

# Gateway to the Chinese POU/POE Market – How to Obtain a Sales Permit in China

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## Introduction

China, as the world's most populous country, has a population of 1.3 billion, four times larger than that of the US. It is the world's second-largest economy behind the United States after 30 years of spectacular growth. Against the background of the global financial crisis, China's economy continues to expand. Historically, the country's growth has been mainly driven by exports of low-end manufactured goods. China's new development plan over the next five years calls for a deepening of the country's economic structural reform by shifting its export and investment-led growth model to one driven by technology and domestic consumption. China's POU/POE market is booming as well. Due to the lack of regulations in the water market and product innovation, there are many opportunities for foreign companies to sell high-quality POU/POE products. It is believed that in the future, China will be the world's largest POU/POE market and the biggest water consumer.

Thirty years ago, the general public was unfamiliar with POU/POE products. In the early 1980s, bottled water entered the Chinese market and it is still dominant in the market today. After many incidents of water contamination, people realized that POU/POE products were the best solution for their drinking water needs.

All POU/POE products are governed by the China Ministry of Health (MOH) under two regulations:

1. *China State Council Order No. 412, 2004.*
2. *Policy for Drinking Water Health Supervision* (Ministry of Construction and Ministry of Health, No. 53, 1997).

According to these regulations, all POU/POE products must be evaluated in terms of health and safety. To access this market, a foreign company must have a health permit issued by the MOH prior to the initiation of sales. POU/POE products are officially defined by the MOH as a health-related product or a drinking water-related product for health and safety. The process to obtain a permit includes qualification, testing and permit approval (receipt of application, review and approval).

## Qualification

Before testing, the MOH needs to review and approve a representative in China. A foreign company must have a sole representative who could be a distributor/dealer, importer or a professional agency. A foreign company must authorize its Chinese representative to apply for a relevant government permit and sign and seal all application materials. The authorization is required to be valid for at least five years. A foreign company also needs to provide a sales certificate in the manufacturing country. The representative needs to submit a notarized authorization letter, sales certificate and acceptance letter from the representative to the MOH for review and approval.

## Testing

China MOH has authorized its agencies for testing of POU/POE products since 2003. MOH agencies include:

1. Institute for Environmental Health and Related Product Safety (IEHS), Chinese Center for Disease Control and Prevention, Beijing.
2. Shanghai Municipal Center for Disease Control and Prevention, Shanghai.
3. Center for Disease Control and Prevention of Guangdong Province, Guangzhou.

In general, foreign manufacturers shall submit the following documents and samples for testing:

1. *The Ministry of Health Application Form for Health-Related Product Testing*, two copies (this form must be signed and stamped with the manufacturer's seal). The form contains the product information, testing purpose and manufacturer's contact information.
2. Product manual in Chinese, two copies (stamped with manufacturer's seal)
3. Samples of submission
  - a. Drinking Water Treatment Unit (DWTU): five units, or eight units if applying for a series B product testing)
  - b. Main wetted parts, such as carbon and filter housing. Need to attach *Testing Technical Parameter Form for DWTU*. This form includes the information for sample type, filter media, treatment mechanism, flowrate and treated capacity.
4. Testing fee (dependent upon the product type and testing items).

After receiving the first three items mentioned above, the testing agency will review and decide if the product meets the requirements for the MOH permit. The testing agency will then issue a testing contract. Before any testing, the manufacturer or its Chinese representative is required to pay a testing fee. Testing turnaround time is usually 60 days.

The testing protocol follows China MOH *Sanitary Standard for Hygienic Safety and Function Evaluation on Treatment Devices of Drinking Water* (2001) and *Standard for Testing Hygienic Safety on Drinking Water Treatment Devices*. This standard includes a test protocol for general devices, mineralizers and RO devices. General devices include activated carbon filter, ultra- and micro-filtration, ceramic filters, etc. All treated water quality must meet the *China Standards for Drinking Water Quality (GB5749-2006)*. The testing for general devices includes three parts: overall performance, spike and extraction. Other types of filters may test differently based upon functionality.

## Overall performance testing

The testing is performed with tap water at a claimed flowrate. The protocol does not specify any cycle time and inlet water

**Table 1. Water quality analysis**

Evaluated parameter	Maximum level allowed	Evaluated parameter	Maximum level allowed
Color, pt/co scale	15	Phenols, mg/L	0.002
Turbidity, NTU	1	Cyanide, mg/L	0.05
Taste and odor	No bad taste and odor	Fluoride, mg/L	1.0
Visible particles	0	Arsenic, mg/L	0.01
pH	6.5 to 8.5	Selenium, mg/L	0.01
Total hardness, mg/L	450	Mercury, mg/L	0.001
Aluminium, mg/L	0.2	Cadmium, mg/L	0.005
Iron, mg/L	0.3	Chromium (VI), mg/L	0.05
Manganese, mg/L	0.1	Nitrate (N), mg/L	10
Copper, mg/L	1.0	Lead, mg/L	0.01
Zinc, mg/L	1.0	Chloroform, mg/L	0.06
Sulfate, mg/L	250	Carbon tetrachloride, mg/L	0.002
Chloride, mg/L	250	Total counts/HPC, CFU/mL	100
TDS, mg/L	1,000	Total coliforms, CFU/100 mL	0
Dissolved oxygen, mg/L	3	Heat-resistant coliforms, CFU/100 mL	0

pressure for the testing. It runs continuously during business hours and stops upon business day end. Flowrate must remain the same throughout the testing. Although free available chlorine will be monitored, there is no requirement for the reduction.

**Table 2. Spike testing parameters**

Spike chemical	Spike concentration (mg/L)	Minimum reduction (%)
Dissolved oxygen (BOD)	3	25
Phenol	0.025	80
Chloroform	0.410	80
Carbon tetrachloride	0.020	80

One sample for the control and two samples for filtered water are collected at the beginning and end (claimed capacity) of the testing (total six samples). The filtered water must meet China's *Standards for Drinking Water Quality* as indicated in Table 1.

#### Spike testing

According to the protocol, four chemicals are spiked at the beginning, 1/4, 2/4, 3/4 and 4/4 of the claimed capacity. For each spike, one sample for the control and two samples for the filtered water are collected and analyzed for a total of 15 samples. All filtered samples throughout the testing must meet specific requirements for reduction efficiency (Table 2).

#### Extraction testing

The extraction water shall contain 100 mg/L hardness, 0.5 mg/L free available chlorine and pH 8. After flushing the filter with tap and extraction water, extraction water will

be kept in the filter system for 24 hours at 25°C (77°F). Extracted water and control (extraction water) samples are collected and analyzed. The extracted water must meet the requirements as noted in Table 3.

Filter wetted parts also need to undergo extraction testing. Aside from the parameters mentioned in Table 3, some other parameters are monitored as well, such as pH, TDS, barium, tin and tellurium.

#### Permit approval

If all testing is passed, the agency will issue the testing reports for permit application. The manufacturer will receive two official reports. After receiving the reports, the manufacturer must file the permit application within two years; otherwise, the report is no longer valid for the application. Prior to the permit application, the representative must visit the official website of the MOH to register. Qualification for the representative, approved by MOH, must be entered to the system for a validation check. There are many templates for document preparation online.

According to the National Center for Health Inspection and Supervision – China MOH, all permit application materials shall

be submitted to the Receiving Office of Permit Application. The following application documents need to be prepared for the permit application:

1. *Permit Application Form*: information about the product, manufacturer and Chinese representative
2. Product materials and formulations: information includes features of the product, water treatment process/technology, names, specifications, quantity and material life for main wetted parts, capacity for treated water, flowrate and operation pressure/temperature.
3. Product quality standard: It could be a manufacturing standard operation procedure. The standard could specify the product definition, model number, name, the technical requirements, test methods, inspection rules, labeling, packaging, transportation and storage.
4. Original reports from the testing agency (together with a test application, notice of acceptance testing and product manual)
5. Product labels (or name plate): including product name,

**Table 3. Extracted sample requirements**

Evaluated parameter	Maximum increment	Evaluated parameter	Maximum increment
Color, pt/co scale	5	Cadmium, mg/L	0.0005
Turbidity, NTU	0.5	Mercury, mg/L	0.0002
Taste and odor	No bad taste and odor	Chromium (VI), mg/L	0.005
Visible particles	0	Arsenic, mg/L	0.001
Dissolved oxygen, mg/L	2	Total counts/HPC, CFU/mL	100
Lead, mg/L	0.001	Total coliforms, CFU/100 mL	0
Phenols	0.002	Heat-resistant coliforms, CFU/100 mL	0

model number, manufacturer's contact information, batch number/manufacturing date, capacity, pressure and flowrate

6. Product installation manual: including product features and benefits, installation procedures, working conditions, notices and specifications

7. Original reports from the testing agency for main wetted parts

8. Sales certificate for the product in the manufacturing country: it is required to have this document from a government or POU/POE industry association, like the Water Quality Association (WQA).

9. Authorization documents for a Chinese representative: a foreign manufacturer must authorize its Chinese representative to apply for relevant government permits and to sign and seal all application documents. The authorization is required to be valid for at least five years. An original authorization letter and its notarized translation must be submitted for the application.

10. Other information may help for the review, such as certificate for NSF/ANSI Standard 42 and/or NSF/ANSI Standard 53, ISO and GMP certification.

11. A complete water filtration system as a sample: it must be the same as the one for the testing.

The original application documents (required on A4-size paper) should be declared and the official seal stamped page by page. When submitting, one original document with six additional copies should be put in a binder. Chinese legal units of measurements must be used in the application documents. The US system of measurements, such as gallon and psi for pressure, is not acceptable for the permit application. All application documents must be translated into Chinese (except for foreign addresses). All translated documents must be notarized by a Chinese notary agency (with a fee). There is no fee for permit application and approval.

The official application processing time is about 95 days, including five days for initial review, 70 days for technical review and 20 days for approval. If accepted after the initial review, an official notice will be issued to the applicant. If documents do not meet the requirements or more information is needed, all application documents will be returned with recommendations and suggestions for a revised submission. The China MOH permit is good for five years. After five years—although there is no retesting for the product—a renewal application is needed to obtain a new permit. If the foreign product name is changed or the manufacturing location moves to China, the product needs to be tested again and the company must reapply for a permit.

### **New drafts for testing and applications**

The China MOH *Sanitary Standard for Hygienic Safety and Function Evaluation on Treatment Devices of Drinking Water* (2001) has been used for over 10 years. There is a new draft but it has not yet been approved. Major changes include monitoring more contaminants in extraction testing and decreasing the concentrations of spiking chemicals for spike testing. All reduction performance claims must be at least 80 percent. There is no more dissolved oxygen (BOD) reduction in spike testing. A new test apparatus like the one in NSF/ANSI Standards 42/53 is published in the draft.

For permit applications, there are more requirements for the documents. Except for the requirements mentioned before, the new requirements are listed below:

1. A copy of the manufacturer's business license

2. Production capacity: a production flow chart, list of production equipment, color product photos showing external and internal structures, Chinese custom document and a video of

the manufacturing facility approved by the Chinese Consulate.

These new test protocols and requirements for permit application could be approved in the near future. As can be seen, there are no significant changes for the testing and permit application.

### **Summary**

In order to access the Chinese POU/POE market, foreign manufacturers must obtain a sales permit first. For issuing a permit, the Chinese government does not accept any certification for products tested in any other country, such as certification for NSF/ANSI Standards 42/53. The process to obtain a permit includes qualification, testing and permit approval, and could take at least five months. The China CDC testing for POU/POE products is different than NSF/ANSI Standard 42 and NSF/ANSI Standard 53, specifically spike testing. Preparing application documents is a time-consuming process and very complicated, since the China MOH requires application documents only in Chinese. It is not convenient for foreign companies that all government documents, including application forms, are in Chinese. Generally, testing is the most important step. With passing results, filing an application and getting approval are just a matter of time, but it could be a very tedious process. Once the permit is approved, it can be used for up to five years. For permit renewal, there is no requirement for re-testing of the product.

### **About the authors**

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### **About the companies**

◆ *For more than two decades, Selecto Scientific has provided innovative technologies and advanced products for a host of applications, including water filtration, pharma, biotech, beverage and fuel cells.*

◆ *The Institute for Environmental Health and Related Product Safety (IEHS), China CDC, is an agency accredited by the China MOH for the testing of cosmetics, POU/POE and sanitization products. IEHS also focuses on the research in indoor air quality, drinking water quality, hygiene and safety in public areas, chemical pollutants and health impacts on electromagnetic radiation. IEHS is currently involved in official testing of electromagnetic radiation products, building materials,*

*paints, air purification products and other health-related products.*

◆ *Senwater Tech Co., headquartered in Shanghai, China, is committed to introduce the best available technologies for commercial/residential water treatment and air purification, to develop advanced products suitable to the Chinese market, and to provide customers with safe and reliable quality products and services.*