The China melamine milk scandal and its implications for food safety regulation

Xiaofang Pei a, Annuradha Tandon b, Anton Alldrick c, Liana Giorgi b,e, Wei Huang a, Ruijia Yang a

aWest China School of Public Health, Sichua University, Chengdu, China
bThe Interdisciplinary Centre for Comparative Research in the Social Sciences, Austria
cCamden BRI Food and Drink Research and Services, United Kingdom

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Abstract
This article examines the development of the Chinese dairy sector since 2000 and investigates how this has affected food safety. The ongoing problems caused by melamine contamination are linked to the rapid and unregulated development of this sector. Currently, China is faced with demands – both from home and abroad – to improve its food safety record. This will necessitate it upgrades its regulatory framework to meet the standards of Codex Alimentarius and the EU. A serious restructuring of the dairy sector as well as of the public food safety control agencies is called for. The costs and benefits to be accrued by these reforms are the subject of this article.

Introduction
Fewer than three years ago, melamine was a term known only to chemists. This changed almost overnight in 2006 when the pet food scare broke out. In 2008, the much more serious milk powder contamination scandal followed. Since then it has been known that melamine can lead to serious or even fatal renal and kidney failure under specific conditions and for specific forms of metabolism.

In the long term, melamine contamination will probably be remembered mostly for bringing about a comprehensive reform of the Chinese food safety regime. Reforming the Chinese food sector is, however, no small undertaking by reason of the country's size. Clearly, China should opt for the reform pathway which guarantees the best results with respect to food safety without seriously endangering the country's economic development course and its approximation to Western standards and trade relations.

The present article aims to contribute to this reform process by offering a systematic overview of the Chinese dairy sector and food regulatory system in juxtaposition with the situation within the European Union, and in individual European countries. The latter are taken as benchmarks, against which China can take its bearings and measure the progress of its reforms. From the European perspective, the article is an interesting study on compliance with higher food safety standards.

The paper is structured as follows. The first section deals with problem identification reporting on the hazardous nature of melamine, the case of milk contamination with melamine and the Chinese dairy sector. The subsequent section entitled 'Benchmarking the way towards greater food safety' explains the use of the benchmarking approach to address the main issues of compliance with food safety regulations. 'Regulatory issues' looks at the first of these issues, i.e. the regulatory framework, and compares the situation in China with that of the EU. A similar format is followed in the next two sections: 'Official controls' compares the systems of official controls in the EU and China, whilst 'Private standards and the role of the dairy industry' looks at the dairy industry and private standards in the two countries. Against this background, the final section, 'Assessment and comparisons' considers the advantages and disadvantages of different policy options for reforming the Chinese food safety regime.

Problem identification
Melamine as a health hazard

Melamine is a nitrogen-rich organic compound and an intermediate chemical frequently used for the manufacture of fertilizers, plastics, laminates, paints and adhesives. Studies carried out on rats in the mid-1940s indicated that melamine was not toxic (Lipschitz and Stokey, 1945). However, in 1953, a follow-up study on
dogs documented toxicity at higher intakes. Animal studies in the 1970s and 1980s showed that the danger of toxicity differed according to the age of the animal (Heck and Tyl, 1985; Newton and Utley, 1978). The first study to suggest that the toxicity of melamine was proportional to its metabolic output was performed by researchers in the former USSR during the 1980s. Their results suggested that melamine cyanurate (a salt formed between melamine and cyanuric acid, commonly used as a fire retardant) could be more toxic than either melamine or cyanuric acid alone (Babayan and Aleksandryan, 1985). The toxicity of melamine cyanurate crystals has since been linked to their inability to dissolve easily, and this can lead to chronic toxicity (Wilson, 2007). The combination of melamine and cyanuric acid can therefore lead to acute renal failure. This was confirmed by a toxicology study (Puschner et al., 2007) carried out following the recalls of contaminated pet food in the U.S. and Canada.

In humans, the ingestion of melamine may lead to reproductive damage and bladder or kidney stones. As with animals, the danger is greatest among the very young, whose organs have yet to form fully and whose nutrition is more restricted. In China in 2008, the melamine contamination of milk powder led to the deaths of six infants and the hospitalization of 52,000. A further 250,000 children were estimated to have suffered mild kidney and urinary problems. The immediate cost to the health system was estimated at 58 million Euro.

The EU tolerable daily intake for melamine in the context of the contact of food with packaging and other materials is 0.5 milligrams per kg of body mass. This was judged as sufficient also after the melamine crisis (EFSA 2008). In the United States, the threshold was set at 0.063 mg prior to the melamine crisis, but was revised downwards to 0.063 mg in the aftermath of the scare. According to the WHO, the tolerable daily intake (TDI) is 0.2 mg per kg of body mass.

**Melamine in milk**

The contamination of Chinese milk by melamine represented a case of fraud. Melamine was added to mask a dilution in protein. Specific tests for milk quality, e.g. freezing point depression, specific gravity analysis and fat content should have detected such fraud, but these tests were either not carried out properly or were ineffective. Rapid automated systems for testing the content of protein, fat and other ingredients were also not used properly, thus were ineffective for detecting fake protein. Two other factors contributed to the melamine scandal. The first was that melamine was not specifically listed as an illegal additive. The second was that many dairy giants in China, including the main distributor of the contaminated milk, Sanlu, were exempted from official controls. This is a point we return to later in this article.

**The Chinese dairy sector**

The Chinese dairy sector began to grow rapidly in 2000 following a more moderate growth rate between 1995 and 2000. It is highly likely that the problems currently being faced are due to this fast growth, which occurred largely in unregulated fashion.

In 2000, the annual production of cow’s milk amounted to just over 8 million tonnes. By 2008, this had increased close to fivefold to over 36 million. Similar growth rates were observed for dry milk products, which went up from less than one million tons in 2000 to close to four million in 2007 (China Ministry of Agriculture, 2008).

This rapid growth is mainly driven by changes in domestic consumption patterns. The consumption of dairy products has been on the increase by an average of 15% annually since 1995. With increasing affluence, the Chinese food consumption patterns have tended to shift closer to those in the West. The Chinese government has also actively promoted the consumption of milk by children through a school milk scheme. China is also rapidly evolving as an export country for dairy products, and especially for dry milk products.

Table 1 compares the changes in domestic consumption patterns with the changes in production and exports over the period from 1995 to 2008. In 2007, around 50 percent of milk produced was channelled into domestic consumption, whereas less than 0.5 percent was directly used for export. This also means that 40 to 50 percent of the total production of cow’s milk is channelled into the production of other dairy products, of which a large proportion is then also exported.

China’s surging exports of milk products are to be explained by the increased demand in Hong Kong, Macao and Southeast Asia against the backdrop of decreasing supplies from the traditional milk producing countries, namely Australia, New Zealand and the European Union. By contrast, the dramatic shift in the domestic consumption of milk products was made possible by a major restructuring of the Chinese dairy sector in conjunction with rising per capita incomes. Throughout the 1990s and the first years of the new century, the growth of the dairy sector was actively supported by the Chinese government with various programs. These included allocation of farmland to raise cattle, improvement of grasslands and yields, economic incentives like waving of land-use fees or the provision of discount loans to farmers or processing and packaging operators. As a result, the number of farm holdings has doubled in a very short period of time from 3098 in 2003 to 6478 in 2008. Similarly, the number of enterprises involved in dairy processing rose from 355 in 1998 to 717 in 2007 (China Ministry of Agriculture 2008). The main dairy producing areas are the regions of Hebei, Henan, Shandong, Heilongjiang, Guangdong, Sichuan and Shanxi, which together account for nearly 67% of farm holdings by reason of their climate and grasslands. The majority of the Chinese farm holdings (60% in 2007) are medium-size and organized as cooperatives with 100 to 200 cattle each. A total of 6478 holdings presently accounts for an employment of just over 7 million – still a comparatively small number which points to intensive agricultural production techniques, but also suggests that there is scope for growth. The 1990s also witnessed a renewal of interest in foreign investment in the Chinese dairy sector. Today, big corporate names such as Danone, Friesland and Nestle are all present in China.

**Table 1**


<table>
<thead>
<tr>
<th>Year</th>
<th>Production</th>
<th>Consumption</th>
<th>Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>5.7</td>
<td>6.8</td>
<td>0.03</td>
</tr>
<tr>
<td>1996</td>
<td>6.3</td>
<td>7.4</td>
<td>0.031</td>
</tr>
<tr>
<td>1997</td>
<td>6.6</td>
<td>7.8</td>
<td>0.039</td>
</tr>
<tr>
<td>1998</td>
<td>6.4</td>
<td>7.5</td>
<td>0.037</td>
</tr>
<tr>
<td>1999</td>
<td>7.1</td>
<td>8.4</td>
<td>0.04</td>
</tr>
<tr>
<td>2000</td>
<td>8.2</td>
<td>9.6</td>
<td>0.048</td>
</tr>
<tr>
<td>2001</td>
<td>10.2</td>
<td>11.5</td>
<td>0.043</td>
</tr>
<tr>
<td>2002</td>
<td>12.9</td>
<td>14.7</td>
<td>0.051</td>
</tr>
<tr>
<td>2003</td>
<td>17.4</td>
<td>n.a.</td>
<td>0.049</td>
</tr>
<tr>
<td>2004</td>
<td>22.6</td>
<td>n.a.</td>
<td>0.060</td>
</tr>
<tr>
<td>2005</td>
<td>27.5</td>
<td>15.9</td>
<td>0.070</td>
</tr>
<tr>
<td>2006</td>
<td>31.9</td>
<td>17.5</td>
<td>0.075</td>
</tr>
<tr>
<td>2007</td>
<td>35.2</td>
<td>n.a.</td>
<td>0.12</td>
</tr>
<tr>
<td>2008</td>
<td>36.5</td>
<td>n.a.</td>
<td>0.12</td>
</tr>
</tbody>
</table>

1 This has also led to significant milk price rises in New Zealand and the United States. In the European Union, milk prices could be kept low through providing subsidies to farmers.
Benchmarking the Way towards Greater Food Safety

How should China improve its regulatory framework towards greater food safety? And what are the costs and benefits of this reform process? This is the main theme of this paper. As discussed above, China has recently enacted a new legislative framework for upgrading its food safety standards. However, the enactment of legislation is only the first step in a long process of implementation (Hong-Gang and Hui, 2009). Therefore, the present study considers regulatory issues (see ‘Regulatory issues’), to then examine the practical steps that would need to be undertaken at the levels of official controls (see ‘Official controls’) and the dairy industry (see ‘Private standards and the role of the dairy industry’) for effectively implementing the new legislation.

In order to assess the costs of this process, we follow a comparative benchmark study design comparing the Chinese dairy sector in its present form with the Austrian dairy sector. The two countries differ quite significantly and not least with respect to the size of the food production sector and the size of the country as such. Still, Austria was considered a good benchmark for three reasons:

• First, for being an EU Member State, hence following the EU regulatory framework on which China has modelled its recent reforms.

• Second, for displaying a dairy sector with high levels of quality and food safety.

• Third, for having a dairy sector structurally organized in cooperatives – a model also favoured by the Chinese dairy industry in view of the large number of small farm holdings delivering to large dairies.

With respect to the regulatory framework of official controls, we also consider the examples of the UK and Germany. This is because official controls are organized differently, depending on the political structure of the country and its public administrative history. In reforming its system of government oversight and official controls, China may therefore have to consider different institutional models – each entailing different assets and liabilities.

Regulatory issues

Food safety in the dairy sector – the EU framework

In 2002, the European Union introduced a General Food Law (Regulation 178/2002) based on the ‘farm to fork’ principle, i.e. the application of good safety practices and controls at each and every point in the food chain and the obligation for food to be traceable right back to the original source. This was followed by several new regulations and directives on official controls or the testing and analysis of specific contaminants in specific food commodities. In addition, the last decade has seen major institutional reforms at EU and national levels, including the establishment of a European Food Safety Authority (EFSA) and equivalent bodies at national level and the introduction of the Rapid Alert System for Food and Feed (RASFF). Table 2 summarizes those regulations or directives of specific relevance for the dairy sector.

EC Regulation 852/2004

Lays down general rules for food business operators on the hygiene of foodstuffs. This requires the application of the HACCP system by food operators (Article 5) and recommends its use also at the primary production level. In recognition of the possible non-feasibility of the application of HACCP to primary production (preamble, 11), the regulation recommends using appropriate hygienic practices and suggests Member States develop national guides to good practice for food operators along the food chain and in accordance with the codes of practice of Codex Alimentarius (Article 8). Annex I lays down the general hygienic provisions for primary production and Annex II lays down the hygienic provisions for all food business operators.

EC Regulation 853/2004

Lays down specific rules on the hygiene of food of animal origin. The regulation is justified with reference to the specific hazards to human health represented by food of animal origin, in which microbiological and chemical hazards have frequently been reported (preamble, 2). Section IX of Annex III specifies the requirements for raw milk and dairy products.

EC Regulation 854/2004

Lays down specific rules for the organization of official controls on products of animal origin intended for human consumption. Such controls can only be carried out by certified establishments (Article 3) and must include an audit of good hygienic practices and HACCP and official controls specified for each product category (Article 4). For raw milk and dairy products, the specific

Table 2

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Main purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation (EC) No 852/2004</td>
<td>Lay down hygiene rules for food (852) and feed (853), in addition to defining requirements for raw milk and dairy products</td>
</tr>
<tr>
<td>Regulation (EC) No 853/2004</td>
<td>Sets out rules for official controls on products of animal origin</td>
</tr>
<tr>
<td>Regulation (EC) No 854/2004</td>
<td>Sets maximum levels for veterinary drugs in animal products, including milk</td>
</tr>
<tr>
<td>Regulation (EEC) No 2377/90 – as amended</td>
<td>Sets the maximum levels for number of chemical contaminants in foods</td>
</tr>
</tbody>
</table>

Table 3


<table>
<thead>
<tr>
<th>Regulation agency</th>
<th>Main food safety problems in the link</th>
</tr>
</thead>
<tbody>
<tr>
<td>New food safety commission under the State Council</td>
<td>Co-ordinate and oversee the new food supervision apparatus</td>
</tr>
<tr>
<td>Ministry of Health (MOH) under which is the State Food and Drug Administration (SFDA)</td>
<td>Assess food safety risk, set national standards of food safety, release information relating to food safety, regulate food safety testing, and investigate serious food safety incidents</td>
</tr>
<tr>
<td>Administration for quality, supervision, inspection and quarantine (AQSIQ)</td>
<td>Supervision of food production and food export/import</td>
</tr>
<tr>
<td>State Administration for Industry and Commerce (SAIC)</td>
<td>Supervise the domestic wholesale and retail food sectors</td>
</tr>
<tr>
<td>Ministry of Agriculture (MoA)</td>
<td>Responsible for non-processed farm products</td>
</tr>
</tbody>
</table>

2 A brief description of the EU regulatory framework is provided by Giorgi and Lindner, 2009. More detailed overview of the legislative acts is provided by Alemanno 2007.
requirements are spelt out in Annex IV and include criteria for control of milk production holdings and control of raw milk upon collection (see Table 4), which has to be in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation 853/2004 (which sets out the plate count, somatic cells count and checks for antibiotic residues).

The Chinese regulatory system on dairies

The melamine contamination of milk powder has triggered a comprehensive reform of the Chinese food safety regime. A new law enacted in February 2009, which entered into effect in June 2009, foresees the adoption of the ‘farm to fork’ food chain principles also governing the EU regulatory framework. In consecutive steps, and following UN recommendations, the Chinese government is expected to adopt the Good Agricultural Practices (GAP) as well as the Good Manufacturing Practices (GMP) across all food sectors and proceed with the implementation of the HACCP at firm level.

Until recently, the Chinese food sector was governed by the ‘Food Hygiene Law of the Peoples’ Republic of China’, dating from 1995. The Chinese Food Standard3 set out the institutional and supervisory food controls. As in Europe in the 1980s, prior to the BSE scandal, the Chinese food safety regime was characterized by institutional fragmentation with responsibilities spread out across several ministries (Chen, 2009; Tam and Yang, 2005). To overcome these difficulties, the new law tries to restructure the responsibilities and provide a clearer division of powers (Table 3).

Under the previous regime, several large dairy companies were granted inspection-free status on the basis of their past food safety record and in an effort to increase production with the view to boost demand at home and abroad. As a result, the Chinese food safety system was characterized by insufficient co-ordination, lack of resources, and a significant imbalance of the number of official controls between urban and rural areas (UN, 2008). According to Chen (2009), ‘China’s current food safety supervision system is doomed to making the supervision passive and ex-post, leaving redress as the only route’ (737).

Prior to the melamine scandal there was more emphasis placed on supporting the dairy industry. Following the melamine scandal, the government has shifted gears, and is now laying more emphasis on strengthening the regulatory framework and quality control. The new Food Law of 2009, which contains 104 rules in 10 chapters, foresees better co-ordination between national and provincial authorities, anticipates a significant increase in institutional and monitoring capacity through certified laboratories and plans the introduction of a food recall system modelled on the European RASSF. As in the EU, the primary responsibility for food safety will lie with food producers and operators. A weak point of the Chinese food safety system resides in the lack of trained personnel. In order to remedy these shortcomings, the Chinese government plans to reinforce its training schemes.

Under the new law introduced in 2009, China’s State Council will establish a national food safety commission that will co-ordinate and oversee the new food supervision apparatus. The MOH will be in charge of elaborating uniform national standards for food safety, including standards for food inspection. New enforcement authorities, anticipates a significant increase in institutional and monitoring capacity through certified laboratories and plans the introduction of a food recall system modelled on the European RASSF. As in the EU, the primary responsibility for food safety will lie with food producers and operators. A weak point of the Chinese food safety system resides in the lack of trained personnel. In order to remedy these shortcomings, the Chinese government plans to reinforce its training schemes.

Comparison EU-China

The decision by the Chinese government to embark on a major reform of its food safety regime is a step in the right direction. The new Chinese Food Law from earlier in 2009 displays a number of positive elements, especially with respect to establishing the principle of the responsibility of food producers and operators for food safety and the decision to upgrade the official control infrastructure and introduce a recall system. There remain, however, significant differences between the EU and the Chinese food regulatory system which are worth highlighting. It is not unlikely that these are being anticipated by subsequent legislation and regulatory initiatives already in-the-making as a follow-up of the new Chinese Food Law:

- Within the European Union, the General Food Law is principally just that – a general legal framework created to establish the main principles to guide subsequent legislation or regulatory activity. The ‘thickness’ of the EU food safety regulation derives

<table>
<thead>
<tr>
<th>Country</th>
<th>Wholesale production of raw milk ('000 tonnes)</th>
<th>Farm numbers</th>
<th>National herd ('000 head)</th>
<th>Official laboratories</th>
<th>Control plans</th>
<th>Quality and data management system</th>
<th>Provincial and district level staff resources (food, feed, animal health, animal welfare and plant health)</th>
<th>Frequency of checks – dairies</th>
<th>Private sector control</th>
<th>Average number of on-site controls (yearly)</th>
<th>Average number of laboratory tests (yearly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>2682</td>
<td>47,500</td>
<td>525</td>
<td>Yes (8)</td>
<td>Yes</td>
<td>Yes (ALIAS)</td>
<td>444</td>
<td>Depends on risk assessment of enterprise</td>
<td>HACCP guidelines</td>
<td>900</td>
<td>1768</td>
</tr>
<tr>
<td>Germany</td>
<td>27,681</td>
<td>99,000</td>
<td>4087</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, Information platform (FIS-VL)</td>
<td>12,293</td>
<td>Depends on risk assessment of enterprise</td>
<td>HACCP guidelines</td>
<td>N.A</td>
<td>38,656</td>
</tr>
<tr>
<td>UK</td>
<td>13,647</td>
<td>14,400</td>
<td>1977</td>
<td>No (public analysts)</td>
<td>Yes</td>
<td>Under implementation</td>
<td>8841</td>
<td>Depends on risk assessment of enterprise</td>
<td>HACCP guidelines</td>
<td>N.A</td>
<td>11,000</td>
</tr>
</tbody>
</table>

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a | 204 are food inspectors, 75 veterinary services and 150 administrative authorities.

b | Information for Bremen and Mecklenburg-Vorpommern not available.

c | Based on the Auditing and Sampling Plan for 2008 in Austria.

** | Number of formal samples taken in 2006/2007.

* | For 2006/2007 the sample plan for milk and milk products.
rather than from the subsequent more detailed regulations on specific aspects of the food safety system across the food chain. In the case of the dairy sector, for instance, the General Food Law is at best a reference point of constitutional value; far more important are the regulations on official controls and hygienic rules. In China, we have yet to see the elaboration of legislation or guidance in these more detailed areas of food safety.

- A problem which we will see recurring with respect to official controls, but which is also evident at the regulatory level, is that of centralization. In this respect, it is revealing that even under the new law China specifies two bodies for monitoring implementation in the dairy sector—the Ministry of Agriculture for the production side and the AQSIQ for official controls. Within the EU, implementation and oversight rest with the Member States, which, in turn, share this responsibility with regional authorities and various agencies. Admittedly, the better co-ordination with authorities at regional level, and especially those active in the dairy sector, is explicitly mentioned as a goal in the Chinese General Food Law. However, considering that China, unlike the EU or the United States, does not have any tradition in federalism and/or decentralization, operationalizing this goal represents a real challenge.

Addressing these basic shortcomings will require the introduction of additional reforms and a streamlining of the legislative framework to present and future institutional capacities.

**Official controls**

**Official controls in the Austrian dairy sector**

The implementation of the EC legislation in Austria is governed by the National Food Safety and Consumer Protection Act (LMSVG) BGBl. I No 13/2006 modelled according to the EU General Food Law. In Austria, there is a federalized system of monitoring and supervision of food safety. The standards are set in accordance with European regulations by the Federal Ministry of Health, Family and Youth (BMFL) and are implemented and monitored by the federal provinces (Länder). The BMFL is also in charge of defining the so-called integrated multi-annual control plans or the MIK, which specify inspection and sampling plans for each food sector. The execution of food controls is delegated to food inspectors working for provincial food inspectorates.

The control plans cover sampling and inspection issues and concern all facilities dealing with food including food of animal origin. These plans are prepared on the basis of risk categories (RIK). Those sectors considered as at higher risk for contamination are the targets of more frequent official controls. The procedures to be adhered to in controls are specified by the ALIAS system, which additionally serves as an internal audit system and a clearing-house for controls. Laboratories are expected to enter the results of controls into ALIAS and the data are then transferred to the Ministry of Health. Meetings between all relevant stakeholders are organized twice a year.

In Austria, there are eight laboratories with accreditation for testing samples for the purpose of official controls. All federal provinces but one (Burgenland) host an official laboratory. All laboratories work under the jurisdiction of the National Agency on Food Safety AGES and have ISO 17025 accreditation. These laboratories employ their own technical staff for laboratory tests in addition to a total of 260 inspectors working on-site. The food inspectors are collectively in charge of controls in 140,000 enterprises.

The comparatively low number of inspectors is attributed to the high levels of self-regulation within the industry. The official controls are organized in line with the HACCP principles. These are explained in Box 1.

**Box 1. HACCP and Critical Control Points in the Dairy Sector**

(Leitlinie über mikrobiologische Kriterien für Milch und Milchprodukte, Gutachten des Ständigen Hygieneausschusses, Bundesministerium für Gesundheit und Frauen, November 2006.)

The main parameters controlled in the dairy industry are temperature and time of processing. Two critical control points (CCP) normally identified during the processing of milk are reception and the heat treatment step (pasteurization or sterilization) used to reduce to microbial load. In accordance with HACCP principles, the efficacy of these steps has to be verified on a periodic basis, among else through laboratory analyses of appropriate samples. Details are provided below:

CCP for raw milk: upon delivery, before processing and following heat treatment
CCP for milk powder: immediately after production, at end of production and MHD (Mindestenshaltbarkeitsdatum – expiration date)
Tests carried out on raw milk: (a) microbial counts (upon delivery and before processing), (b) somatic cell counts (upon delivery) and (c) tests for *Listeria* and enterobacteria (following heat treatment).
Tests carried out on milk powder: (a) *Listeria* (upon production), (b) *Salmonella* and mould (at MHD) and (c) *staphylococci* and enterobacteria (at end of production process).

Following the HACCP guidelines, these tests are the responsibility of food operators. Official controls concentrate on establishing whether the HACCP system is in place (on-site inspections and laboratory tests) and on inspecting end products (laboratory tests).

**Official controls in other European countries**

The organization of official controls in Germany is similar to that in Austria. The main authorities for the implementation of the European food safety law is the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV), the Federal Agency for Consumer Protection and Food Safety (BVL) and the Federal Institute for Risk Assessment (BfR). The implementation of laws is carried out by the federal states (Länder), which are also in charge of the registration and approval of establishments. The BMELV sets out the national control plan and on this basis the BVL defines a monitoring plan. The 16 federal states designate official laboratories for carrying out official controls. These also employ in-house personnel as well as food inspectors for carrying out on-site inspections. The main difference between Austria and Germany is that German official laboratories, unlike their Austrian counterparts, are not entitled to carry out work for commercial purposes. This ensures that no conflicts of interest emerge.

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4 A category of risk in a scale from 1 to 9 has been attributed to each type of establishment and in the plan is foreseen to carry out at least one inspection every year for the establishment falling in the two highest category, if risk (8 and 9). Information confirmed in interview with Food Inspector from lower Austria – Mr. Neugenschwandner.

Table 5
Controlling quality of raw milk in China and the EU – a comparison. Source: Authors’ analysis based on EU and Chinese regulations.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>China</th>
<th>EU Regulation 2597/97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative density (20 °C/4 °C)</td>
<td>≥1.028 g L⁻¹</td>
<td>≥1.028 g L⁻¹</td>
</tr>
<tr>
<td>Protein</td>
<td>2.95% (m/m)</td>
<td>2.9% (m/m)</td>
</tr>
<tr>
<td>Fat</td>
<td>≥3.1% (m/m)</td>
<td>&gt;3.5 (m/m)</td>
</tr>
<tr>
<td>Nondair milk solids (fat-free dry matter)</td>
<td>&gt;8.1% (m/m)</td>
<td>&gt;8.5% (m/m)</td>
</tr>
<tr>
<td>Titratable acidity (measure of microbiological quality)</td>
<td>&lt;18</td>
<td>Not specified</td>
</tr>
<tr>
<td>Degree of impurity</td>
<td>≤4 mg kg⁻¹</td>
<td>Not specified</td>
</tr>
<tr>
<td>Aflatoxin M</td>
<td>≤0.5 μg kg⁻¹</td>
<td>≤0.05 μg kg⁻¹</td>
</tr>
<tr>
<td>Lead</td>
<td>≤0.05 mg kg⁻¹</td>
<td>≤0.02 mg kg⁻¹</td>
</tr>
<tr>
<td>Dioxins</td>
<td></td>
<td>3.0 μg dioxin per g fat or 6.0 μg dioxin like PCB per g fat</td>
</tr>
<tr>
<td>Inorganic arsenic</td>
<td>0.05 mg kg⁻¹</td>
<td>No EU-wide regulation and therefore dependent on Member State; currently 1.0 mg kg⁻¹ in UK</td>
</tr>
<tr>
<td>CaH4Cl2</td>
<td>0.02 mg kg⁻¹</td>
<td>Absence</td>
</tr>
<tr>
<td>DDT</td>
<td>0.02 mg kg⁻¹</td>
<td>Absence</td>
</tr>
<tr>
<td>Mesophilic bacteria (30 °C)</td>
<td>≤500 000</td>
<td>≤100 000</td>
</tr>
<tr>
<td>Somatic cell count (raw milk)</td>
<td></td>
<td>≤400 000</td>
</tr>
<tr>
<td>Antibiotics</td>
<td></td>
<td>Regulation 2377/90</td>
</tr>
<tr>
<td>Streptomycin &lt;50 μg/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin &lt;3 μg/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnahan ADM &lt;50 μg/L</td>
<td>4 μg/L (total)</td>
<td></td>
</tr>
</tbody>
</table>

The situation is somewhat different in the United Kingdom, which is not organized federally, but by devolution of implementation to local authorities. The main authorities for the implementation of the European Food Safety Law in the UK are the Department of Food and Rural Affairs (Defra) and the Department of Health (DH). Official controls are set out in the statutory Food Law codes of practice and practice guidance for local authorities. Inspections are carried out by the so-called animal health dairy hygienic inspectors acting on behalf of the Food Standards Agency. The Food Standards Agency is currently developing a database to hold details and results of samples taken by food enforcement officers. The UK Food Surveillance System (UK FSS) is similar in format to the Austrian ALIAS system. The key difference between Austria and Germany, on the one hand, and the United Kingdom, on the other, is that the UK does not have regional laboratories for organizing official controls. Given the more devolved nature of local government, local authorities either operate their own laboratories or contract out such tests to a commercial laboratory. Every local authority is required by legislation to appoint a ‘public analyst’ who must hold an approved post-graduate qualification.

Official controls in China

Until now, official controls have been performed in a varied manner. Prior to the melamine crisis larger enterprises were hardly ever controlled, the assumption being that they had quality control checks in place within their operating units and vis-à-vis their suppliers. This assumption was proven wrong by the melamine scandal. In the provinces or areas where the official supervision was stringent, there were fewer food safety problems as compared with the areas where supervision was lax.

According to the new regulation, health authorities under the State Council will be responsible for setting up national safety standards for dairy foods. A new standard which sets out the HACCP requirements for dairy enterprises was introduced in 2009 after the melamine crisis and includes guidelines and regulations from milk purchasing and processing to package, storage and transport (Bai Li et al., 2007a,b; Jin et al. 2008). Official controls will have to orient themselves on these HACCP guidelines. However, the specifics remain undefined. Indeed, a residual problem in the system of official controls is the absence of a plan for on-site inspections. In this respect, the new legislation only clarifies that as of now, ‘raw milk-purchasing stations will now need approval from local authorities to operate […] Other organizations and individuals are banned from collecting raw milk.’

In China, there are currently around 447 accredited laboratories employing 1000 chemists involved in tests for the dairy sector, including for melamine. However, many of them are not certified up to the latest standards and require infrastructure upgrading or training for personnel. In total China has 5094 certified labs employing 50,000 personnel with different specializations.

Comparison EU-China

Table 5 summarizes the parameters which are monitored by official controls in Austria and China. This shows that there are quite significant differences in the control plans used by the two countries, whereby by far the most important divergent parameters are those entailed in the more recent EU regulations of 2004 (No. 804) and 2006 (No. 1881). Other differences reflect disparities in emphasis due to the different levels of risk associated with the hazards. Whilst both systems check microbial parameters in each batch, for instance, the Chinese system also requires analysis for specified chemical contaminants. This may reflect lack of confidence in the supply chain.

However, the main problem in China is that there are no on-site inspections as part of official controls. Instead, controls concentrate on the end products and are organized on an overall smaller scale than within the EU. The guiding logic of regulatory control in China has been that of supporting concentration within the dairy sector under the assumption that major enterprises would install high-quality assurance systems stretching back to their suppliers; hence also the producers. This, in turn, would justify adopting a quality control approach with respect to official controls. Even though this is also a common assumption among European regulators, this...
does not translate into the deposition of the official control system. In addition, the European system places a heavy emphasis on a quality assurance approach – both for industry and for official controls. This is a process-oriented approach which seeks an optimization of the production process and all subsequent steps in the food chain. It involves understanding the hazards, designing systems to eliminate them or substantially reduce the risk of them occurring and having in place the routines necessary periodically to verify their continuing efficiency. The Chinese system appears to be more prescriptive and based on an approach more reliant on quality control principles, as these apply to products rather than processes. These differences may well reflect the different stages of evolution in food manufacture within the two regimes. It also reflects the low levels of implementation of HACCP systems in China. According to the UN (2008), ‘the enforcement in China of food control places an excessive reliance on end-product testing with very little use of auditing as an inspection tool'.

The two approaches evince a different understanding of where risk is to be found and how it can be dealt with. Under the quality assurance approach, risk is multi-factorial and endemic to the food chain process. It can therefore only be managed by a systems approach (Chen, 2009). The quality control approach ignores the way in which hazards occur at different points of the food chain as irrelevant. Instead, it assumes that it is possible to manage risk by concentrating on the removal of those end products that display low quality. The quality control approach is possibly useful for business management in specific contexts but less so for risk management.

Private standards and the role of the dairy industry

Austrian dairies

In a system of co-regulation, self-regulation by business enterprises plays a key role. HACCP is a concept of risk management and represents a tool which is used within the framework of the quality and safety management of a company in the food industry. HACCP is obligatory in Austria, but applied flexibly. In the dairy sector, however, it represents the standard: nearly 99.9 percent of the dairies in Austria apply HACCP.8

In the dairy sector, quality assurance depends on the relationship between the farmer and the dairy. Dairies with high food safety standards will often sign specific supplier quality assurance (SQA) contracts with farmers which set out the rules of production and transport and which may include incentives (such as premiums for exceeding minimum fat requirements) or penalties (e.g. breach of specifications which are subject to regular surveillance). There are two consecutive steps of quality checks:9 (a) at the stage of production at the farm and the subsequent transfer of the raw milk to the dairy where it is pasteurized; and (b) at the stage of transfer of the pasteurized milk from the dairy to a dried milk processing factory and its subsequent conversion into dried milk.

In a typical Austrian dairy, milk will be collected from individual farms on either a 24 or 48-h basis. Before loading the tanker, the driver controls the temperature of the delivery and collects a sample for reference. Milk is then loaded into the tanker and bulked with collections from other farms. On arrival at the dairy, the bulk milk is tested for certain key parameters before being off-loaded. Other tests are undertaken on a periodic basis on either random bulk raw milk or the individual samples collected from the farmer.

Depending on the sizes of the herds and volumes of milk collected, tankers may be compartmentalized to take a more restricted number of deliveries, thus facilitating a more rapid traceability system. In any event, bulk materials are subject to quality control checks before being offloaded. Samples collected from farms will be analyzed either if the bulk lot is found to be non-conforming or on a periodic surveillance basis. The nature of these checks depends on the intended use of the milk and on processing requirements.

Chinese dairy quality controls

The downstream level of milk collection in China includes several modes of market organization. Most prominent are the spot market chain and the co-operative chain. The former is a traditional dairy supply chain where farmers milk their cows and bring the milk directly to retail market to sell to consumers. The milk, in other words, is not treated or pasteurized. The second prominent mode is the co-operative or village chain, in the framework of which individual farmers bring and milk their cows in central milking stations. Nearly 80% of the milk collected in China is via these two modes (Fuller et al., 2006; Schiere et al., 2007).

After milking, farmers take their milk to a central collection point, which then chills it down and bulks it for onward delivery to a dairy or milk processor. The main control point here is the temperature, as the milk stored in refrigerated tanks has to be below 4°C and is delivered to the milk station twice a day. The temperature of refrigerated tanks is checked by the farmers themselves and other checks are made by the inspectors at the milk stations. The milk is transported within 48 h to the dairy, where the tests are conducted both by the dairy and the controlling authorities. The dairies test the quality of every batch of milk delivered and the controlling authorities carry out spot checks according to the relevant regulations and law. According to the present regulation, one-thousandth of the product delivered at the milk station or the dairy is sampled for reference. The frequency of tests on these samples varies according to the judged ‘self capacity’ for tests of the enterprises or milk stations. How this works in practice is unclear, as there have been no or few independent checks. An inquiry carried out in 2008–2009 led to the immediate closing of 4000 out of 20,393 milking stations due to substandard operating conditions or the lack of the right equipment or sanitary conditions.10

The situation is better in bigger dairies with 100 percent self-farming of cows, thus not dependent on milk stations or dairy farmers. This facilitates storage and transportation as well as pasteurization and food safety testing procedures. Such dairies are more likely to have installed a HACCP system for processing and checking. Under the new law, they must send samples of finished products to AQSIQ twice a month. The government authority checks the products at random and depending on the past record of the dairy. If no quality problems have occurred in the past, for example, checks are undertaken twice a year. On the other hand, if a dairy has had problems in the past, the detection frequency can increase dramatically. During the melamine crisis, every product batch was checked by government authority labs.

Comparison EU-China

There are several differences between the EU and China with regard to the structure and operation of the dairy industry which are relevant for food safety. The key, however, to understanding the failings of the Chinese food safety system lies in the system of milk

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8 Source: Interview TDV, private quality control firm.
9 This is based on the information collected from various Austrian dairies.
10 Source: www.china.org.cn.
collection and distribution from farms to dairies. As we have seen, 80 percent of the milk collected in China is either through the spot market chain or the co-operative chain. Milk collected and then sold through the spot market is not subject to any controls whatsoever. Milk collected through co-operatives is controlled regularly by dairies and occasionally by authorities, but there is no tracing mechanism in place given that no samples are collected from farmers delivering to dairies. As a result, there is no sustainable re-structuring effect on the production chain.

Assessment and comparisons

Let us recap our findings so far.

The EU and Chinese systems of food safety regulation for the dairy sector differ in several respects. Three issues were identified as of primary importance: first, the legislative framework, second the system of official controls, and third, the dairy industry.

Following the melamine crisis, the Chinese legislation was submitted to a major overhaul. The new Chinese General Food Law displays many similarities to the European General Food Law. However, unlike the EU, China has still to follow-up on this law with legislation and/or guidance on specific sub-areas or, more importantly, official controls.

The system for official controls is very under-developed. There are several problems. One is the lack of trained chemical and food science staff. There are fewer trained laboratory personnel in the whole of China, which is three times as big as the EU in terms of population, than in Germany alone. As a result, official controls concentrate on laboratory tests, with samples being delivered by companies. There are also no on-site inspections for controlling the implementation of the HACCP. These problems are not solely the result of structural deficits in terms of education or economic deficits in terms of government expenditures. They also reflect the different approach to food quality which prevails in China as opposed to the European Union. The Chinese favour a quality control approach, whereas the Europeans have tended towards a quality assurance approach. The latter is more pertinent to risk management, hence also the food sector, in view of public health issues.

The quality control approach would be more fitting were the dairy industry to operate according to high-quality assurance standards. This is, however, not the case in China where there is still an over-reliance on more traditional forms of raw milk collection and processing. Reforming these and installing tracing routines is therefore of paramount importance.

In view of the above, what would be the way forward for the Chinese government when further reforming and restructuring its food safety regime in the dairy sector? We consider three policy options below: (a) the statutory approach, (b) the non-statutory approach and (c) the co-regulation approach. For reference we also examine the ‘do-nothing’ approach.

Do nothing policy option

The do-nothing policy option entails no further changes to either the legislative or regulatory framework other than those already implemented with the enactment of the new General Food Law in 2009. What speaks in favour of this option is basically inertia. Having mastered the recent melamine crisis and replaced the wrong-doers with new companies or company executives, business could continue as usual with little government intervention in the food sector. That is, till the next scandal breaks out. Notwithstanding the high costs associated with crisis management, maintaining the status quo implies both a heightened risk in terms of public health and the upholding of a bad image vis-à-vis trade partners. It is unlikely that the enactment of a new General Food Law alone will suffice to restore consumer trust in Chinese food and feed products.

Statutory approach

The statutory approach entails the enactment of additional specific legislation for the dairy sector and for official controls and the strict implementation of these through the active engagement of regional governments. For this approach to be effective, China would have to invest a significant amount of capital and human resources in the upgrading of laboratories in different regions. Alone with regard to personnel, a minimum fourfold increase from currently 50,000 would be necessary. This can obviously not be achieved in the short term, but only in the mid-term of the next five to ten years. This, in turn, raises the question as to what will have to be done in the transition period.

Non-statutory approach

The non-statutory approach places greater emphasis on the amelioration and better implementation of private standards as opposed to public ones. This option would appear in line with the Chinese government’s preferences towards the concentration of economic power within the dairy sector and hence the gradual phasing-out of the traditional systems of milk collection. This is a plan for major industrial reform that is unlikely to be realized in the near future. In this context, it is worth recalling that China already embarked on the re-structuring of the dairy industry in the 1980s, yet today 80% of all raw milk is still collected and processed according to traditional forms of co-operatives. It is also worth considering whether replacing these co-operatives with economic multi-national giants would be reasonable from the perspective of subsistence farming and agriculture.

Co-regulation approach

The co-regulation approach combines elements of the statutory and non-statutory approaches in some form of phased structural reform of both the public and private sectors. This is the approach favoured within the European Union. Effectively implementing this approach would entail interventions both in the private and public sectors – ideally in co-ordination – towards a win–win situation both in the short and medium term. The public sector would come up with guidelines for the dairy sector (rather than new legislation) in addition to providing economic incentives to co-operatives to upgrade their quality systems. In return, the private sector and co-operatives would commit themselves to a gradual implementation of a quality assurance (as opposed to a quality control) system. Official controls under this model of co-regulation would still have to increase in number from the currently very low levels, but not to the same extent (or pace) as under the statutory approach.

This latter system offers the best chances of success and would also appear to be the most sustainable for reforming the Chinese food safety regulatory system – in the dairy sector, but also more generally.

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