

Registration of Disinfection Products in China

- Past, Present and Future



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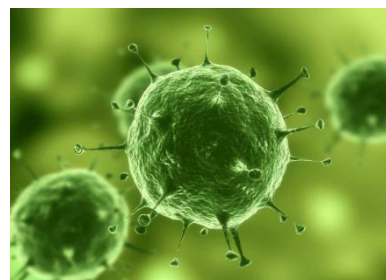
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Abstract: Disinfection products encompass a broad group of products that are used for the general purpose of sterilization and disinfection. They include disinfectant, disinfection device, sterilization indicator and sterilization packaging materials. Up to the end of 2012, there are 3,592 disinfection products which have obtained hygiene licenses and 1829 of them are still valid now. This article looks into the status of registration of disinfection products in China, regulatory updates, special events or occurrences in the last 12 years, and then analyzes the connections between them.



Introduction

In accordance with **the licensing procedures for the administration of the health-related products issued by the Ministry of Health (MOH) of China on 1 Jun 2006**, disinfection products are considered as health-related products. Compared to EU biocide regulation (BPD/BPR), disinfection products in China not only include disinfectants but also cover disinfection device/equipment, sterilization indicator (chemical indicator and biological indicator) and sterilization packaging materials.

Any companies who plan to place disinfectants on the Chinese market must apply for and obtain a hygiene license. Any foreign companies wishing to obtain a hygiene license must appoint a Chinese Responsible Agent to deal with this application.

Regulation History

On 18 September 1987, **the administrative measures regarding disinfection product** were issued by the MOH. The Chinese government started regulating disinfectants and disinfection devices with hygiene licenses. There was big change in 1992 when sanitary products and disposable consumer products (for example, breathing mask) were added to the scope of disinfection products. The MOH then removed registration requirements on disposable consumer products and sanitary products in 2003 and 2004 respectively by issuing public notices.

In 2005, the MOH issued a Notice No. 208 and the following products were excluded in the scope of disinfection products.

- Disinfectants used for specific human body parts: feet, eyes, nails, axilla, scalp, hairs and nasal;
- Breathing mask and condom;
- Ultraviolet germicidal lamp, tableware disinfection cabinet, pressure steam sterilizer and 75% Ethanol disinfection solution.

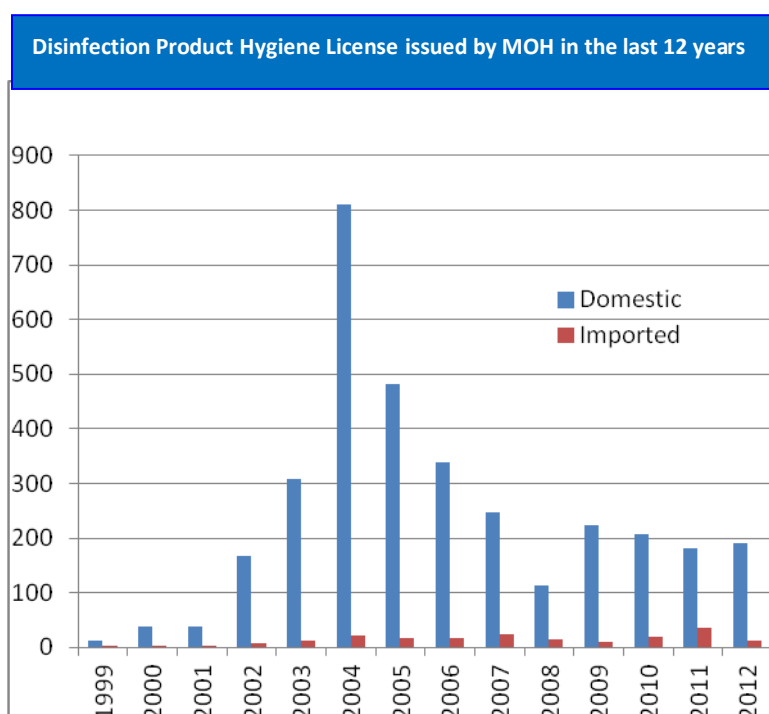
In 2006, the MOH issued the Guidance on Application of Administrative Approval License of Disinfectants and Disinfecting Apparatuses (2006) and the Administrative licensing procedure for health-related products (2006). Since then, they have been used as primary guidelines for ensuring disinfection products get approved in China.

In April 2011, the draft version of the Guidance on Application of Administrative Approval License of Disinfection products and Drinking water-related products had been released for public consultations.

Registration Status of Last 12 Years

There are 3592 disinfection products that have been issued with hygiene licenses. 1829 of them are still valid up to the end of 2012. The table and chart below show the number of approval licenses issued by the MOH in the past 12 years.

Year	Domestic	Imported
1999	12	1
2000	38	4
2001	38	4
2002	167	7
2003	307	12
2004	811	21
2005	482	16
2006	338	16
2007	246	23
2008	114	15
2009	224	11
2010	208	19
2011	182	35
2012	190	13
Total	3357	197



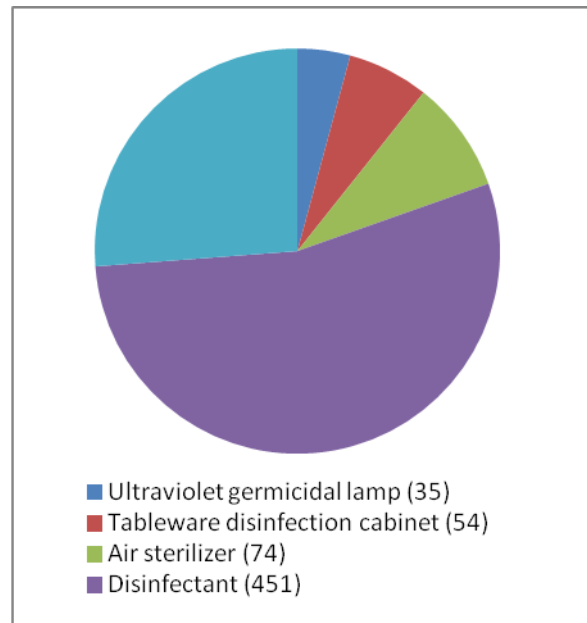
P.S. The red bars show the number of hygiene licenses issued to imported products. The blue bars indicate the number of licenses issued to domestic products.

In 1999, the first hygiene license for an imported product was issued to 3M Company. This product was called chemical integrator strip, which is a chemical indicator. Since then more and more manufacturers and importers began applying for hygiene licenses for their disinfection products.

The number of licenses issued to domestic products each year reached their peak (832) in 2004 and then gradually decreased to a normal level with around 200 approvals per year. Compared to domestic disinfection products, the number of approved imported disinfection products is very small. For example, the annual number of registrations of imported disinfection products peaked in 2011 with a number of only 35. With the development of China's economy, high-quality health-related product will have bigger market potential.

Year 2004 – Worthy of Attention

As it is indicated in above bar chart, the number of licenses issued for domestic disinfection products peaked at 2004. One of the main possible reasons for this could be associated with the break-out of SARS (Severe Acute Respiratory Syndromes) in China between November 2002 and August 2003. During this period, 8422 cases of SARS were diagnosed and 916 Chinese people died. Due to this occurrence, a lot of domestic manufacturers started producing some specific disinfection products, especially those aimed at controlling SARS. Ultraviolet germicidal lamps, tableware disinfection cabinets and Air sterilizers were placed on the market in large numbers in 2004. The pie chart below indicated the distribution of hygiene licenses issued in 2004.



After 2005, the number of licenses decreased significantly. That is because the MOH Notice 208 of 2005 removed registration requirements on ultraviolet germicidal lamps and tableware disinfection cabinets.

What's the difference between production hygiene license and product hygiene license?

There are two types of hygiene licenses: production hygiene license and product hygiene license.

In China, any manufacturers of food, disinfection products, water-related products and cosmetics are required to obtain a production hygiene license, without which companies cannot produce corresponding products. It is better to call this type of license a production license.

When we talk about 'hygiene license', we usually mean product hygiene license, a license issued by authority for a product, without which the product cannot be sold on the Chinese market. Companies must go through a product registration process to obtain such licenses. Please note that some products are exempt from product hygiene license requirements, for example, disposable consumer products and sanitary products. However, production hygiene licenses are required for manufacturers in China.

Foreign companies are only required to provide product hygiene license when they are importing disinfection products into China unless they are producing and repackaging those products in China.

Regulatory Updates

The draft version of the Guidance on Application of Administrative Approval License of Disinfection products and Drinking water-related products had been released for public consultations in 2011. We predict that the final version will be released this year. The draft regulation clearly indicates that the period of validity of a product hygiene license is 4 years and some licenses cannot be renewed under certain circumstances. Detailed procedures apply regarding any change of company name, address and product brand. Another notable change is that registrants will be given only one year to submit additional data if a previous dossier is not complete.

The National Center for Health Inspection and Supervision (NCHIS) is working on establishing an effective management system for health related products. Many internal meetings were held last year. The Local helpdesks is are also more effective now, which is good news for the industry.

Summary

We have summarized the evolving history of regulations regarding disinfection products in China and we have analyzed the number of hygiene licenses issued by the MOH for the past 12 years. We have also predicted what is or may be to come next regarding the management of disinfection products in China.

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