What’s new and changing in the regulation for nutrition in China

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Content

Backgrounds
Regulatory framework
Healthy foods and health claim
Future prospect
Food consumption increasing with trends of unbalanced diet

both foods sales and consumption, 2007
Consumption of animal products in household

<table>
<thead>
<tr>
<th>Year</th>
<th>Meat (g/day/person)</th>
<th>Eggs (g/day/person)</th>
<th>Aquatic Product (g/day/person)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1982</td>
<td>34</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>1992</td>
<td>59</td>
<td>28</td>
<td>15</td>
</tr>
<tr>
<td>2002</td>
<td>80</td>
<td>34</td>
<td>24</td>
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</table>

National | Urban | Suburban

Graph showing the consumption of meat, eggs, and aquatic products from 1982 to 2002 for national, urban, and suburban areas.
Food intake in outdoor dinner

<table>
<thead>
<tr>
<th></th>
<th>Pro g</th>
<th>Fat g</th>
<th>CHO g</th>
<th>Na mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table</td>
<td>56</td>
<td>50</td>
<td>87</td>
<td>2885</td>
</tr>
<tr>
<td>Buffet</td>
<td>94</td>
<td>65</td>
<td>167</td>
<td>1689</td>
</tr>
</tbody>
</table>

more population, especial youth in urban would like to choose semi-manufactured products or dining outdoors (>25%)
Key issues must be concerned

• Food nutrition, food safety
• Food demand and diet balance
• Food consumption and chronic disease
• ...

• Healthier food or functional food
Content

Backgrounds

Regulatory framework

Healthy foods and health claim

Future prospect
Food Safety Law of the PRC, 2009

• Issued on Feb. 28, 2009, by National People’s Congress
• Go into effect on June 1, 2009
• From the foods production line to the dining table.
• First time calling for food safety, not only food hygiene.
  – Dealing with supervision, monitoring, enforcement, recall, trace back, licensing, registration, and development of standards and regulations.
Food Safety Law

Food Safety Committee

National Standard for FS

Regulary for HF, NF, GMF

Surveillance & Assessment

Food Safety Risk
Food Safety Committee

- Oversee food-safety monitoring
- Composed of members from the Ministry of Health (MOH), Ministry of Agriculture (MOA), General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), State Food and Drug Administration (SFDA) and the State Administration for Industry and Commerce (SAIC).
Surveillance and Assessment of Food Safety Risks

• A national surveillance system for food safety risks shall be setup.
• The executive department of health in conjunction with other relevant departments of the State Council
• To assess the risks on biological, chemical and physical hazards in foods and food additives.
• The results shall be the scientific basis for developing and modifying food safety standards, as well as regulating food safety.
Food Safety Standards—mandatory

• The limits of pathogenic microorganisms, pesticide residues, veterinary drug residues, heavy metals, contaminants, and other substances hazardous to human health in food and food-related products;

• Varieties, scope of application, and dose of food additives;

• Requirements for nutritional ingredients in staple and supplementary food dedicated to babies and other specific populations;

• Requirements for labeling, identification and instructions relevant to food safety and nutrition;

• Hygienic requirements for food production and trading processes;

• Quality requirements related to food safety;

• Methods and procedures for food testing;

• Other particulars necessary for developing food safety standards.
Food Safety Standards
-consolidated, unified

Some common criteria have been constructed

- GB 2760-2011 food additive
- GB 7718-2011 food labelling
- GB 25596-2010 special medical used infants formula
- GB 10769-2010 cereal supplement for babies
- GB 10767-2010 formula for 6m-36m babies
- GB 10765-2010 formula for infants

Some is in drafting

- GB 14880 for food supplement
- GB 13432 for special used diet
- Regulation for food nutrition labelling
Content

- Backgrounds
- Regulatory framework
- Healthy foods and health claim
- Future prospect
Traditional Chinese Medicine: “the medicine food homology”

- “Medicated diet”, “tonic concentrated syrup”
Health food

* nutrients supplement without claims
* functional food with claims for health care.

* suitable for use by specific groups of people to improve their body functions or nutrients intake.
* it is not aimed at treating diseases.
MOH public list of raw materials that can be used in healthy food

- 87 as both food and medicament
- >100 can be used
- 59 can't be used
Current regulations

• The guideline of registration for Health Food: the main directive document of functional food.

• General hygiene regulations for Health foods
• The Good Manufacture Practice of Health foods
• Regulation on nutrients supplements
• Regulation on the advertisement of health foods
• more ...
• Health food (Functional food) in China adopt an procedures of examined and approved.

• Case by case
  – Safety, nutrition, functional factor
  – Function assessment
    • animal experiments
    • human trials

• SFDA authorized all affairs for functional food since 2003.
Substantiation of a claim should be based on the following experiments:

- The toxicology test
- The functional test
- Functional components and composition analyzing
- The stability test
- The hygiene test
- Other test which will help application (such as a identifying test of raw material, or virulence of bacterial categories).
Functional Foods: from homemade to food Industry, and to quasi-pharmaceutical Industry

Regulatory Aspects

- Regulations of health foods
- Sanitary regulations for health foods
- Labeling regulations for health foods
- Approval by MOH
- Bankrupt of large companies

- Regulations for health food registration
- GMP • 5 years valid period
- Regulations for direct sales
- Censorship for health food Ads

Health care Drug Approval by local authority

Abolishment of health care drug

SARS

01-02

Annual Sales(m)

Maker Numbers

<table>
<thead>
<tr>
<th>80s</th>
<th>88-95</th>
<th>96-97</th>
<th>98-00</th>
<th>01-02</th>
<th>3</th>
<th>5</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>16億</td>
<td>3000</td>
<td>1000</td>
<td>3000</td>
<td>848</td>
<td>1640</td>
<td>500億</td>
</tr>
</tbody>
</table>

Sales in billion

50000
45000
40000
35000
30000
25000
20000
15000
10000
5000
1000
500
100

The process of registration & authorizing

1. Sample test
2. Application
3. Basic check formal
4. Evaluation
5. Certificate

- Lab.
- Center of FF
- SFDA
- Expert committee
healthy foods distribution

- Assisting the protection against chemical injury of liver, 3.80%
- Improving sleep, 4.40%
- Assisting blood sugar reduction, 4.61%
- Facilitating feces excretion, 4.75%
- Antioxidative, 6.05%
- Assisting blood lipids reduction, 8.84%
- Enhancing immune, 28.45%
- Others, 23.82%
- Alleviating physical fatigue, 15.28%
- Assisting the protection against chemical injury of liver, 3.80%
- Improving sleep, 4.40%
- Assisting blood sugar reduction, 4.61%
- Facilitating feces excretion, 4.75%
- Antioxidative, 6.05%
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27 health claims approved by SFDA are being revised now

- based on Chinese traditional nourishing concept and modern medical theory.
- adjust body function, decrease disease risk factor, not aim at treatment
- health claim based on scientific evidence
- the method and criterial for function assessment should be authorized
Idioms for 16 health claims re-edited:

stress "adjust"

- Enhancing
- Assisting
- Facilitating
- Improving
- Alleviating

helpful, aids
Stress evidence based on methods for assessment

• *Assisting the protection against* chemical injury of liver *alcohol injury*

• *Weight control* body fat reduction

• *Alleviating physical fatigue* sports fatigue
Combined similar functions

• helpful improving gastrointestinal function
  • —Regulating gastrointestinal tract flora function
  • —Facilitating digestion function
  • —Facilitating feces excretion function
  • —Assisting protection against gastric mucosa damage function

• helpful improving face skin health
  • —Eliminating skin chloasma function
  • —Eliminating acne function
cancelled 5 unreasonable functions

• *Improving child growth and development function*
• *Assisting irradiation hazard protection function*
• *Improving skin water content function*
• *Improving skin oil content function*
• *Assisting blood pressure reduction*
Guidelines on Food Nutrition Labeling

- MOH 2007
- nutrition claim is encouraged
Functional Claims

• Claims on well established functions of nutrients allowed
  – Examples
    • Calcium helps build strong bones and teeth
    • Protein helps in tissue building and growth
    • Iron is one of the essential minerals vital for life
    • Folate plays a role in the formation of red blood cells

23 nutrients FC established
Prohibited claims

- claims for therapeutic or prophylactic action;
- claims which could be interpreted as advice of a medical nature from any person;
- claims that a food will prevent, alleviate or cure any disease or condition affecting the human body; and
- claims that health or an improved physical condition may be achieved by consuming any food.
Food and Function food

- FOOD label :
  -- Nutrition information
  -- nutrition Claim
  -- function claim for nutrients

- Function Food :
  -- function Claim
  -- reduce risk of disease
The future of health foods will undoubtedly involve a continuation debate of the Scientific Substantiation of Claims.

- Scientific Evidence based on EMB
- The modification of the procedure of test for health claim
- The forms of functional food with claim
Thanks

Good Luck

Good Fortune