties to a "foreign-related" contract may choose the law applicable to the contract. According to the general definition in No. 178 of the Opinion on Civil Law, a legal relationship is "foreign related" if one or both parties are foreigners, stateless, or foreign legal persons, if the subject matter of the legal relationship is in a foreign country, or if the legal circumstances of the development, change or lapse of rights or duties occur in a foreign country.

In this context, if either of the above conditions for being "foreign related" is satisfied, the contractual parties may chose foreign law for interpreting their contract and resolving any dispute.

However, some PRC laws and regulations prohibit the direct marketing of certain products by companies not incorporated in the PRC. For example, PRC law does not permit direct marketing of motor vehicles by companies not incorporated in the PRC. Under normal circumstances the purchaser is a PRC citizen or legal person; a contract involving foreign interests therefore would not exist and foreign law could not apply.

5. Damages

In product liability cases, claims by injured parties for damages fall into one of the following categories:

- damages for personal injury
- damages for emotional injury
- damages for property damage or other pecuniary loss
- punitive damages

Damages will only be awarded to the plaintiff if he can show that the damage was actually suffered. That being said, it is widely accepted that the plaintiff in product liability cases merely has to prove the possibility that the product defect could have lead to the damage in question.

5.1 Personal Injury

If the injured party suffers a personal injury as a result of a product defect, then the manufacturer and the seller must compensate the plaintiff for, amongst other things, the following costs (Product Quality Law, Article 44):

- medical expenses
- nursing expenses during medical treatment
- loss of income due to absence from work
- in case of permanent disability, cost of self-help devices, cost of living bonus, disability damages and necessary living expenses for the invalid's dependents; and
- in the case of death, the funeral costs, compensation for the death and living costs for the deceased's lifetime dependents.

5.2 Emotional Injury

a) Emotional Damages for Injury to Health and Body

The Interpretation on Emotional Damage (Art. 1 (1) and 8 (2)) and the Interpretation on Personal Injury (Art. 18) restrict claims for emotional damages to persons who have suffered a major injury to their health or body.

b) Emotional Damages in the Event of Death

If the product defect causes death, then the spouse, parents and children of the deceased may have a claim for emotional damages in the form of damages for pain and suffering. If the deceased had none of these family members, then other near relatives can also make the claim (Interpretation on Emotional Damage (Art. 7) and the Interpretation on Personal Injury (Art. 18)). It is not yet clear to what extent, in the context of damages for the pain and suffering to relatives, the Chinese courts require as an additional element that the damage be "major" (Interpretation on Emotional Damage (Art.8)).

c) Method of Calculation

In the calculation of the level of emotional damages the following factors must be taken into account (Interpretation on Emotional Damage, Art. 10)):

- the seriousness of the prohibited conduct
- the means, circumstances and manner of the prohibited conduct
- the consequences of the prohibited conduct
- the income gained as a result of the prohibited conduct
- the economic capacity of the wrongdoer to bear the liability
- the average living standard in the place of the competent court.

5.3 Damage to Property and Consequential Pecuniary Loss

The manufacturer shall be liable for damages if a defect in a product causes personal injury or damage to property other than the defective product (Product Quality Law, Art. 41). Therefore, the injured party has a claim for compensation for damage that is caused by the defective product to objects other than the defective product itself. With regard to damage to the defective product itself, the decision of the case **Qi Qingmin v. Shanghai Volkswagen Automotive Co., Ltd** renders some clarification. Notwithstanding Art. 41 of the Product Quality Law, damage to the defective product itself can be included in a compensation claim based on the Product Liability Law, and thereby making use of the evidence rules which are advantageous to the plaintiff. However, for the calculation of the damages, the court in this case made use of the general rules according to the Civil Law. The court argued that in such cases it could be unfair to the injured party and may not be economical from the view of the judicial

cost if the injured party would have to base its claim against the manufacturer / seller on contractual liability.

In addition, the injured party can claim consequential pecuniary losses caused by this damage, such as loss of profits. This follows from the requirement that the person who causes the injury must compensate "other major loss" to the injured party (Product Quality Law, Art. 44 (2)). The question of when such losses are "major" has not yet been established in case law. If only trifling damage is excluded, the scope of this limitation would be quite narrow. The injured party may also make a claim for consequential pecuniary losses directly caused by the defective product (Product Quality Law, Art. 40, 41 and 43).

5.4 Punitive Damages

The Tort Liability Law (Art. 47) allows an injured party to seek punitive damages if a manufacturer or seller has clear knowledge that a product contains a defect, but nonetheless continues to produce or sell the same, resulting in death or serious injury.

Art. 55 paragraph 1 of the Consumer Protection Law, requires a seller that practices fraud, to pay an amount that is three times the payment made by the consumers for the goods purchased, or in the amount of RMB 500 if the increased compensation is less than RMB 500. This provision had also been applied in Guiding Case Nr. 17 **Zhang Li v. Beijing Heli Huatong Auto Service Co., Ltd.** where a car had been sold as "new" even though it had undergone previous repairs.

Art. 55 paragraph 2 of the Consumer Protection Law further requires a merchant who knowingly provides defective goods causing the death of, or serious health damage to, the consumers or other victims to pay the additional punitive damages up to an amount twice the losses suffered. In case of food products, the buyer may be entitled to an amount of ten times the purchase price as punitive damages if the seller (see details in the Chapter on "Food" below).

5.5 Contributory Negligence

Damage awards are reduced proportionally when an injured party's negligence contributes to the damage (Civil Law, Art. 131).

6. Administrative Liability

The Consumer Protection Law provides that, unless other specific regulations prevail, the competent AIC may impose administrative sanctions against a merchant who has contravened the Product Quality Law or other relevant laws or regulations (Art. 50). Corresponding rules appear in the Standardization Law (Art. 20) and the Standardization Regulations (Art. 33).

6.1 Administrative Penalties

Administrative penalties listed in the Consumer Protection Law (Art. 56) include the confiscation of unlawful proceeds; the imposition of a fine of between one and ten times the value of the unlawful proceeds. If there are no unlawful proceeds, a fine of up to RMB 500,000 may be imposed. In serious cases, the business may be closed or the business license withdrawn.

a) Circumstances of Liability under Art. 56 of the Consumer Protection Law

- manufacture or sale of products that do not meet the requirements for protection of safety of person and property
- products fitted out with fake parts, inferior products sold as quality products, or non-compliant goods sold as compliant goods
- manufacture of products superseded by formal decree of the State, or sale of ineffective or deteriorated goods
- misrepresentation about place of manufacture, false or unauthorized use of the name or address of another's factory, false or unauthorized use of quality labels such as accreditation or award symbols
- sale of commodities that are not inspected or quarantined, if required, or forging the results of inspections or quarantines
- misleading a consumer through false information about goods or services
- refusing to comply with or delaying in complying with the orders issued by relevant administrative departments on taking measures relating to the defective goods or services, such as the measures to stop sales, issue warnings, conduct recalls or innocuous treatment, destroy the goods, stop production or services, etc.

- deliberate delay or unreasonable refusal of consumer's requests for repair, remanufacture, replacement, exchange, completion of the quantity of goods, or compensation

- violating the human dignity or personal freedom of consumers, or infringing upon the rights of consumers to obtain protection of their personal information in accordance with the law

- other circumstances in which laws or regulations prescribe that an infringement of the rights and interests of consumers is to be punished

b) Circumstances of Liability under the Standardization Regulations

Circumstances of administrative liability are also provided in the national regulations that regulate the prescription of standards:

(1) Standardization Law

According to the Standardization Law the competent AIC is (insofar as other regulations do not provide otherwise) responsible for punishing the violation of standards prescribed by law or regulation by the imposition of an administrative fine, confiscation of goods and confiscation of unlawful profits (Art. 20).

(2) Standardization Regulations

According to the Standardization Regulations, non-compliance with mandatory product standards can have the following consequences for the manufacturer or seller (Art. 33):

- cessation of production

- prohibition on sales

- confiscation and/or destruction of goods

- performance of necessary technical treatment

- imposition of a fine of up to RMB 5,000 on the person responsible

- imposition of a fine in the sum of 20%-50% of the value of the goods.

Other administrative sanctions may be imposed by the administrative departments responsible for standardization and the administrative departments in charge of

industry and commerce in accordance with their competence (Standardization Regulations, Art. 33 (4)).

6.2 Duty to Act under the General Regulations

The Consumer Rights Contravention Provisions require merchants to implement the following measures without delay upon discovery that supplied goods or services are defective (Art. 2):

- cessation of sale of the defective product or supply of the defective services
- lodgment of a defect notice with the responsible authority (e.g., the authority for industry and trade)
- timely and effective public announcement of the fault (e.g., through public media, notices in place of business, telephone, fax, email, SMS);
- recall of the defective products or provision of appropriate aid in the case of services already provided.

If these obligations are not fulfilled, the AIC has the authority to order their fulfilment and record a corresponding report in the "Information on the Reputation of Firms".

6.3 Obligation to Act under the Recall Provisions

At present, there is a patchwork of recall provisions for special products. The first recall provisions were promulgated for automobiles in 2004 against a backdrop of foreign manufacturers not affording Chinese consumers the same rights as enjoyed in other jurisdictions. Other recall provisions in relation to food, toys and drugs were enacted in 2007.

These provisions now require the manufacturer to recall the defective product and pay all associated costs. In some serious cases, the manufacturer could be punished with an administrative fine, which could also be imposed on the seller or repairer under some circumstances. The refusal of a manufacturer to recall a defective product is punishable by the temporary suspension or withdrawal of the mandatory certification for the product.

The recall of defective products does not relieve the manufacturer of its liability to pay civil damages to buyers or third parties injured by the defective product.

7. Criminal Liability

7.1 General

The Criminal Law (Art. 140-150) also regulates the manufacture and sale of false and inferior products. Art. 140 and 146 apply in general, whereas Art. 141-145, 147 and 148 specifically regulate certain products, such as drugs, food and cosmetics.

7.2 Deception about Product Quality

A manufacturer or seller who mixes up or adulterates products, passes fake imitations for genuine, sells seconds at a top quality price or passes unqualified products as qualified ones is punishable under the Criminal Law (Art. 140).

The penalty for this offence depends on the amount of the proceeds resulting from the sale of the defective product:

- For proceeds of RMB 50,000 to RMB 200,000: imprisonment for up to two years or short term imprisonment and/or a fine of 50% to 200% of the sale proceeds
- For proceeds of RMB 200,000 to RMB 500,000: imprisonment for between two and seven years and a fine of 50% to 200% of the sale proceeds
- For proceeds of RMB 500,000 to RMB 2,000,000: imprisonment for at least seven years and a fine of 50% to 200% of the sale proceeds
- For proceeds above RMB 2,000,000: imprisonment for between 15 years and life imprisonment and a fine of 50% to 200% of the sale proceeds or confiscation of assets

7.3 Failure to Comply with Safety Standards

If a product that does not comply with the standards prescribed for the protection of safety of persons and property is produced or knowingly sold, and results in damage that is "serious", a maximum term of imprisonment of five years and a fine in the amount of 50% to 200% of the sale proceeds can be imposed (Criminal Law, Art. 146).

If the consequences are "particularly serious", a term of imprisonment of not less than five years and a fine of between 50% and 200% of the sale proceeds may be imposed.

7.4 Subjective Elements of the Offence

Negligent conduct is only punishable if the law so prescribes (Criminal Law, Art. 15 (2)). Since there is no such prescription in Art. 140 or 146 of the Criminal Law, deliberate conduct must be a requirement for culpability. Specific intent is required by Art. 146 of the Criminal Law as an element of the offence of "selling". This conduct is only punishable in the case of knowledgeable conduct; that is, only if the seller knew of the defectiveness of the product.

7.5 Persons Criminally Liable

Criminal liability falls on the company as well as specific natural persons who have acted for the company. A company that has engaged in the conduct described in Art. 140-148 of the Criminal Law will be liable for a fine (Criminal Law, Art. 150). Furthermore, the manager directly responsible and other persons directly responsible are punishable according to Art. 140 to 148, respectively.

7.6 Relationship between Articles 140 and 141 to 148 Criminal Law

Art. 140, as a general provision, would apply when individual cases do not fulfil the conditions of the specific articles. In the case of "the People's Procuratorate of Rongchang County, Chongqing Municipality v. Liao Zhengmei and etc.", two of the illegal manufacturers were sentenced to imprisonment under the count of "manufacture, sell of fake or inferior products" according to Art. 140; and the other two were guilty under Art. 143 "manufacture, sell of food inconsistent with hygiene standard".

If the conduct fulfils the elements of the offence of both Art. 140 and 141 to 148 of the Criminal Law, then the perpetrator will be punished according to the provision that stipulates the higher penalty (Criminal Law, Art. 149 (2)).

8. Jurisdiction

8.1 Competency of the People's Courts

The contractual and tortious product liability claim of the injured party underlies the jurisdiction of the courts of the PRC, as long as their jurisdiction is not excluded by an effective international choice of forum agreement or arbitration agreement.

a) Breach of contract

In claims concerning contractual product liability, the local jurisdiction of the People's Court is decided according to Art. 24 of the Civil Procedure Law. According to this provision, the People's Court where the defendant resides or where the contract was performed will have jurisdiction.

b) Prohibited conduct

For tortious liability claims, the People's Court with jurisdiction is located where the tortious conduct takes place, where the results of this conduct arose or where the defendant resides.

8.2 International Choice of Forum Agreement

Enforcing foreign judgments in the PRC remains extremely difficult, partly because of the lack of Sino-foreign treaties regarding judicial cooperation.

8.3 Agreement to Arbitrate

Parties may agree to arbitrate contractual and tortious product liability claims. Arbitration agreements must be in writing. An effective arbitration clause has the effect that the court of arbitration, rather than the court with local jurisdiction, adjudicates upon the claims.

However, typically product liability also involve claims that are not based on contract but only on tortuous liability (be it under the Tort Law, Product Quality Law, Consumer Protection Law or other laws and regulations). Lacking a contractual agreement such cases leave no room for arbitration as a means of dispute resolution.

The Contract Law only allows parties to a contract involving a foreign interest to select an arbitration court outside of the PRC (Art. 128 (2)). Enforcement of foreign arbitration awards has proven to be easier than the enforcement of foreign court judgments. However, difficulties remain.

Chapter 2: Food

1. Introduction

In early September 2008, the melamine contaminated milk scandal involving inter alia, the Sanlu Group, broke out, which was the biggest food safety scandal in the PRC history and marks the beginning of concerted efforts to tackle food safety violations in China. It has been reported that contaminated milk products have claimed the lives of at least six babies and left 300,000 others with various urinary tract ailments, including kidney stones.

The whole scandal involved three parties, among which one was Sanlu Group who produced and sold the dairy contaminated with melamine to the general public, one was the illegal producer who produced the "protein powder" made of melamine and other materials, and the third party linked Sanlu Group and the producer by selling milk containing the "protein powder" to Sanlu Group. It appears that Sanlu Group was at first not aware of such quality problem of the milk. However, after inspection conducted by the quality supervision department of the people's government of Hebei Province, group management passed the resolution to continue the sales of the stored dairy contaminated with relative lower level of melamine.

The verdicts handed down by the courts in 2009 were unprecedented in their scale. Sanlu Group was sentenced to a fine in the amount of RMB 49,374,822.00. The former chairman of Sanlu Group, Tian Wenhua was sentenced to life imprisonment and a substantive fine under a charge of "crimes of producing and selling inferior food". Of those who produced the "protein powder", one was sentenced to death, one was sentenced with a suspended death penalty and the other two were sentenced to life imprisonment under the charge of "crimes of endangering public security". Of those who sold the milk to Sanlu Group, one was sentenced to death under the charge of "crimes of producing and selling poisonous or harmful food". All together 25 persons were found guilty and had to bear criminal liabilities.

After the Sanlu case, the increased focus on food safety has led to a crack-down on several substandard food producers and venues and brought more food scandals to light in the process. Among those where some that were primarily concerned with smaller food stalls, such as locally produced dumplings tainted with insecticides and pesticides, the use of "recycled" gutter oil, and the "fake" lamb meet scandal in Shanghai in 2013, where meat labelled as "lamb meat" was found to contain meat of rats, foxes or minks. In August 2013, China then also experienced another large scale food safety incident when it had to ban all imports of milk powder from New Zealand after its main dairy exporter, Fonterra, found a bacterial strain in some of its products that can cause botulism, a rare and potentially fatal illness.

2. Applicable Provisions

In addition to the laws and regulations listed above in Chapter 1, section 2, which generally also apply to food product liability cases, the following laws and regulations are the main provisions particularly promulgated for regulating the food safety:

a) National Laws and Regulations

- Provisions of the Supreme People's Court on Certain Issues concerning the Application of Law in the Hearing of Cases Involving Food and Drug Disputes of 23 December 2012 ("SPC's Provisions on Food and Drug Disputes")

- Measures for the Administration of the Safety of Imported and Exported Food of 13 September 2011 ("Measures for Imported and Exported Food")

- Implementing Regulations of Food Safety Law of 20 July 2009 ("Food Safety Regulations")

- Food Safety Law of the PRC of 28 February 2009 ("Food Safety Law")

- Administrative Provisions on Recall of Food Products of 24 July 2007 ("Food Recall Provisions")

- Special Rules of the State Council on Strengthening the Supervision and Administration of the Safety of Food and Other Products of 26 July 2007 ("State Council Special Rules")

As a general legal principle under the PRC legal framework, special provisions have precedence over general provisions as long as the former are not in violation of the latter. Therefore, the particular and specific stipulations in the Food Safety Law and Food Recall Provisions as well as other provisions relevant to the food product apply to food product liability provided that the said provisions is in conformity with general laws and regulations on product liability, whether the particular food provisions are more stringent or not. On the other hand, where certain aspects are not governed by the particular food safety provisions, then the general provisions, as set-out in Chapter 1 of this book, apply.

3. Civil Liability

3.1 Grounds of Civil Liability

The civil liability in terms of unsafe food on producers and business operators under the PRC product liability regime is based mainly on the Civil Law, Contract Law, Product Quality Law, Consumer Protection Law and the Food Safety Law.

Consumers can seek damages and compensation for personal injury and damages suffered from sub-quality food. Under the PRC laws, claims can be based on two grounds as below, which have been elaborated in Chapter 1:

- Tortious liability
- Contractual liability

The SPC's Provisions on Food and Drug Disputes clarify that liability is not excluded if a food product is given to a consumer as a gift.

3.2 Liability of Online Sales Platform Providers

Where a consumer suffers damage caused by a food or drug product purchased via an online transaction platform, and the provider of the online transaction platform is unable to provide the real name, address and valid contact details of the manufacturer or the seller of the food or drug product, the online transaction platform provider is liable.

After the provider of the online transaction platform has performed its compensation liabilities, the provider can take recourse against the manufacturer or the seller of the food or drug product.

3.3 Joint and Several Liability

Where a consumer sues only the seller or the manufacturer, the competent people's court may, where necessary, add relevant parties to the proceedings (The SPC's Provisions on Food and Drug Disputes, Art. 2).

The Food Safety Law (Art. 52) provides joint and several liability for food safety lapses to the food business operator and a sponsor of a centralized trade market, lessor of sales counters or organizer of a trade fair if one of the latter fails to perform obligations such as checking the licenses of the business operators or regularly checking their business operation environment and conditions.

Where the provider of an online transaction platform fails to take necessary measures although it knows or should know that the manufacturer or the seller of a food or drug product makes use of the said platform to infringe upon the legitimate rights and interests of consumers, thus causing harm to a consumer, the provider of the online transaction platform is jointly and severally liable with the manufacturer or the seller of the food or drug product (The SPC's Provisions on Food and Drug Disputes, Art. 9).

Social organizations or other organizations or individuals who recommend certain food products to consumers that later damage their legitimate rights and interests bear joint and several liability along with the producers and business operators involved with the defective food (Food Safety Law, Art. 55).

3.4 Burden of Proof regarding causation

The SPC's Provisions on Food and Drug Disputes not only stipulate that manufacturers and sellers bear the burden of proof for the claim that their food products meet quality standards, but also the lower threshold for consumers to proof causation: where "preliminary evidence" shows causation between the damage and the consumption of the food or drug product, the burden of proof shifts to the manufacturer and/or seller to prove that the damage is not caused by the non-compliance with quality standards of the food or drug product (The SPC's Provisions on Food and Drug Disputes, Art. 5 and 6).

3.5 Punitive Damages

According to Article 96 of the Food Safety Law, where a manufacturer manufactures or a seller knowingly sells food which fails to comply with the food safety standard, consumers may in addition to claiming damages, also require the manufacturer or the seller to pay punitive damage of an amount of ten times of the food price. In the Guiding Case Nr. 17 of the People's Supreme Court of **Sun Yinshan v. Jiangning Store of Nanjing Auchan Supermarket Co., Ltd.,** the consumer bought 14 bags of sausages of which he knew that the production date had expired and immediately asked for compensation. After his request was rejected, he sued the supermarket for an amount of ten times of the food price according to Article 96 of Food Safety Law. The court awarded the amount and it also held that the previous knowledge of the consumer regarding the expiration did not impede his claim. The defendant in the case had argued that the plaintiff had not acted in his capacity as "consumer" because he never intended to consume the goods of which he knew were expired, but the defendant was not heard with this argument. The SPC's Provisions on Food and Drug Disputes further confirm this interpretation stipulating that a court shall not uphold the defense by the manufacturer and/or the seller that the consumer has bought the

food or drug product despite clear knowledge that the food or drug product has quality issues. However, a line may be crossed if a person returns substandard goods on a regular basis for profit and thus does indeed not act in any capacity of a consumer.

3.6 Payment Priority

If a producer or business operator is subject to civil damages, administrative fines and capital punishment for his misconduct, their property will first be used to discharge the civil liability to their victims (Food Safety Law, Art. 97).

4. Criminal Liability

As mentioned in Chapter 1, the PRC Criminal Law stipulates the criminal liabilities regarding producing and/or knowingly selling fake, inferior or defective products, including poisonous and harmful food, or food which is not up to hygiene standards (Art. 140-150). Art. 143 and 144 apply specifically to food. Art. 143 provides that if individuals or companies produce or sell food which does not comply with the safety standards to an extent sufficient to result in serious food intoxication incidents or other serious diseases caused by food-borne bacteria, such individuals or companies are subject to:

- detention or imprisonment of not more than three years and
- fines

Where the defective food caused serious damage to personal health or if there are other grave circumstances, such individuals or companies are subject to:

- imprisonment of not less than three years and not more than seven years and
- fines

Where the consequences are exceptionally serious, the individuals or companies are subject to:

- imprisonment of no less than seven years or life imprisonment and
- fines or confiscation of property

The Criminal Law (Art. 144) subjects individuals or companies who add poisonous or harmful non-food materials to food when it is in production or on sale, or knowingly sell such food, to:

- detention or imprisonment of not more than five years and
- fines

Where the defective food caused serious harm to human health or there are other grave circumstances, such individuals or companies are subject to:

- imprisonment of no less than five years and no more than ten years and
- fines

Where the defective food caused death or other exceptionally serious damages to personal health, the individuals or companies are subject to:

- imprisonment of not less than ten years or life imprisonment
- death penalty and
- fines or confiscation of property

A company held criminally liable for supplying defective products (including foods) is itself only subject to a fine (Criminal Law, Art. 150). The person in charge of the company and other relevant responsible persons are subject to the criminal sanctions mentioned above.

5. Administrative Liability

5.1 Duty to Act under Food Safety Law

Promulgated on 28 February 2009, the PRC Food Safety Law entered into effect as of 1 June 2009. Compared to the Food Hygiene Law which was repealed accordingly, the Food Safety Law has made some adjustments and focuses more on the food safety supervision and management from an overall perspective starting from the source to the end consumption of the food so as to ensure consumers to be provided with safe food. Subsequently on 20 July 2009 the Food Safety Regulations were promulgated accordingly.

5.1.1 Health Check Requirement

Personnel engaging in food production and food-related business must have a health examination every year and may only work after obtaining a health certificate.

5.1.2 Establishment of a System of Compulsory Food Safety Standard

The administrative departments of health both at state and local level are in charge of formulating and implementing a system on monitoring food safety. Should any potential food safety hazard be found under the monitoring system, the State Council's Administrative Department of Health must organize and establish an expert panel to conclude a food safety risk assessment. In case the food product is proved to be unsafe by the risk assessment, the production and operation of the unsafe food product must be ceased and a compulsory safety standard thereon must be formulated, if necessary.

Such system of compulsory safety standard must be formulated and published by the State Council's Administrative Health Department. It is intended that the State Council Administrative Department of Standardization provide standard series numbers for the public's reference.

In the absence of any state food safety standard, the local administrative health departments of provinces, autonomous regions and centrally-governed municipalities may formulate local food safety standards and must report such standards to the State Council Administrative Health Department. The Food Safety Law further provides that for food with neither state safety standard nor local standard, the manufacturer must formulate its own safety standards to be the basis on which the manufacturer organizes production (Art. 25). Such manufacturer standard applies only within the manufacturing enterprise and must be reported to the administrative health department at provincial level for record.

5.1.3 Mandatory Recall System for Unsafe Food

Where a food product is found to be not in compliance with the food safety standards, the food producer must immediately cease the production and recall the food products which are for sale on the market and notify the business operators and consumers of such incompliance. The recall and notification information must be recorded. Where a business operator finds the food products not conforming to food safety standards, it must immediately cease the sale of the food product in question and notify the food producer and consumers of such incompliance and keep record of the cessation and notification information. If the food producer fails to cease the production or recall the unsafe food product, the local quality supervision authority, the AIC, and/or the supervision and administration department of food and drug may order the producer to recall the unsafe food product and/or to cease the business operation involving the food.

The producer must make remedies to dispose of or destroy the recalled food, and report to the quality supervision department at and above county level about the recall and the disposal of the food.

The recall system provided in the Food Safety Law is in consistence with similar requirements under the Food Recall Provisions.

5.1.4 Inspection and Recordal Obligation

Food producers that procure raw materials for food products, food additives and food-related products, and food-related business operators that procure food products must check the license of the suppliers and the product quality certificates.

Food producing enterprises must establish a check and inspection record system for the purchased food raw materials, food additives and food-related products, and a food ex-factory check record system. An enterprise engaging in the business operation of food products must establish a check and inspection record system.

5.1.5 Licensing System

The state adopts a licensing system for the food production and business operation as provided in the Food Safety Law (Art. 29), which is categorized as follows:

- food production license
- food circulation license and
- catering services license

Pursuant to the Food Safety Regulations (Art. 20 (3)), the term of the above three kinds of licenses is three years.

The competent authorities which have the authority to grant such licensing include the quality supervision department, the AIC and the food, pharmaceutical supervision and administration department at and above county level. To obtain the respective license, the food producer and business operator should ensure that the production and operation of food comply with the relevant food safety standard and conform to a series of requirements, including but not limited to:

- having places for treating food raw materials and food processing, packaging and storage, which adapt to the varieties and quantities of the food under its production or business operation; keeping the environment of the said places tidy and clean, and ensuring that they are at a prescribed distance from toxic and hazardous sites and other pollution sources;

- having production or business operation equipment or facilities, which adapt to the varieties and quantities of the food under its production or business operation, and having the corresponding equipment or facilities for disinfection, changing clothes, toilets, day-light, illumination, ventilation, anti-corrosion, anti-dust, anti-fly, rat proof, mothproof, washing, disposal of waste water, and storage of garbage and waste;

- having professional food safety technicians and managerial personnel, and rules and regulations for ensuring the food safety; and

- having reasonable equipment layout and technical flowchart so as to prevent cross pollution between the food to be processed and ready-to-eat food, and between raw materials and finished products, and to prevent the food from contact with toxic substances or unclean articles.

The food producer and business operator may be required to submit documentation evidencing the forgoing conditions and requirements have been satisfied. The said competent authorities will verify such documentation and conduct on-site inspection, if necessary, to decide whether to grant relevant license to the food producer and business operator or not.

For the production of food additives, the state also adopts a licensing system, of which the requirements and application process must be in accordance with the legal provisions on the licensing of industrial products.

5.1.6 Import and Export of Food Products

Art. 48 of the Measures for Imported and Exported Food provides that the imported food, food additives and food-related products must conform to the PRC national

food safety standards and relevant state inspection and quarantine requirements. The imported food must be subject to the inspection of the entry/exit inspection and quarantine institution. If the food product passes the said inspection, a clearance certificate must be issued and the customs office must release the food product accordingly.

The AQSIQ implements the registration system over overseas food manufacturers that export food to China, and the registration shall be implemented in accordance with the relevant provisions of the AQSIQ. Exporters or agents that export food to China shall go through the formalities for record-filing with the AQSIQ. The exporters or agents that apply for record-filing shall provide the enterprise information according to the requirements for record-filing, and be responsible for the authenticity of such information. The name list of registration and record-filing will be announced publicly on the website of the AQSIQ.

Imported pre-packed food products are required to bear labels and instructions in Chinese. Such labels and instructions must conform to the Food Safety Law, Food Safety Regulations, other relevant laws, administrative regulations and the PRC national food safety standards, and state the place of origin as well as the name, address and contact information of the domestic agent. No pre-packed food may be imported if it does not have labels and instructions in Chinese or if the labels and instructions do not conform to the requirement as demonstrated in the previous sentence (Art. 15 and 18 of the Measures for Imported and Exported Food).

The importer shall establish a recording system for food import and sale, faithfully recording the serial number of the hygiene certificate, product name, specification, quantity, date of production, batch number, shelf life, exporter and purchaser's name and contact information, date of delivery and other contents. Such record shall be authentic, and kept for at least two years (Art. 20 of the Measures for Imported and Exported Food).

Art. 25 of the Measures for Imported and Exported Food provides that an exported food manufacturer shall establish a sound quality and safety management system. It shall establish an inspection record-keeping system, a production record-keeping system and a pre-delivery inspection record-keeping system and all records shall be kept for at least two years.

An exporter or agent to export food from the PRC must go through the record-filing formalities at the AQSIQ (Art. 26 of the Measures for Imported and Exported Food).

The food to be exported is subject to the supervision and sampling inspection of the entry/exit inspection and quarantine institution and may be released by the customs office upon issuance of the clearance certificate by the entry/exit inspection and quarantine institution.

Art. 48 of the Measures for Imported and Exported Food provides that where imported food has any safety problem which has damaged, or is likely to damage, human health and life safety, the importer shall voluntarily recall such food and report the same to the local entry/exit inspection and quarantine institution. The importer shall announce relevant information to the public, notify wholesalers and sellers to stop the wholesale and sale thereof, advise consumers to stop using such food, and properly record the information on the recall of such food. If the importer does not voluntarily recall such food, the relevant local entry/exit inspection and quarantine institution shall issue a notice to the importer on ordering the importer to recall such food, and report the same to the AQSIQ. If necessary the AQSIQ can order it to recall such food.

Art. 49 of the Measures for Imported and Exported Food provides that where exported food is found to have safety problems which has damaged, or is likely to damage, human health and life, the exported food manufacturer shall take measures to avoid and reduce damage, and promptly report the same to the local entry/exit inspection and quarantine institution.

The importer and the exported food manufacturer may be punished according to Art. 85, 87 and 89 the Food Safety Law, if either of them violates the requirements under the Measures for Imported and Exported Food.

5.2 Administrative Penalties

The potential administrative penalties imposed on the conduct that does not conform to the Food Safety Law are as follows (Food Safety Law, Art. 84, 85, 87 and 89 and Food Safety Regulations, Art. 55-58):

- confiscation of illegal proceeds
- confiscation of food and food additives illegally produced
- confiscation of utensils, equipment, raw materials etc. used for illegal operation
- imposition of fines
- cessation of business
- withdrawal of the business license

The following conducts may be deemed to be relevant circumstances under which the aforesaid administrative penalties must be assumed by the relevant food producer or business operator:

(1) engaging in the production and business operation of food or in the production of food additives without administrative licensing

(2) failure to perform due obligations as to ensure the safety of food

(3) illegally importing or exporting food, food additives, food-related products

(4) misconduct in the production, sale or business operation of food, such as:

- producing food with non-food raw materials, or food containing non-food-additive chemical substances and other substances potentially hazardous to human health, or producing food with recycled food as raw materials
- producing or engaging in the business operation of food in which substances that are hazardous to human health exceed the limits as prescribed in the food safety standards
- producing or engaging in the business operation of staple or supplementary food exclusively for infants or other particular groups of people, of which the nutrient ingredients do not meet the food safety standards
- engaging in the business operation of food that is putrid or deteriorated, spoiled by rancid oil or fat, mould, infested with pest, contaminated and dirty, mixed with strange objects, adulterated and impure, or abnormal in sensory properties
- engaging in the business operation of the meat of poultry, livestock, beasts and aquatic animals that died from disease, poisoning or other unknown cause, or related meat products
- engaging in the business operation of meat that has not been quarantined or has failed the quarantine by the animal health inspection institution or meat products that have not been inspected or have failed the inspection
- engaging in the business operation of food of which the quality warranty period has expired
- producing or engaging in the business operation of food, the production and business operation of which is expressly banned by the state for anti-disease purpose or for other special reasons
- producing food with new food raw materials or producing a new food additive or new food-related product without undergoing the food safety assessment

- refusing to recall or stop the business operation of the food product which does not conform to the food safety standards, after the relevant competent department so orders

- engaging in the business operation involving food contaminated by packaging materials, containers, transportation vehicles, etc.

- producing or engaging in the business operation of pre-packaged food or food additives without labels, or producing or engaging in the business operation of food products or food additives of which the labels or instruction for use do not conform to the provisions of the Food Safety Law

- purchasing or using the food raw materials, food additives or food-related products which do not conform to the food safety standards

- adding medicines to food

- failing to take remedial measures, or cease the production and operation and report to competent authorities, or reapply for the license, if necessary, in the event that any change in the production and sale of food product leads to the incompliance thereof with relevant requirements on food production and business operation

- catering services provider's failing to perform the obligations on purchase control of raw materials or inspect the food or raw materials to be processed, or continuing to use the food or raw materials which is found to be putrid, deteriorated or abnormal in sensory properties

For each of the above circumstance, the administrative penalties apply respectively in accordance with the Food Safety Law.

Chapter 3: Toys

1. Introduction and Applicable Provisions

In recent years, several toy makers had to recall their toys "Made in China" due to potential or existing defects that could have been harmful to the users.

In 2007, toys imported by Mattel Inc. from the PRC to the USA were proved to be grossly inconsistence with the legal standard for lead content of lacquer coating. The company had to recall all these toys from the market, including toy brands such as Big Bird, Elmo, Dora, Barbie, etc. The total value of recalled toys reached USD 2,000,000.00.

As stated in Chapter 2, section 2, the laws and regulations listed above in Chapter 1, section 2 generally also apply to toy product liability cases. In addition, the main legal provisions particularly promulgated for regulating the toy products are as follows:

- Measures on Administration of Inspection and Supervision of Import and Export of Toys promulgated on 2 March 2009 ("Toys Import and Export Measures")

- Provisions on Administration of Mandatory Products Certification promulgated on 3 July 2009 ("Mandatory Certification Provisions")

- Provisions on Administration of Recall of Children's Toys promulgated on 27 August 2007 ("Toys Recall Provisions")

- Measures for Administration of Mandatory Products Certification Institutes, Inspection Institutions and Laboratories promulgated on 23 June 2004 ("Mandatory Certification Measures")

- PRC Certification and Accreditation Regulations promulgated on 3 September 2003 ("Certification Regulations")

With respect to the relationship in application between the generally applied law and regulations as mentioned in Chapter 1 and the above legal provisions, our comment regarding the food products as specified in the last paragraph of Chapter 2, section 2 may also apply to toy products.

2. National Safety Technical Code for Toys

The National Safety Technical Code for Toys ("Code") entered into effect as of 1 October 2004 (GB 6675-2003), repealing the older National Standard for Toy Safety. The Code is a general technical standard of compulsory application on all toys sold within the territory of the PRC, which means that any toy which fails to conform to this Code is forbidden to be produced, sold in and imported into the PRC market.

2.1 Definition of Toys

The Code defines "Toys" to mean products or materials designed for playing or otherwise targeted for children under the age of 14.

2.2 Scope of Application

The Code applies to all toys sold or distributed (including toy samples and toys given free of charge), produced in or otherwise targeted for the PRC market. The Code to all toys which are being properly used and misused, provided that such misuse could be reasonably foreseeable considering that the target group for toys are children with limited (legal) responsibility. The Code does not apply to toys where the target users are not children, or toys which require supervision or other special requirements for use.

The Code stipulates different safety requirements for toys designed for children of different age ranges in light of children's intelligence, physical strength and ability to handle dangers.

Besides the Code, there are two special standards regarding the "Safety and Quality of Sewn, Plush and Cloth Toys" (GB 9832-2007) and "Safety Requirements of Soothers for Babies and Young Children" (GB 28482-2012) as well as several "voluntary" standards, e.g. "General Technical Requirements of Inflatable Toys" (GB/T 27708-2011) and "General technical requirements for bamboo and wooden toys" (GB/T 28495-2012).

2.3 General Principles

- after proper use or reasonable overuse toys must still conform to the requirements of the Code and not harm the safety or health of the user or any other third persons

- the scope of the Code is of a general nature and does not cover all possible potential dangers of toys in detail

- the Code does not exempt the parents from their responsibility to choose proper toys and to supervise and keep safe children in accordance with requirements of children of different age groups

- the Code adopts the standard of toys safety formulated by the International Organization of Standardization (ISO08124-1: 2000), and Appendix A, Appendix B and Appendix C of the Code provide the relevant technical requirements and testing methods for toys

2.4 Instruction for Use

Instructions for use must be provided together with the toys in question. The instructions for use can be provided in different forms, such as separate instruction manuals, information on the packaging, labels and signs, etc. The instruction for use of toys must provide information on the safe use of the toys and must conform to the requirements of the Code as well as the "Instructions for Use of Products of Consumer Interest - Part 5: Toys".

2.5 Implementation and Supervision

Toys which fail to conform to the Code are forbidden to be produced in, sold in and imported to the PRC market. Any person or entity may report acts of violation of the Code.

The State adopts a supervision and inspection system on toy quality, for example by conducting spot-checks. Where safety certification or production licensing is required, relevant laws and regulations apply (as further set-out below).

2.6 Legal Liabilities

The purpose of the Code is to protect the children to the largest extent against any damages caused by any defects of toys, including but not limited to design defects, manufacture defects and defects of the materials.

The Code provides that the PRC Standardization Law, the PRC Product Quality Law and other relevant laws and regulations apply for the determination of the legal liabilities incurred by any act of violating the Code.

3. China Compulsory Certification

Products listed in the PRC Products Catalogue for Mandatory Product Certification may be sold, imported or otherwise used in business activities only after satisfying the following:

- passing the China Compulsory Certification (also known as CCC)
- bearing the certification mark.

In the toy industry, according to Catalogue on Toy Product for CCC-3C Mandatory Product Certification, the following six categories of toy products fall in the scope of the CCC:

- cars for children
- electronic toys
- plastic toys
- metal toys
- projectile toys
- dolls

3.1 Certification Process

According to the Mandatory Certification Provisions and the Mandatory Certification Measures, producers, sellers or the importer of toy products may engage a certification institute designated by the State Certification and Accreditation Administration to conduct the CCC. In normal cases, such certification institute makes a decision on certification and must notify the producer, seller or importer thereof within ninety days from the day of engagement.

3.2 Administrative Liability

(1) For producers, sellers, importers and/or business operators who produce, sell, import or use the products without due CCC, the administrative liabilities include an order for proper certification, fines ranging from RMB 50,000 to RMB 200,000 and confiscation of illegal proceeds (Certification Regulations, Art. 67).

(2) Products that are not certified according to the Mandatory Certification Provisions are subject to administrative liabilities including fines of up to RMB 200,000 (Art. 49).

(3) Products that have passed the CCC but do not have a certification mark used in a way consistent with relevant legal provisions are subject to an order for correction within a statutory time limit, failing which the relevant producer, seller, importer or other business operator may be fined up to RMB 20,000 (Mandatory Certification Provisions, Art. 55 (2)).

4. Import and Export Inspection

The Toys Import and Export Measures are effective since 15 September 2009. The Measures apply to such products which are required to be inspected before importation or exportation according to applicable laws and regulations, and such products as listed in the catalogue for compulsory inspection.

4.1 Import

The AQSIQ is in charge of nationwide inspection, supervision and administration of import and export of toy products. Local inspection and quarantine agencies are established to address the inspection, supervision and administration of import and export of toy products within the area under their respective administrative jurisdiction. Such inspection and quarantine agencies must issue an inspection certificate to such imported toys which are in accordance with the safety standards. Where the imported toys do not conform to the safety standards, the inspection and quarantine agencies will issue a disposal notice. If the toys have defects which may harm personal health and safety, property, or environment, the inspection and quarantine agency will issue an order to return or destroy the defective toys. If the defects are other than the aforementioned, such toys may be re-worked under the supervision of the agencies and sold or used after the quality is confirmed by another inspection.

4.2 Export

a) Registration

Enterprises can engage in the production and export of toys only after the toys intended for export are registered with the inspection and quarantine agencies.

b) Inspection Standard

The inspection is subject to the technical regulations or standards of the importing country. Where parties to the trade agree on technical standards more stringent than the above technical regulations or standards, such agreement prevails. If no technical standards in the importing country are available, the technical standards of the PRC apply.

c) Inspection Results

If toys do not comply with the safety standards, the inspection and quarantine agencies at the place of production will issue a non-compliance notice. If the toys

comply with the safety standards, the inspection and quarantine agencies will issue a certificate of compliance. Such certificate of compliance will stipulate a period of time during which the consignor must apply for testing of the toys with the inspection and quarantine agencies at the port of exit. Only if the toys pass such test, can they be exported. Where a consignor fails to export the toys within the inspection validity period or changes the country or region of destination where the inspection standards are different from the original ones, the consignor may apply for new inspection with the inspection and quarantine agencies.

5. Recall

The Toys Recall Provisions are applicable for recalling toys produced or sold within the territory of the PRC.

5.1 Information Management

The AQSIQ must set up an information system on the defects and recall of Children's toys. Local quality and technology supervision departments must collect the information regarding the defects of children's toys and consumer complaints arising therefrom and report to AQSIQ.

In order to promote such information system, the manufacturers of children's toys are required to record the information regarding the product design, purchase of raw materials, production and sale, labels as well as the consumer complaints, product damages, disputes and product recalls in foreign countries and file the said information with local quality and technology supervision departments. Similarly, the sellers of children's toys are required to record the information on purchase and sales, and must properly maintain the information on consumer complaints, product damages and disputes.

5.2 Defect Investigation and Risk Assessment

When a manufacturer becomes aware of any potential defects of its toy products, the manufacturer has the obligation to timely conduct an investigation to ensure whether such potential defects exist. Where the quality and technology supervision department at and above provincial level starts a defect investigation, the manufacturer and the seller must assist in and provide necessary documents for the investigation. If the toy products are proved to be defective after the investigation, an assessment on the risks of the defects must be conducted in accordance with relevant law and regulations. The result of the assessment will form the basis for determining whether or not to recall the defective products.

5.3 Defective Toy Recall

Toys can be voluntarily recalled by the manufacturer or the AQSIQ can order a compulsory recall.

a) Voluntary Recall

If the toy products are proved to be defective after investigation, the manufacturer must:

- immediately cease the production of the products in question
- publish information on the defect for the general public
- notify the sellers to cease the sales of the products
- notify the consumer to stop using the products
- voluntarily recall the defective products

The manufacturer must formulate a recall plan and submit it to the local quality and technology supervision department at provincial level for filing. Any changes in the plan must be reported to the supervisory department, which will keep the AQSIQ informed of the filing and changes information. Where the local quality and technology supervisory department finds the voluntary recall is not as effective as anticipated, it may urge the manufacturer to take more effective measures, or the department itself may take other measures in accordance with the law. Within fifteen working days after the lapse of the recall period as set out in the recall plan, the manufacturer must voluntarily submit an overall recall conclusion to the supervisory department.

b) Compulsory Recall

Where the toy products are defective and the manufacturer fails to perform a voluntary recall, or where the toy products are found to be defective by spot-check and may cause damage to personal health and safety, the AQSIQ should order a compulsory recall and inform the local quality and technology supervisory department at provincial level (at the place of business of the manufacturer) to take corresponding measures.

After receiving the order from the AQSIQ, the manufacturer must:

- immediately cease the production and sale of the products in question
- submit a recall plan to the AQSIQ within five working days, which, if approved, is the basis for the recall (if such recall plan is not approved, the recall must be conducted in accordance with requirements as stipulated by the AQSIQ)
- submit recall conclusion phase by phase during the recall
- formulate and maintain a record for the compulsory recall and submit a overall recall conclusion within fifteen working days after the lapse of the recall period

5.4 Legal Liabilities

Art. 35 to 41 of the Toys Recall Provisions provide the manufacturer's administrative liabilities as a result of violating this Provision.

a) Administrative Penalties

- warning
- order of correction
- imposition of fines

b) Circumstances of Liability

- failure to file relevant information or to establish information record according to the Toys Recall Provisions
- failure to conduct an investigation into a potential defect in a timely manner; refusal to assist the quality and technical supervisory department at and above provincial level in the defect investigation; or failure to report the investigation result to the quality and technical department at and above provincial level pursuant to the Toys Recall Provisions
- failure to cease the production of the defective children toys (Toys Recall Provisions, Art. 21 and 28)
- failure to publish the information on the defect of toys to the general public, to notify the sellers to cease the sales of the products, to notify the consumer to stop the consumption of the products, or to voluntarily recall the defective products pursuant to Art. 21 and 22 of the Toys Recall Provisions
- failure to formulate a recall plan (Toys Recall Provisions, Art. 23), or failure to submit a overall recall conclusion (Toys Recall Provisions, Art. 29)
- failure to submit various documents (Toys Recall Provisions, Art. 26, 32 and 34)
- failure to perform recall obligation (Toys Recall Provisions, Art. 31)

For each of the above circumstance, the administrative penalties apply respectively in accordance with the Provisions.

Chapter 4: Pharmaceuticals

1. Relevant Laws and Regulations

The following list provides an overview of the most important laws and national regulations that are relevant to pharmaceutical quality liability in the PRC. Additional legislation may apply in certain cases.

a) National Laws

- Administration of Pharmaceuticals Law of the PRC of December 2013 ("Pharmaceuticals Law")
- Criminal Law of the PRC of 14 March 2012 ("Criminal Law")

b) National Regulations

- Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Certain Issues Concerning the Application of Law in Handling Criminal Cases of Endangering Drug Safety of 3 November 2014 ("Interpretations on Criminal Cases on Endangering Drug Safety")
- Administrative Norms on Quality in Trading of Pharmaceuticals, released by the Ministry of Health on 22 January 2013 ("Pharmaceuticals Trading Norms")
- Provisions of the Supreme People's Court on Certain Issues concerning the Application of Law in the Hearing of Cases Involving Food and Drug Disputes of 23 December 2012 ("SPC's Provisions on Food and Drug Disputes")
- Administrative Norms on Quality in Production of Pharmaceuticals (2010 revised version), released by the Ministry of Health on 17 January 2011 ("Pharmaceuticals Production Norms")
- Measures for the Administration of Pharmaceuticals Recalls, approved by the State Administration for Food and Pharmaceuticals on 6 December 2007 ("Pharmaceuticals Recall Measures")
- Special Rules of the State Council on Strengthening the Supervision and Administration of the Safety of Food and Other Products of 26 July 2007 ("State Council Special Rules")

- Measures for the Administration of Pharmaceuticals Registration, approved by the State Administration for Food and Pharmaceuticals on 18 June 2007 ("Pharmaceuticals Registration")

- Implementing Rules of Administration of Pharmaceuticals Law of 4 August 2002, released by the State Council ("Pharmaceuticals Rules")

2. Legal Concepts

In general, defective pharmaceuticals can be classified by two categories, fake pharmaceuticals and inferior pharmaceuticals, both of which are prohibited to be produced and sold. The Pharmaceuticals Law respectively provides the conditions and circumstances under which pharmaceuticals are deemed either fake or inferior (Art. 48 and 49).

According to Art. 48 of Pharmaceuticals Law, pharmaceuticals, as a general rule, are deemed to be fake if:

- the ingredients of the pharmaceuticals do not conform with the ingredients specified in the State pharmaceutical standard
- it is a non-pharmaceutical product being passed off as pharmaceuticals or it is one kind of pharmaceuticals being passed off as another kind of pharmaceuticals

Pharmaceuticals are in particular treated as fake if:

- the State Council's pharmaceuticals regulatory department has prohibited the use thereof
- the Pharmaceuticals Law requires that approval be obtained for the production or import of the pharmaceuticals but the same are produced or sold without such approval, or the Pharmaceuticals Law requires that the pharmaceuticals be inspected but the same are sold without having been inspected
- the pharmaceuticals have gone bad
- the pharmaceuticals have been contaminated
- the pharmaceuticals were produced with raw materials for which the Pharmaceuticals Law requires an approval number, but no such approval number was obtained
- the indication(s) or primary function(s) indicated on the pharmaceuticals exceed the stipulated scope of indications or primary functions.

Pharmaceuticals containing ingredients that do not conform to State pharmaceutical standards are deemed as inferior (Pharmaceuticals Law, Art. 49).

Pharmaceutical are treated as inferior if:

- the expiry date period thereof is not indicated or has been altered
- the batch number thereof is not indicated or has been altered

- its expiration date has passed
- the packaging materials or the container in direct contact with the pharmaceuticals has not been approved
- a colorant, preservative, flavoring, corrective or excipient has been added to it without permit
- other circumstances where the pharmaceuticals do not conform with the pharmaceuticals standard

3. Tortious Product Liability and Contractual Product Liability

As the pharmaceuticals quality liability falls within the general scope of product liability, the consumers who are injured or harmed by the pharmaceuticals may claim against the pharmaceuticals producer or trader on the ground of either tortuous product liability or contractual product liability as explained in detail in Chapter 1 of this guide.

Some of the concepts relating to food as explained in Chapter 2 are also applicable to pharmaceuticals, such as the liability of online transaction platform providers (Chapter 2, 3.2) and the rules regarding the burden of proof with respect to causation (Chapter 2, 3.4).

4. Administrative Liability

Unless specific laws governing the supervision and administration of product safety exist, the State Council Special Rules apply (State Council Special Rules, Art. 2). Therefore in this section, we mainly focus on two legal provisions, that is, the Pharmaceuticals Law and the State Council Special Rules.

4.1 Licensing System

The PRC has adopted a licensing system for pharmaceutical manufacturing, trading and medicinal preparations (Pharmaceuticals Law, Art. 7, 14 and 23). Enterprises or medical institutions cannot engage in such activities without a license. Non-conforming entities could bear the following administrative liabilities:

- closing down of operations in accordance with the law
- confiscating of illegally produced or sold pharmaceuticals
- confiscating of illegal proceeds derived therefrom
- a fine of not less than two and not more than five times of the value of pharmaceuticals illegally produced or sold

4.2 Production and Sale of Fake or Inferior Pharmaceuticals

The production (including compounding) and sale of fake or inferior pharmaceuticals are prohibited (Pharmaceuticals Law, Art. 48 and 49).

In case of fake pharmaceuticals, the following administrative liabilities may be incurred:

- confiscating of illegally produced or sold pharmaceuticals
- confiscating of illegal proceeds derived therefrom
- a fine of not less than twice and no more than five times of the value of pharmaceuticals illegally produced or sold
- revoking the perpetrator's pharmaceutical approval certificate, if any
- suspension of production or business and rectification

- in serious cases, revoke the Pharmaceutical Production License, Pharmaceutical Trading License or Preparation Compounding License for a Medical Institution, if any

In case of inferior pharmaceuticals, the following administrative liabilities can be incurred:

- confiscating of illegally produced or sold pharmaceuticals
- confiscating of illegal proceeds derived therefrom
- a fine of not less than one and no more than three times of the value of pharmaceuticals illegally produced or sold
- in serious cases, suspension of production or business and rectification
- revoking the Pharmaceutical Production License, Pharmaceutical Trading License or Preparation Compounding License for a Medical Institution, if any.

The raw materials, excipients, packaging materials and production equipment exclusively used in the production of the fake or inferior pharmaceuticals by the producer should be confiscated. In addition to the above, where the circumstances are serious, the person directly in charge and other directly responsible personnel of an enterprise or other entities producing or selling fake or inferior pharmaceuticals are not permitted to engage in the production and trade of pharmaceuticals for ten years.

4.3 Certification under Pharmaceuticals Production Norms, Pharmaceuticals Trading Norms and Other Relevant Quality Control Standards

Pharmaceutical producers and traders must arrange production or trade in pharmaceuticals in accordance with the Pharmaceuticals Production Norms and the Pharmaceuticals Trading Norms (Pharmaceuticals Law, Art. 9, 16 and 79) (hereinafter collectively "Pharmaceuticals Norms").

A pharmaceutical producer or a pharmaceutical trader who fails to conform to the above Pharmaceuticals Norms is subject to the following administrative liabilities (Pharmaceuticals Law, Art. 79):

- warning, order of correction within a specified time limit

In case of failure of correction within the said time limit:

- suspension of production or business

- rectification
- a fine of not less than RMB 5,000 and not more than RMB 20,000
- in cases of serious circumstances, revocation of Pharmaceutical Production License, Pharmaceutical Trading License

4.4 Purchase and Sale of Pharmaceuticals

Except for the traditional Chinese medicinal materials not subject to the issuance of approval numbers, pharmaceutical producers, pharmaceutical traders and medical institutions must purchase pharmaceuticals from enterprises qualified to produce or trade in pharmaceuticals (Pharmaceuticals Law, Art. 34). Violations are subject to the following administrative penalties (Pharmaceuticals Law, Art. 80):

- order of correction
- confiscation of purchased pharmaceuticals
- a fine of not less than twice and not more than five times of the value of pharmaceuticals illegally purchased
- confiscation of illegal proceeds
- in serious cases, revocation of Pharmaceutical Production License or Pharmaceutical Trading License

4.5 Import and Export

Pharmaceuticals must be imported through a port which is permitted for the importation of pharmaceuticals (Pharmaceuticals Law, Art. 40). Every import has to be registered by the importer with the pharmaceutical regulatory department of the place where the port is located. If the importer fails to register with the pharmaceutical regulatory department, the administrative liabilities as below may be imposed (Art. 81):

- warning and order of correction within a specified time limit
- in case of failure of correction, revocation of the registration certificate for pharmaceuticals importation

Imported pharmaceuticals must comply with the relevant technical standards and the requirements on inspection (State Council Special Rules, Art. 8). If the importer or

seller practices fraud in the course thereof, the importer or seller could bear the following administrative penalties:

- confiscation of pharmaceuticals and illegal proceeds
- a fine of three times of the value of the pharmaceuticals

The producer or trader of exported products must ensure that product quality complies with the standards of the country or region where they are exported, or with the stipulations of the contract (State Council Special Rules, Art. 7). In some cases laws and regulation require pre-export inspection. If the producer or trader evades inspection or practices fraud in the course thereof, the following administrative penalties may be imposed:

- confiscation of pharmaceuticals and illegal proceeds
- a fine of three times of the value of the pharmaceuticals

4.6 Examination and Acceptance of the Pharmaceuticals

Pharmaceutical traders must establish and implement a system for the examination and acceptance of the pharmaceuticals they purchase to verify the pharmaceutical quality certificates and other marks before accepting them (Pharmaceuticals Law, Art. 17). The traders must require the suppliers to provide inspection reports issued by qualified inspection institutes in terms of a batch of the products purchased (State Council Special Rules, Art. 5). Products without the inspection report are not allowed to be sold. If the trader is in violation of such requirement, the following are the subsequent administrative liabilities:

- order to cease the sale
- confiscation of illegal proceeds and products illegally sold
- a fine of three times of the value of the products
- in serious cases, revocation of the license

4.7 Recall

Promulgated on 6 December 2007 and entered into force as of the date of promulgation, the Pharmaceuticals Recall Measures govern specifically the issue of pharma-

ceutical recalls. The recall of all pharmaceuticals sold within the territory of the PRC is governed by the Pharmaceuticals Recall Measures. "Defect" refers to the unreasonable danger in pharmaceuticals which may threaten the personal health and safety and which is caused by the research, development or production of the pharmaceuticals in question.

4.7.1 Classes of Recall

Where a manufacturer of pharmaceuticals finds potential defects in the pharmaceuticals it produced, it must conduct pharmaceutical defect investigation, which may also be conducted by the pharmaceutical regulatory department. In latter cases, the manufacturer must provide assistance. After the pharmaceutical defect investigation, a defect assessment must be arranged accordingly.

Based on the pharmaceutical defect assessment, recalls for defective pharmaceuticals can be divided into three classes:

- first class recall, which refers to the recall of defective pharmaceuticals that may cause serious harm to a person's health
- second class recall, which refers to the recall of defective pharmaceutical that may cause temporary or reversible harm to a person's health
- third class recall, which refers to the recall of defective pharmaceutical that generally would not cause harm, but are recalled for other reasons

4.7.2 Recall process

Generally the recalls of defective products are either voluntary, as initiated by the manufacturer, or compulsory, as initiated by the competent authority.

a) The process of voluntary recall

The manufacture who initiates the recall must:

- formulate recall plan and make preparations for implementation
- inform relevant trading companies and other entities to cease the sale or consumption of the defective pharmaceuticals
- at the same time, report the recall to the pharmaceutical regulatory departments at provincial level

For first class recalls, the notice and report must be made within 24 hours after making recall decisions; for second class, 48 hours; and for third class, 72 hours.

- after the commencement of the recall, the assessment report and the recall plan must be submitted to the pharmaceutical regulatory department for filing, within one day in cases of first class recalls, three days in cases of second class recalls and seven days in cases of third class recalls. For first class recalls, after receiving the required materials, the regulatory department must report to the CFDA

- during the recall process, reports thereof must be issued to the pharmaceutical regulatory department at provincial level every day for first class recalls, every three days for second class recalls and every seven days for third class recalls

- the manufacturer must keep detailed records of the disposition of the recalled pharmaceuticals

- after completion of recall, the manufacturer must submit the overall conclusion of the recall to the pharmaceutical regulatory department at provincial level

- within ten days after receiving the overall conclusion, the pharmaceutical regulatory department must arrange examination and assessment on the recall, and notify the manufacturer of the results

b) The process of compulsory recall

- the regulatory department makes a decision on the recall and serves the notice to the manufacturer

- after receiving the notice, the manufacturer informs relevant trading companies and using entities to cease the sale or consumption of the defective pharmaceuticals

- recall plan is formulated and preparations for implementation is made

In addition, the items set-out under voluntary recall also apply in a compulsory recall process.

For both voluntary recall and compulsory recall, if the pharmaceutical regulatory department finds the result of the recall not satisfactory, or finds it necessary to take more effective measures, the regulatory department may require the manufacturer to arrange another recall or expand the scope of the recall.

4.7.3 Legal Liabilities

According to the Pharmaceuticals Recall Measures, the following administrative liabilities may be incurred:

a) Administrative penalties

- warning
- order of correction within a specified time limit
- a fine (either three times of the value of the pharmaceuticals or RMB 30,000)
- revocation of Pharmaceutical Approval Certificate
- revocation of Pharmaceutical Production Certificate

b) Liability circumstances

- failure to arrange voluntary recall despite awareness of potential defects of the pharmaceuticals
- refusal to arrange recall after receiving notice of compulsory recall
- failure to inform relevant trading companies and pharmaceuticals users to cease the sale or consumption of the defective pharmaceuticals
- refusal to take measures as duly required by the pharmaceutical regulatory department
- failure to keep detailed record of the recall process
- failure to establish a recall system, refusal to provide assistance in the pharmaceutical defect investigation conducted by the regulatory department, failure to submit relevant materials as required by the Pharmaceuticals Recall Measures and failure to report to the regulatory department for filing in cases of alteration of the recall plan

5. Criminal Liability

Art. 141 and 142 of the Criminal Law apply specifically to pharmaceuticals. Article 141 provides that if pharmaceuticals manufactured or sold are fake, the manufacturers or sellers are subject to:

- detention or imprisonment of not more than three years
- a fine

Where the fake pharmaceuticals caused serious harm to human health or if there are other serious circumstances, the manufacturers or the sellers are subject to:

- imprisonment of not less than three years and not more than ten years
- a fine

"Causing serious harm to human health" is defined (Interpretations on Criminal Cases on Endangering Drug Safety, Art. 2) as:

- Where minor or serious injuries are caused
- Where minor or moderate disability is caused
- Where organ and tissue damage is caused, leading to general dysfunction or severe dysfunction
- Where there are other circumstances causing serious harm to human health

"Other serious circumstances" (Interpretations on Criminal Cases on Endangering Drug Safety, Art. 3) means

- Where a relatively large-scale public health emergency is caused
- Where the amount of production or sales is more than RMB 200,000 but not more than RMB 500,000
- Where the amount of production or sales is more than RMB 100,000 but not more than RMB 200,000 and the perpetrator falls under any of the circumstances prescribed by Article 1 (see below); or
- Where the perpetrator shall be deemed as reaching the threshold of grave circumstances according to the time and quantity of production or sales, the types of counterfeit drugs involved, etc.

Art. 1 of the Interpretations on Criminal Cases on Endangering Drug Safety states several circumstances that warrant heavier penalties. Those circumstances are:

- Where the perpetrator produces or sells counterfeit drugs whose main users are pregnant women, infants, children or critically-ill patients
- Where the perpetrator produces or sells counterfeit drugs that are narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive drugs, contraceptive drugs, blood products or vaccines
- Where the perpetrator produces or sells counterfeit drugs that are injection drugs or drugs for emergency rescue
- Where the perpetrator producing or selling counterfeit drugs is a medical institution or a staff member of a medical institution
- Where the perpetrator produces or sells counterfeit drugs for response to emergencies during the period of natural disasters, accidents and disasters, public health incidents, social security incidents and other emergencies
- Where the perpetrator has been subject to administrative or criminal punishments within the past two years due to illegal and criminal activities of endangering drug safety
- Where the perpetrator shall otherwise be given heavier punishments depending on actual circumstances

Where the fake pharmaceuticals caused death or if there are other especially serious circumstances, the manufactures or sellers are subject to:

- imprisonment of not less than ten years or life imprisonment
- death penalty
- a fine or confiscation of property

"Other especially serious circumstances" (Interpretations on Criminal Cases on Endangering Drug Safety, Art. 4) means

- Where the perpetrator causes a person to suffer severe disability
- Where the perpetrator causes three or more people to suffer serious injuries, moderate disability or organ and tissue damage that leads to severe dysfunction;

- Where the perpetrator causes five or more people to suffer mild disability or organ and tissue damage that leads to general dysfunction

- Where the perpetrator causes ten or more people to suffer minor injuries

- Where the perpetrator causes a major or an extraordinarily major public health emergency

- Where the amount of production or sales exceeds RMB 500,000

- Where the amount of production or sales is more than RMB 200,000 but not more than RMB 500,000, and the perpetrator falls under any of the circumstances prescribed by Article 1 herein

- Where the perpetrator shall be deemed as reaching the threshold of extraordinarily grave circumstances according to the time and quantity of production or sales, the types of counterfeit drugs involved, etc.

If inferior pharmaceuticals caused serious damage to human health, the manufacturers or sellers thereof are subject to (Art. 142):

- imprisonment of not less than three years and not more than ten years

- a fine of not less than 50% and not more than two times of the sales revenue.

If the inferior pharmaceuticals caused exceptionally serious consequences, the manufacturers or sellers thereof are subject to:

- imprisonment of not less than ten years or life imprisonment

- a fine of not less than 50% and not more than two times of the sales revenue or confiscation of property

If a company is held criminally liable for supplying defective products (including pharmaceuticals), the company itself is only subject to a fine (Criminal Law, Art. 150). The person in charge of the company and other relevant responsible persons are subject to the criminal sanctions mentioned above.

Chapter 5: Motor Vehicles

1. General

1.1 Introduction and Applicable Provisions

Due to the inherently fatal consequences deriving from quality defects in the automotive sector, motor vehicles are another product that are strictly governed by product liability provisions. In fact, the automotive industry was the first industry in the PRC to be a target of product liability measures.

In addition to the laws and regulations mentioned in Chapter 1 hereof which generally apply to motor vehicle products, such products must in addition comply with the relevant provisions specifically formulated toward it.

In 2012, the State Council issued new recall regulations, and the AQSIQ issued provisions regarding the repair, replacement and return ("three guaratees") of family automobiles.

1.2 National Regulations

- Regulations on the Administration of Recall of Defective Automotive Products by the State Council of 22 October 2012 ("State Council Automotive Products Recall Regulations")

- Administrative Regulations on the Recall of Defective Motor Vehicles of 12 March 2004 by the General Administration of Quality Supervision, Inspection and Quarantine; National Development and Reform Commission; Ministry of Commerce; General Administration of Customs ("AQSIQ Motor Vehicle Recall Regulations")

- Provisions on the Responsibilities for Repair, Replacement and Return of Family Automobile Products by the AQSIQ of 29 December 2012 (" Automotive Warranties Provisions")

1.3 Important Cases

- Shangdong Yutai Safflower Products Co., Ltd. v. Chang'an Ford Mazda Auto Co., Ltd. (judgment of 15 December 2008), Beijing Chaoyang District People's Court

- Liu v. Beijing Bentz-Daimler Chrysler Auto Co., Ltd. and Haerbin Yuegang Xianfeng Automobile Sale and Maintenance Co., Ltd. (judgment date unknown; but handed down after 3 November, 2008), Beijing Intermediate People's Court No. 1

- Yang v. Chery Automobile Co., Ltd. and the Beijing Tengyuan Auto Service Centre (judgment of March 15, 2004), Beijing Chaoyang District People's Court

- Deng and Li v. Auto Trading Co., Ltd., Beijing (judgment of August 6, 2003), Beijing Intermediate People's Court No. 2

- Chen Meijin & Lin Dexin v. Mitsubishi Auto Industry Co., Ltd. (judgment of August 10, 2000), Beijing Intermediate People's Court No. 2

- Zhang Jieting v. Toyota Automobile Co., Ltd. (judgment of May 16, 1996), Intermediate People's Court of Beijing Haidian

- Dong Jing Chun v. Si Ping Zhuan Yong Automobile Factory Corporate Group (judgment date unknown; but handed down after January 10, 1995), Jinlin Higher People's Court

2. Essential Features of Product Defectiveness

2.1 Technical Safety Standards for Motor Vehicles

The PRC has issued specific safety guidelines on technical safety standards for motor vehicles, which motor vehicle manufacturers must comply with. The guidelines deal, amongst other things, with:

- maximum height, breadth and length of vehicles
- engine power
- layout
- compulsory fitting of seatbelts
- vehicle lighting
- fuel tank
- noise level

2.2 Defects in Cars – Examples from Case Law

a) Defective Windscreen

In the case of **Chen Meijing and Lin Dexin v. Mitsubishi Auto Industry Co.,** the plaintiff's husband was driving in the plaintiff's sports utility vehicle, which was manufactured by the defendant. While driving, the vehicle's windscreen shattered and injured Mr. Lin, who died as a result of the accident.

The Beijing Intermediate People's Court No. 2 accepted, in accordance with the principle of **res ipsa loquitur** ("the thing speaks for itself"), that the shattering of the windscreen would not normally have occurred unless someone (the manufacturer) was negligent, or there was a defect. In addition, the defendant did not bring any evidence to show that the windscreen was not defective or that another external force had led to the breaking of the windscreen.

b) Inadequate Operating Instructions

In the case of **Zhang Jieting v. Toyota,** the Beijing Haidan Intermediate People's Court held that the operating instructions that came with the vehicle were not suf-

ficient to warn the user of the possible malfunction of the airbags, and that this constituted a defect. The defectiveness of a product due to the non-existence or existence of an inadequate operating instruction derives from Art. 18 (1) of the Consumer Protection Law. This regulation requires that a product that poses a danger to person or property be equipped with a clear warning, an explanation of the product's functions and instructions to avoid danger.

c) Defectiveness of the Rim and spokes of a Steel Rim

The case of **Dong Jing Chun v. Si Ping Zhuan Yong Automobile Factory Corporate Group** was based on the following facts: The plaintiff was driving a truck manufactured by the defendant when the back wheels broke and caused the vehicle to roll over. The permissible weight of the vehicle was 10 tons. However, the plaintiff had clearly overloaded it. The gross weight of the laden vehicle at the time of the accident was 12.9 tons.

The Jilin Province Higher People's Court held that the rim and spokes of the vehicle's steel wheels were faulty as the wheels exhibited not only microscopic fissures, but also additional impurities in the processed steel.

The Court rejected the defendant's argument that it could not be held liable for impurities in the steel since it was only responsible for the assembly of the vehicle, and not for the manufacture of the raw materials.

The Court further explained in its reasons that the seller could not avoid its civil liability despite the plaintiff's contributory negligence. Since it was established that the plaintiff had overloaded the vehicle, and that this had contributed to the rolling of the vehicle, the defendant was only liable for 80% of the damage and the plaintiff had to bear the remaining 20% himself. Such decision had its source in Art. 131 of the Civil Law which provides that if the injured party bears part of the fault for the injury suffered, then the civil liability of the injurer will be reduced." In another word, the PRC has adopted the "comparative fault-based" system in the adjudication of damages. This differs from the United States in particular, in which the "contributory negligence system" ("**All or Nothing Principle**") is applied.

d) Excessive Noise Levels

In July 2002, Mr. Yang purchased a Chery brand car from the Beijing Tengyuan Auto Service Centre. He found that the operational noise of the vehicle was unbearably loud. He had the car repaired six times in order to remedy this noise. The workshop of the Beijing Tengyuan Auto Service Centre could not, however, remedy the noise problem.

The Beijing Chaoyang District People's Court held in **Yang v Chery Automobile Co. Ltd. and the Beijing Tengyuan Auto Service Centre** that the noise produced by the plaintiff's vehicle was louder than that of other vehicles of the same model, and therefore there was clearly a quality defect.

e) Engine Explosion and Crooked Connecting Rod

In the case of Shangdong Yutai Safflower Products Co., Ltd. v Chang'an Ford Mazda Auto Co., Ltd., the plaintiff bought a Fox brand car manufactured by the defendant on 26 July 2008. One month later, the engine of this car exploded while driving.

The plaintiff brought a lawsuit to the court claiming for the withdrawal of the defective car as well as the compensation of relevant economic losses.

The verification report showed that the explosion of the engine was relevant to the crack of the connecting rod. However, as the engine had been stored for too long after being dismantled, the verification report failed to reach a definite conclusion but merely stated that the crack of the connecting rod may be due to either the water inflow in the engine which had the connecting rod crooked, or the crooked status of the connecting rod at the time when the car was delivered out of the factory.

In this context the defendant argued that the accident was caused by the water inflow in the engine arising from improper use. However, the court held that considering the conclusion of the verification report could not excluded the possibility that the accident was incurred by the defects of the car and the defendant did not bring any evidence to prove that the car was not defective, the defendant should be responsible for the consequence caused by the accident.

f) Defective Airbag (Case No. 1)

In the case of Deng and Li v. Auto Trading Co. Ltd. in Beijing, the plaintiff bought a BMW brand vehicle from the defendant on February 16, 2002. On March 21 of the same year, the four airbags on the passenger side of the vehicle opened without any external impact. The activation of the airbags injured the passenger's face and eyes.

The defendant argued in court that the opening of the airbags was caused by an earlier accident that the vehicle was involved in. The "State Oversight Authority for Car Quality" and the test centre determined that the plaintiff's vehicle had previously had at least one accident, but that this did not cause the activation of the airbags. The Beijing Intermediate Court No. 2 decided upon this that the activation

of the airbags could be traced back to a design fault with respect to the road and traffic conditions in China.

The court went so far as to say that in its opinion, even if the product defect did not directly cause the injury to the plaintiff, the seller would be liable.

g) Defective Airbag (Case No. 2)

The case of Liu v Beijing Bentz-Daimler Chrysler Auto Co., Ltd. (defendant 1) and Haerbin Yuegang Xianfeng Automobile Sale and Maintenance Co., Ltd.(defendant 2) was based on the fact that the airbag at the first front seat of the plaintiff's car, manufactured by the defendant 1 and sold by the defendant 2, did not open on impact during an accident occurring on 6 July 2006 while the airbag at the second front seat deployed in a regular manner. As a result, Sun who sat on the second pilot seat was merely injured but Liu, who was driving the car seated on the first front seat, died.

The Beijing Court held that the airbags at the first and second front seats are supposed to open together at the same time. The fact that the airbag at the second front seat opened while the one at the first front seat did not revealed that the car was defective. Furthermore, the comparison between Sun's injury under the protection of the opened airbag and Liu's death without such protecting also showed that the defectiveness of the car led to the death of Liu. Therefore, the defendant 1 and defendant 2 respectively as the manufacturer and seller of the car were held liable for the damages incurred by the defects of the car.

3. Administrative Liability

The AQSIQ announced in 2004 the Motor Vehicle Recall Regulations which came into force on 1 October 2004. In 2012, the State Council issued the new Automotive Products Recall Regulations without explicitly repealing the previous recall regulations of the AQSIQ, but amending them on various issues significantly. From the promulgation of the Motor Vehicle Recall Regulations until the end of 2008, a total of 1,840,000 defective motor vehicles relating to 180 vehicle types manufactured by 54 PRC and foreign car manufacturers had been recalled. In the year of 2008, such recalled motor vehicles amounted to 538,629, which exceeds the total number of the previous four years, i.e. from 2004 to 2007. In 2010 alone, the "year of car recalls", nearly one million defective motor vehicles were recalled.

Under the new recall regulations of the State Council:

- the definition of motor vehicle defect has been widened
- any organization or individual is now entitled to ask for a recall of defective motor vehicles
- the definition "manufacturer" has been limited to local manufacturers and importers and does not contain foreign manufacturers anymore
- manufacturers have more duties regarding documentation and reporting
- punishments for non-compliance are more severe

3.1 Definition of Motor Vehicle Defect

Art. 3 (1) of the State Council Automotive Products Recall Regulations defines "defect" as not being in compliance with the relevant national standards for vehicle safety or other circumstances that result in unreasonable danger for the safety of people or property, which arises as a result of the design, manufacture or from other grounds of a group, model or category of vehicle products in an identical and general way. Previously, the non-compliance with national standards was not only a sufficient but a necessary requirement for the motor vehicle to be considered defective.

3.2 Definition of Manufacturer and Filing Requirements

According to the new State Council's recall regulations, "manufacturer" shall only refer to those companies which are legally established in China to manufacture auto-

motive products and issue product qualification certificates in their own names. Also, importers of automotive products are deemed to be manufacturers. Not included anymore are foreign manufacturers.

Manufacturers shall establish and keep records of the information of automotive products including design, manufacture, label and inspection as well as the information of first-time purchasers of automotive products for at least a decade AQSIQ (State Council Automotive Products Recall Regulations, Art. 9).

All manufacturers have to file and report certain information to the AQSIQ (State Council Automotive Products Recall Regulations, Art. 10). This information contains the following items:

- Manufacturers' basic information
- Technical parameters of automotive products and information of first-time purchasers of automotive products
- Information of repair, replacement and return due to the malfunction of automotive products that endanger personal and property safety
- Information of automotive product recall abroad
- Other information that should be filed in accordance with the requirements of the product quality supervision department under the State Council for the record

3.3 Voluntary Recall

Where manufacturers have learned about the possible defects of automotive products, they shall immediately organize investigations and analyses, and report investigation and analysis results to the AQSIQ. Where manufacturers have confirmed the defects of automotive products, they shall immediately stop selling, leasing or importing defective automotive products and recall these products (State Council Automotive Products Recall Regulations, Art. 12).

3.4 Enforcement Mechanisms

Where the AQSIQ has learned about the possible defects of automotive products, it shall immediately inform manufacturers to conduct investigations and analyses; where manufacturers have failed to conducted investigations and analyses, the AQSIQ shall

conduct defect investigations or directly conduct investigations themselves if the products may have defects that may cause serious consequences. (State Council Automotive Products Recall Regulations, Art. 13).

Where AQSIQ deemed that automotive products have defects, it shall inform manufacturers to recall these products. Manufacturers may, within 15 working days from the dates of receiving notices, raise objections with the AQSIQ and provide supporting materials. The department shall organize the experts that have no interest relationship with manufacturers for the demonstration of supporting materials, and for the technical detection or appraisal of automotive products when necessary (State Council Automotive Products Recall Regulations, Art. 15).

If manufacturers do not recall defective automotive products nor raised objections within the time limit, or where automotive products have been confirmed to be defective upon testing organized by the AQSIQ, the AQSIQ shall order manufacturers to recall defective automotive products; manufacturers shall immediately stop manufacturing, selling or importing defective automotive products and recall them (State Council Automotive Products Recall Regulations, Art. 15 (3)).

When recalling defective automotive products, manufacturers must formulate and file recall plans in accordance with the provisions of the AQSIQ. Any modification to the filed recall plans need to be re-filed for record (State Council Automotive Products Recall Regulations, Art. 16 (1)).

Manufacturers must inform sellers of the recall plans that have been filed with the AQSIQ for the record, and sellers shall stop selling defective automotive products (State Council Automotive Products Recall Regulations, Art. 17).

When recalling defective automotive products, manufacturers have to release relevant information to the public, and inform car owners of relevant matters including existing defects of automotive products, emergency disposal methods to avoid damages and manufacturers' measures for defect elimination. The AQSIQ also makes public the confirmed information of defective automotive products and the information of manufacturer's recall. Car owners shall assist manufacturers in recalling defective automotive products (State Council Automotive Products Recall Regulations, Art. 18).

For recalled defective automotive products, manufacturers shall take measures for defect elimination including label correction or supplement, repair, replacement and return. Manufacturers shall bear the cost of defect elimination, and the cost of transporting defective automotive products if necessary (State Council Automotive Products Recall Regulations, Art. 19).

3.5 Consequences of Breach of Duty

(1) Where manufacturers have been involved in any of the following circumstances and have refused to make corrections after being told so by the product quality supervision departments, they shall be imposed a fine of more than RMB 50,000 and less than RMB 200,000:

- Manufacturers have failed to keep records of the information of automotive products and car owners in accordance with relevant provisions
- Manufacturers have failed to file relevant information and recall plans for the record in accordance with relevant provisions
- Manufacturers have failed to submit relevant recall plans in accordance with relevant provisions

(2) Where manufacturers or operators have been involved in any of the following circumstances and have refused to make corrections after being told so by the product quality supervision departments, they shall be imposed a fine of more than RMB 500,000 and less than RMB 1,000,000; if they have illegal earnings, their illegal earnings shall be confiscated; if circumstances are serious, licensing authorities may revoke their licenses:

- Manufacturers or operators have not assisted product quality supervision departments in defect investigations
- Manufactures have failed to recall defective automotive products in accordance with filed recall plans
- Manufacturers have failed to inform sellers of recall plans

(3) Where manufacturers have been involved in any of the following circumstances, the product quality supervision departments shall order them to make corrections and impose a fine of more than 1 percent and less than 10 percent of the value of defective automotive products; if they have illegal earnings, their illegal earnings shall be confiscated; if circumstances are serious, licensing authorities may revoke their licenses:

- Manufacturers have not stopped manufacturing, selling or importing defective automotive products
- Manufacturers have concealed defects

- Manufacturers have refused to recall defective automotive products against orders

3.6 Recall Term

The 2004 AQSIQ Motor Vehicle Recall Regulations contained a provision on "safe use periods" during which the products need to be free from any safety defects. Correspondingly, this was also the maximum term in which a recall of the defective motor vehicle products had to be carried out. In case of assembly, it was defined as the period from its delivery to the first owner of the vehicle to the period of safe use as instructed by the vehicle manufacturer (AQSIQ Motor Vehicle Recall Regulations 2004, Art. 7). If the vehicle manufacturer failed to clarify the period of safe use, or the period of safe use is less than ten years, the term will be ten years after the date when the seller delivers the car product to the first owner of the vehicle. The time limit for recall of car tires was considered three years from delivery to the first owner of vehicles. The new State Council Automotive Products Recall Regulations do not contain any provision on a safe use periods, but manufacturers are well advised to either indicate a certain safe use period or continue to consider those periods mentioned above as minimum periods.

3.7 Liability

The recall of defective vehicles does not relieve the manufacturer from its liability to pay damages to vehicle owners or third parties injured by the defective product (State Council Automotive Products Recall Regulations, Art. 28).

3.8 Conclusion

It is recommended that vehicle manufacturers develop emergency plans in advance for both voluntary recall actions and recall actions ordered by the authorities.

Chapter 6: Medical Devices

1. General

The term medical devices, as defined by the Medical Devices Administration Regulation, refers to the instruments, equipment, apparatuses, in vitro diagnostic reagents and calibrators, materials, and other similar or related articles that are directly or indirectly used on human bodies, including the computer software needed. The effectiveness of medical devices is obtained mainly through physics and other means, rather than through pharmacological, immunological or metabolic ways. Alternatively, pharmacological, immunological or metabolic ways may be involved, but only play a supporting role. The purposes of medical devices are as follows:

- To diagnose, prevent, monitor, treat or mitigate diseases
- To diagnose, monitor, treat or mitigate injuries or compensate the functions lost due to injuries
- To examine, substitute, regulate or support physical structures or physiological processes
- To support or sustain life
- To control conception
- To provide information for medical treatment or diagnostic purposes by checking samples from human bodies

The following legislations outline the basic legal framework for the administration of medical devices in the PRC:

- Measures on the Supervision and Administration of the Business Operations of Medical Devices promulgated by the CFDA on 30 July 2014 ("Medical Devices Operation Measures")
- Measures on the Supervision and Administration of the Production of Medical Devices promulgated by the CFDA on 30 July 2014 ("Medical Devices Production Measures")

- Regulations on the Supervision and Administration of Medical Devices promulgated by the State Council on 7 March 2014 ("Medical Devices Administration Regulation")

- PRC Criminal Law of the PRC of 14 March 2012

- Administrative Measures for the Recall of Medical Devices (For Trial Implementation) promulgated by the Ministry of Health on 20 May 2011 ("Medical Devices Recall Measures")

2. Product Standards and Defectiveness

Art. 6 of the Medical Devices Administration Regulation provides that medical devices products shall be in compliance with mandatory national standards on medical devices, or, in the absence thereof, be in compliance with mandatory industry standards on medical devices. Currently there are hundreds of national standards respectively for different medical devices.

Art. 4 of the Medical Devices Recall Measures provides that "defectiveness" means the unreasonable risk caused by a medical device in normal use that may endanger human health and life safety. Thus, although the compliance with national standards is compulsory for medical devices, the defectiveness however does not purely rely on the compliance with national standards. Any medical devices that causes unreasonable risk that may endanger human health and life safety can be categorized as "defective".

3. Administrative Liability

3.1 Administrative liabilities for various subjects

Medical devices manufacturing entities, business operation entities and the entities using the medical device shall all bear administrative liabilities under different scenarios as provided by national regulations.

Art. 66 (1) of the Medical Devices Production Measures provides that where a manufacturer engages in the manufacturing of medical devices that are not in compliance with mandatory standards or not in compliance with the registered or record-filed product technical requirements, the manufacturer will be punished in accordance with Art. 66 of the Medical Devices Administration Regulation.

In addition, Art. 59 of the Medical Devices Operation Measures provide that where a business operator engages in the business operations of medical devices that are not in compliance with mandatory standards or the registered or record-filed product technical requirements, the operator will be punished in accordance with Art. 66 of the Medical Devices Administration Regulation.

Art. 66 of the Medical Devices Administration Regulation also clearly provides that where an entity engages in the manufacturing, business operations or use of medical devices that are not in compliance with mandatory standards or not in compliance with the registered or record-filed product technical requirements, it will be ordered to make corrections by the competent local CFDA, and have the medical devices under illegal manufacturing, business operations or use confiscated. Where the value of the medical devices products under illegal manufacturing, business operations or use is less than RMB 10,000, the perpetrator will be concurrently given a fine of not less than RMB 20,000 but not more than RMB 50,000, and where the said value reaches or exceeds RMB 10,000, the perpetrator will be concurrently given a fine of not less than five times but not more than ten times the amount of the value of the medical devices products. Under grave circumstances, the perpetrator will be ordered to stop production or business operations, and may even have its Medical Device Registration Certificate, Medical Device Manufacturing Permit or Medical Device Business Operations Permit revoked by the original certificate-issuing department.

Art. 68 (8) of the Medical Devices Administration Regulation further provides that where the perpetrator is a user entity of medical devices that finds safety hazards in the medical devices in use but fails to immediately stop using the same and notify relevant parties to carry out inspection and repair, or that continues to use medical devices that still fail to meet the standards on safe use after inspection and repair, it will be given a warning by the competent local CFDA, and be given a fine of not less than RMB 5,000 but not more than RMB 20,000 if the entity refuses to make correc-

tions. Under grave circumstances, the entity shall be ordered to stop production or business operations, and may even have its Medical Device Manufacturing Permit or Medical Device Business Operations Permit revoked by the original permit-issuing department.

3.2 Recall of medical devices

Defective medical devices that are already in the market are subject to recall management in accordance with the provisions of the Medical Devices Recall Measures. Based on the severity of the defect of the medical device, the recall of medical devices is classified into:

(1) Class 1 recall: The use of the medical device may cause or has already caused severe health hazard

(2) Class 2 recall: The use of the medical device may cause or has already caused a temporary or reversible health hazard

(3) Class 3 recall: The use of the medical device is not very likely to cause health hazard but it is still necessary to recall the medical device

For the defective medical devices, the manufacturer shall immediately decide to recall the defective medical device. If an overseas manufacturer of the imported medical devices recalls its medical device products outside PRC, it shall notify its designated agent in PRC to report such recall to the CFDA in a timely manner. In the case of a recall within the territory of PRC, the designated agent in China shall be responsible for the specific implementation of the recall.

The Medical Devices Recall Measures provides that the CFDA shall supervise and administer work related to the recall of medical devices throughout the PRC.

If, upon investigation and evaluation, the CFDA finds any defect exists while the medical device manufacturer should have voluntarily recalled but failed to do so, the CFDA shall compel the concerned enterprise to recall the concerned medical devices by written notification. Upon the receipt of the notification on compelling a recall, the concerned medical device manufacturer shall inform the medical device trading enterprises and entities using the medical devices, or the concerned users, formulate and submit the recall plan and organize the implementation of the recall plan.

Upon the beginning of the recall process, the manufacturer shall notify the relevant medical device operation enterprises and entities using the medical devices, or inform the relevant users of the recall within specified timeline (i.e. one day in the case of a

Class 1 recall, or three days in the case of a Class 2 recall, or seven days in the case of a Class 3 recall).

Art. 29 of the Medical Devices Recall Measures provides that if a medical device manufacturer fails to voluntarily recall defective medical devices it shall be ordered to recall such medical devices, and a concurrent fine equivalent to three times the value of the medical device that should have been recalled will be imposed on the manufacturer. If serious consequences have been caused, the original license issuing department will revoke the medical device registration certificate or even the license of the medical device manufacturing enterprise.

Art. 29 provides that a medical device manufacturer that refuses to recall the medical devices will be imposed with a fine equivalent to three times the value of the medical device that should have been recalled. If serious consequences have been caused, the original license issuing department will revoke the medical device registration certificate or even the license for the medical device manufacturing enterprise.
Art. 30 provides that if a medical device manufacturer is involved in any of the following situations, a warning shall be issued thereto, and the enterprise shall be ordered to make rectifications within a specified time limit and be imposed with a concurrent fine of no more than RMB 30,000:

(1) the manufacturer fails to inform the medical device operation enterprises, the entities using the medical devices or the concerned users of the decision to recall the medical devices within a prescribed time

(2) the manufacturer fails to take rectification measures or recall the medical devices again as required by the CFDA

(3) the manufacturer fails to keep detailed records of the handling of the medical devices recalled or fails to report such records to the CFDA

4. Criminal Liability

Art. 145 of the Criminal Law applies specifically to medical devices. It provides that whoever produces medical apparatus and instruments or medical hygiene materials that are not up to the national or trade standards for safeguarding human health or sells such things while clearly knowing the fact, which is harmful enough to seriously endanger human health, shall be:

- sentenced to fixed-term imprisonment of not more than three years or criminal detention
- in addition, be fined not less than half, but not more than two times, the amount of earnings from sales

If serious harm is caused to human health, he shall be:

- sentenced to fixed-term imprisonment of not less than three years but not more than ten years and
- be fined not less than half, but not more than two times, the amount of earnings from sales

If the consequences are especially serious, he shall be:

- sentenced to fixed-term imprisonment of not less than ten years or life imprisonment and
- be fined not less than half, but not more than two times, the amount of earnings from sales or be sentenced to confiscation of property

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