Food Safety Governance and Its Reform in China

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About Me

- Law Professor, Law School, Nankai University
- M.S degree, Pharmaceutical Law, China Pharmaceutical University (2000)
- B.S degree, Pharmacy and English (1997)
International Activities

- Visiting Scholar, Yale Law School (2014)
- Give keynote speech or comment at
  - Yale University
  - University of Chicago
  - University of Pennsylvania
  - ABA Section of Administrative Law and Regulatory Practice
  - Washington Law School, American University
Articles in English

- Drug Safety Regulatory Governance and Its Reform in China, University of Pennsylvania East Asia Law Review (Forthcoming)
- The Role of Expert Consultation in Risk Regulation: An Illustration from Drug Approval in China (in English, unpublished)
- The Role of Multi-national Corporations in Pharmaceutical Regulatory Process in China (in progress)
Representative Articles in Chinese

The Role of Central Government in Drug Regulation of China, Journal of the East China University of Political Science and Law, 2014(1)

The Pros and Cons of Latest Drug Safety Regulation Reform in China, Management World, 2008(8)

The Intersection of Government Regulation and Tort Law: Illustration from Drug Regulation, Journal of Comparative Law Study, 2008(2)
Representative Articles in Chinese

*Adverse Drug Reactions and Reform of Government Supervision Mechanism, Legal Science Monthly, 2006(9)*

*What General Administrative Law Theory can Learn from Drug Administration Law, Contemporary Law Review, 2010(2)*

*Food Safety Standard Regimes in China, Public Administration Review, 2011(2).*
Grants

- **Comparative Study on Contract Manufacturing of Drugs**, China Food and Drug Administration, 2013.


- **Legislative Reform on Cosmetic Safety Regulation**, Shanghai Food and Drug Administration, 2013.

- **Pediatric Drug Approval Policy Study**, China Food and Drug Administration, 2012
Grants

- Administrative Law Study on Drug Safety Regulation, National Social Science Fund, 2009
- The Revise of Pharmaceutical Administration Law, CFDA 2011
- Post-marketing Study Commitments and Risk Control in Drug Regulation, 2011
- Vaccine Regulation Strategy of China, 2010
Grants

- Comparative Study on Drug Legislation Framework, 2009
- Law and Policy for Orphan Drugs, 2009
- The History and Evolution of Food and Drug Regulation: 1978-2008, China Food and Drug Administration, 2008
Introduction

- Since the mid-1990s, food-related scares and debates, with Bovine Spongiform Encephalopathy (BSE) and genetically modified (GM) foods in Europe.

- Food safety institutions in Europe have been facing growing demands for a more effective, efficient and balanced and fair regulatory process, by more transparent and participatory decision-making procedures.
Introduction

- China food safety legislation has evolved over 30 years or so, reflecting a blend of scientific, social, political and economic factors.

- As a result, there has, at times, been little coherence in its development, resulting in over-complex and fragmented measures and lack of consistency.

- It is only recently that the China has developed a clear policy framework for food law.
Pre-legal Era (1949-1982)

- In 1952, Business Man, Zhang Xingen and Xu Miaoxin, Shanghai, provide 60,000 kg adulterated beef to China PLA soldiers in Korea War.

- People’s Daily, Feb.17, 1952
After Cultural Revolution (1966-1976), the management goal is to carry out food hygiene management.

On the other hand, to ensure food supply and food amiability, require to decrease the requirement and standard for food hygiene.

Tianjin Health Historic Material, 1986.
Management Law

- **Food Hygiene Law (Trial Implementation),** promulgated at Nov. 19, 1982.

- **Goal,** “Ensure food hygiene, prevent food pollution and potential harm by harmful factors”

- “Before food manufacturing and selling, the related personnel should wash their hands”
Food Hygiene Law

- Promulgated in Oct. 30, 1995
- Adjust related food supervision system
- Introduce new regulatory instruments
- Strengthen food hygiene management for street vendors
Fuyang milk powder accident, 2004
Food Safety Law

- Promulgated in Feb. 28, 2009

- Introduce food safety risk assessment
Food Safety Law

- Precautionary principle
- Technical complexity
- Decision-making under uncertainty

- Guiding principle in risk assessment and standard-setting.
Food Safety Law

- Reform Food Safety Regulatory System and Improve Coordination

- Consumer protection oriented

- Building food safety regulatory regime
Food Safety Risk

- Food Safety, a relative concept
- Inherent risk and danger in food
- Information asymmetry in food market
- Global food risk
- Food consumption may
Food Safety Regulation

- In 2013, Central Communist Party (CCP) mentions,
  - Reform market regulation system
  - Establish authoritative and unified food safety regulatory agencies
From government regulation to regulatory governance

- Reform governance network
- Introduce co-governance in food regulation

- Multi-centered
- From big government to small government
- From national to regional, global
- From public authority to private authority
The Revising of Food Safety Law

Oct.10, 2013, CFDA(China Food and Drug Administration) submit the revised draft to Office of Legal Affairs of State Council(Central Government)

The bill was under first reading in National People’s Congress, June 2014
The Revising of Food Safety Law

- From Regulation to Governance
- Co-governance (Collaborative governance)
- Risk governance
- Regulatory governance
— to sustained and focused control exercised by a public agency over activities that are valued by a community (Selznick, 21985)
Food Safety Regulation

- Food safety “Lemons”
- Market Failure
- Information Asymmetrical
- “Experience Goods”
I. Establish Regulatory Governance Network

A. The role of State Council
1. Enact Administrative Regulations

- The regulatory framework has been laid down by Food Safety Law.

- The more detailed rules are established by China Food and Drug Administration.
2. Issue Decisions and Orders

- Some issued by Office of the State Council (国务院办公厅)
3. Hold Meetings

- Seldom
- —— On food safety accidents
4. Written Instructions

- Written Instructions by top leaders (批示) (by Premier Li Keqiang, etc.)

- Internal channel in hierarchy system
5. Summary

- State Council not only “direct” regulation, but also “administer” the works of food safety regulation.
- No strictly separation of politics and administration.
- State Council cannot make specific decisions in such a professional and technical area.
- State Council try to control or influence the operation of CFDA.
5. Summary

- The “policy window” by State Council
- —— Health and Safety
- —— Political and Social Stability
- —— International Reputation
B. Regulatory Coordination

- A Unified System
- CFDA and local FDA
- Fragmented regulatory authorities
An Illustration, before 2013

- Ministry of Health
- Ministry of Agriculture
- State Food and Drug Administration
- General Administration of Quality Supervision, Inspection and Quarantine
- State Administration for Industry and Commerce
- SAIC
- GAQSIQ
Different regulatory authorities have different capacities, the necessary regulatory information cannot be shared by those regulatory agencies, and the regulation boundary is murmured.
Regulatory coordination

- CFDA is also the Office of Food Safety Committee of State Council
C. Local governance

- Local regulatory governance plays an important role in daily regulation.
- To deal with questions of law, fact and discretion, with specific cases.
- China is a big country, tailored-regulation based on local practice.
- The coordination of agencies need the involvement of local government.
Conflict between food safety and economic development

- Developing state
Local developmentalism

- Since the end of 1970s
- “Developing is of overriding importance”
- Local governments may align with enterprises and provide privileges to them with ignorance of social rights (maybe health right).
Case 1

- Some local governments simplify administrative procedures, reduce taxes and fees to attract the investment of food enterprises.

- Those measures may conflict with Administrative License Law and Drug Administration Law, tax law.
Local gov. conducting “economy” and “health” affairs, Art. 107 of Const.

Government’s role in economic development, Art. 7, 8 and 11 of Const.

Nation should “protect the people’s health”, Section 1, Art. 21 of Const.
Local government should seek for balance between protection of people’s health and development of food industry.

Local gov should not impose economic indicators to regulatory agencies.

Local gov should not intervene daily enforcement activities by regulatory agencies.
Overall Responsibility of Local Government

- Local governments should assume overall responsibility in drug safety regulation in their respective areas (地方政府负总责). (2007, by General Office of the State Council)

- To promote food regulatory capacity
- Funding
Overall Responsibility of Local Government

- establish coordinating bodies for drug safety (Food and Drug Safety Commission under some local government)
- integrate regulatory resources, build agency coordination system
- establish emergency response system
- build internal accountability mechanism
Brief Summary

- Now overall responsibility is political or internal responsibility (Zhou Hanhua, 2009)
Recommendations

- Local government should define specific objectives and targets in certain periods
- Develop uniform regulatory policy in its area
- Provide support for safety regulation from organization, technology, information and finance
4. Street-level Governance

- National FDA
- Province FDA
- Municipal FDA
- County FDA

- It may establish local FDA branch at town and village level.
5. Regulatory agencies

- Clarify the task of food regulation
- Regulatory coordination
- Regulatory capacity building
- Expertise
- Agency self-regulation
6. Quasi-government organization

- National Food Safety Risk Assessment Center
B. Industry Association

- Industry self-regulation
- Know more information than regulatory agencies
C. Food Manufacturers and Salers

- Civil Liability
- Tort Liability
- Contract Liability
1. Complying with rules

- Complying with laws, rules, regulations, standards, guidances.
- Provide relative data and materials to regulators.
- Report actual information on request of regulators.
1. Complying with rules

- Food Traceability
- Introduce of information tools
- Process Control
2. Management-based regulation

- Process Regulation
- Enforced self-regulation

- The combination of administrative regulation and self-regulation

- **HACCP** (Hazard Analysis Critical Control Point)
2. Management-based regulation

- Self-inspection of food safety
- Keep inspection records.
- Food recall
B) Introduce Risk Regulation Philosophy into Food Safety Regulation

- Chapter Two of Food Safety Law ---- “Food Safety Risk Surveillance and Assessment”.

- it can decrease and control inherent and extrinsic factors ...

- to ensure the transparency and accountability of food safety regulation.
D. Mass media

- Journal
- Newspaper
- New social media

- Report objectively, scientifically
E. Public citizen

- Public participation

- Whistleblower/internal reporting
II. Regulatory Governance

- Smart Regulation
- Ex-ante regulation and Ex-post regulation
- Command-and-control regulation vs. incentive regulation
- Deterrence and Compliance oriented regulation
Reduce unnecessary license, combine manufacture license, distribution license and restaurant license into one license

《国务院机构改革和职能转变方案》“按照行政审批制度改革原则，最大限度地减少对生产经营活动和产品物品的许可”
1. License

- It will introduce license for food safety management personnel
Internet food selling

- It will introduce license
Standard setting

- Important regulatory tool
- Criteria for food regulation and food manufacturing practice

- Food Safety Standard-setting Advisory Committee
Recall

- Food recall
U.S, FSIS & FDA公布的信息，1504 cases for food recall, 2008-2011

China, 132 cases for food recall, 2008-11

Information disclosure
5. Warning or Talking

- 食品生产经营过程中存在安全隐患，未及时采取措施消除的，食品安全监督管理部门可以对其法定代表人或者主要负责人进行责任约谈（外部约谈，类似于行政指导）。
鼓励内部人举报（internal reporting）
当组织内个人见证到组织的失范时，可向组织之外的监管者报告。
社会治理：现代社会有赖于私人去发现和举报违法行为
《送审稿》第101条第1款“国家建立食品安全有奖举报制度。县级以上食品药品监督管理部门建立食品安全投诉举报系统，对查证属实的，给予举报人奖励。”

建议增加一款“严格执行举报保密制度，保护举报人合法权益。”
《送审稿》第98条规定了食品生产经营者食品安全信用档案制度，记录许可颁发、日常监督检查结果、违法行为查处等情况。
The right to know for citizens
《送审稿》第119条

被吊销食品生产经营许可证的单位，其主要负责人和食品安全管理人员自处罚决定作出之日起五年内不得从事食品生产经营管理工作。

因食品安全犯罪被判处有期徒刑以上刑罚的，终身不得从事食品生产经营管理工作。（新增）

食品生产经营者聘用不得从事食品生产经营管理工作的人员从事管理工作的，吊销许可证。
8. 行业禁入

从落实行业禁入制度有效性的角度，建议明确规定被禁入者的公告制度。规定监管部门向社会公布对禁入的主要负责人和食品安全管理人员。

从保障被禁入者权利的角度，为禁入年限设定合理的不同阶次，细化禁入程序。
The introduction of Food Safety Liability Insurance

CFDA and Insurance Regulatory Commission

Reduce public risk
10. Administrative Penalty

- Increase the amount of administrative fines/
Reflection on the Cruel Punishment in Food Safety Regulation
Article 143 & Article 144 of Criminal Law of PRC specifies related food crime.

- administrative regulatory agencies should be the main actor in food regulation
- criminal penalty should be the last resort in food regulation.
12. Civil Liability

- Punitive damages.

- The amount is ten times of the price or three times of the total loss.
III. Risk Governance

- Risk surveillance
- Risk assessment
- Risk warning
- Risk communication
Article 11 of *Food Safety Law* specifies that, the nation should establish **food safety surveillance system**, to monitor related diseases, food contamination and hazard factors, and carry out comprehensive analysis and timely announcement.

It should establish **national food safety risk surveillance network**, to guarantee the accuracy and objectivity of related data, to collect and analysis related risk surveillance data.
Introduce Risk Regulation Philosophy into Food Safety Regulation

- Article 13 of Food Safety Law

- National Food Safety Risk Assessment Expert Committee ...

- risk assessment of biological, chemical and physical hazard in food and food additive.

- Risk communication
Risk communication

The role of mass media

— “An open, two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions”

Source USDA, 1992
Current Situation

- Now, regulation more resembles ordinary product regulation.
- No “zero risk” exists in risk regulation.
- Government assume too heavy responsibility.
- Add the fear by ordinary citizens.
A. Constructing Risk Regulatory System

- balance risks and benefits
- The duty of enterprises in risk control.
B. Using Risk Communication to Correct Bias

❖ Source of bias

❖ — Availability Heuristic
❖ “if you can think of it, it must be important”

❖ — Representativeness Heuristic
Source of bias

- Probability Neglect
- "chromium-contaminated" capsules events in 2012

Reference

Risk Communication

- US FDA, Risk Communication Advisory Committee
- In China
- No specific body performing obligation in drug risk assessment
- Being lack of sufficient qualitative and quantitative study on drug risk.
- When drug safety events occurred, drug regulatory authorities cannot give a reliable reply promptly.
Recommendations

(1) Risk Communication Advisory Committee as a bridge between governments and the public, invite experts in pharmaceuticals, law, policy and journalism.
Recommendations

- (2) risk education, in order to guide mass media and the public to develop rational and objective perception on drug risk.
Recommendations

(3) Improving risk communication skills

— Respond promptly,

— Transform complicated scientific terms into plain words which can be understood by the public and the mass media

— Provide suggestions and advices.
C. Establish Risk Warning System
IV. Global Governance

- Standard-setting
- International Regulatory Cooperation
- Import safety
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