



## Update: Licensing Challenges and Best Practices in China

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### Executive Summary

- Companies regularly cite licensing as a top challenge for conducting business in China. Over the past decade, the issue has consistently ranked among the top 10 priority issues in the US-China Business Council (USCBC)'s annual membership survey.
- As is the case in many other jurisdictions, companies operating in China are often required to possess a number of different licenses, permits, and certifications to operate legally in the market. However, depending on industry sector, companies may need up to 100 licenses, many requiring frequent renewal.
- Despite central government efforts to simplify or reduce the licensing burden on foreign companies, a number of key concerns remain. More developed cities in eastern China have enjoyed the most notable improvements, while limited progress remains in central and western jurisdictions.
- Lack of transparency in licensing processes creates operational uncertainty for companies in China—particularly for compliance—with inconsistent procedural timelines, regulatory implementation, and document requirements. Foreign companies report frequent difficulties obtaining licenses that are readily available to domestic competitors.
- Lack of coordination and communication between domestic government agencies, provinces, and other regulators slows and inhibits licensing approvals.
- Companies also report difficulty in gaining routine access to appropriate officials for guidance on licensing processes because of China's anti-corruption campaign. The campaign has made local government agencies more hesitant to make consequential licensing decisions or to suggest qualified local third-party service providers. Delays for new facilities, expansions, and other projects result as licensing applications languish.
- **Best Practices:** To smooth licensing application and renewal processes, USCBC member company executives recommend establishing internal teams to conduct regular reviews of existing and needed licenses and permits. Companies also emphasize the importance of advanced consultation with local regulators prior to undertaking a new project, relocation, or other endeavor requiring a license.

### Introduction

Companies operating in China face a broad array of licensing challenges from transparency to the disclosure of sensitive business information. Consequently, companies consistently identify administrative licensing among the top 10 issues in USCBC's annual survey on China's business environment. Challenges in project approvals, business license application and renewals, certification and permit applications, and many other routine business activities often experience significant delays, added costs, and lost revenue, harming the efficiency of company operations in the market.

While these processes have somewhat improved over the past five years, significant challenges remain. According to [USCBC's 2015 Business Environment Survey Results](#), despite numerous reforms aimed at cutting red tape, 57 percent of companies continue to experience challenges in administrative licensing.<sup>1</sup>

To identify some of the most prevalent problems in China's licensing system, USCBC interviewed more than 30 member companies to discuss company experiences undergoing licensing processes, licensing reform progress, and new challenges for business. The interviews took place in China and the United States with companies representing a wide range of sectors, including manufacturing, healthcare, information technology, retail, and financial services.

## China's Administrative Licensing System and Challenges

As in any jurisdiction, companies operating in China may need a number of licenses, permits, and certifications to operate legally in the market—in some cases up to 100. Many require frequent renewal.

Since the State Council's [announcement of licensing reforms in 2013](#), China's government has released new policies to decentralize or eliminate administrative approvals, reduce administrative fees, and limit local government authority to institute new licensing procedures. Through November 2015, the central government reported its progress, including reductions of [administrative approval items, non-administrative processes, and administrative fees](#). Announced plans to [reduce licensing obstacles](#) in 2016 signal the central government's intention to continue these reforms.

Despite moves to cut bureaucratic red tape, China remains a challenging jurisdiction for business operating license approvals—ranking 84th overall in the World Bank's [Ease of Doing Business ranking in 2016](#), with important approvals like construction permits ranking 176 of out 189.

USCBC member company experiences echo these poor rankings: licensing challenges create a variety of operational concerns for US companies that have expanded or are planning to expand investments in the China market. These challenges include uncertainty about business plans, inability to obtain licenses readily available to domestic competitors, and concern over requirements to provide confidential business information as a part of licensing reviews.

### Project approvals and expansion

Companies are required to receive approval from local government agencies for new investment projects, including a business license and industry-specific approvals. Project approvals often apply to new investments and expansions.

In early 2014, the National Development and Reform Commission (NDRC) introduced [regulations](#) permitting foreign companies with investment projects that do not fall into the restricted or prohibited sections of the Catalogue Guiding Foreign Investment to follow the same registration processes as their domestic counterparts. Previously, NDRC approval of foreign investment projects took at least 20 working days; now, as one company in heavy machinery manufacturing noted in an interview, these processes take an average of five days, but not more than 10, for their industry—providing more clarity on timelines that could otherwise be uncertain.

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<sup>1</sup> USCBC's 2015 member company survey showed progress on administrative licensing, though it has consistently remained a top concern. See page 19 of [USCBC's 2015 Business Environment Survey Results](#) for a list of administrative licensing's ranking as a concern of USCBC members since 2006.

While this reform has expedited the approval of some greenfield investments, companies note that expanding existing operations remains unnecessarily challenging, often requiring all the approval steps of a new investment. For example, one company noted that a small expansion of assets due to a recent acquisition required a supplemental environmental impact assessment in addition to assessments beyond written requirements. The assessment took more than one year to complete, delaying the company's ability to expand operations and serve its customers.

## Environmental Compliance: Progress with New Licensing Challenges

Companies setting up new operations or expanding current investments are required to undergo Environmental Impact Assessments (EIAs) to ensure compliance with local emissions requirements. Following the implementation of China's 2015 [Environmental Protection Law \(EPL\)](#), new regulations on [soil and air quality](#) plus a [sharp increase in environmental inspections](#) have heightened the importance of environmental compliance during the project approval process. These changes create uncertainty in environmental licensing and approvals processes.

- **Stricter enforcement** Before the new EPL, EIAs were often completed after construction, instead of before, and the associated fines were minimal. Under that model, domestic competitors often chose the cost of noncompliance fines rather than creating EIAs prior to development. Under the new EPL, failure to prepare an EIA prior to development can lead to a stop-construction order, a significant daily penalty, and an order to restore the property to its original state.
- **Transparency through public participation** Public participation in EIAs—a feedback request to individuals and organizations potentially impacted by a project—has garnered more influence in recent years after [a push by](#) the Ministry of Environmental Protection ([MEP](#)) for a more transparent process. One company noted that it is increasingly common for local EPBs to call individuals to verify feedback and ensure legitimacy.
- **Improved information protection** Companies note fewer confidential information disclosure requirements in the EIA approval process in some jurisdictions. However, for inexperienced jurisdictions, companies cite continued concern that proprietary information may be disclosed during expert panels and external reviews

Operational concerns remain as the government works to improve the EIA process and overall compliance with environmental regulation.

- **Ambiguous requirements** Some companies hear conflicting statements from different agencies on the need to conduct an EIA. For example, a local environmental protection bureau (EPB) told one company looking to expand employee facilities that it needed a full EIA, but the local NDRC indicated the expansion did not require approval. The disagreement led to a halt in moving forward with the EIA and the dispute led to the company abandoning its original investment plans.
- **Unexpected suspensions or delays** Arbitrary license approval suspensions by local governments also impact company operations. Some companies note unexpected suspensions of EIAs and other building-related permits, such as fire permits in certain jurisdictions, without indication of when local governments would resume review. Such uncertainty leads to investment project suspensions, and negatively impacts companies' internal deadlines and contractual obligations to clients.

- **Insufficient emission quota transparency** Emission standards and emission quotas (a pollution threshold for specific jurisdictions) are not always public. In some cases, regulators are unwilling to approve new projects unless emissions for an existing one are reduced or eliminated to ensure an emissions quota is not exceeded, making public access to this information all the more important. As one company noted, projects risk being shut down after investment plans have begun if they do not have access to local quotas during planning. Moves toward a more transparent carbon trading platform – expected in 2017 – may increase transparency.

Companies expect additional scrutiny of EIAs as MEP continues its reforms. In October 2015, the MEP announced revised regulations aimed at combating corruption in the EIA process by reducing conflicts of interest, improving transparency, and increasing fines and penalties for wrongdoing. Penalties for officials who engage in misconduct or fail to enforce the law may now include demotion, dismissal, or prosecution. These provisions were included to underscore the importance of the EIA process and to ensure that both the public and government officials take it seriously.

## Product Certification

Product certification covers a broad spectrum of approvals, from China Compulsory Certification (CCC)—a safety mark for products sold or used in the Chinese market—to industrial product manufacturing licenses such as the QS mark, along with other industry specific approvals and permits.

Before products can go to market, companies must obtain an industrial product manufacturing license. A company must possess a safe production license and undertake a one-year trial production period before it can formally apply for the license. As a result, a company must produce and store products for more than one year before it is authorized to bring the product to market. Manufacturers recommend regulators amend the rules to increase flexibility and improve the ease of doing business. Specific suggestions include allowing manufacturers to continue business with established suppliers and distributors with a proven safety record while the manufacturer awaits approval for its industrial product manufacturing licenses.

## License Renewals

License renewals are a regular requirement for foreign companies in China. Renewal processes can create uncertainty, however, and can be almost as challenging as the original application process.

For instance, companies report that agencies often refuse to make exceptions for application delays during the renewal process, despite frequent delays caused by other licensing processes or preconditions imposed by other regulators. One company underwent industrial product manufacturing license renewal with the understanding that it would be complete within a set period. However, delays by the multiple agencies ultimately delayed the approval. This unexpected delay resulted in a separate local agency fining the company for non-compliance after its original manufacturing permit expired.

## Market Access Concerns and Unregulated Segments

While explicit restrictions on foreign ownership remain the greatest barrier for foreign companies in certain sectors, uncertainty surrounding administrative licensing regulations can also serve as a *de facto*

limit for companies hoping to move into certain sectors.<sup>2</sup> Businesses are often particularly cautious about advancing into new and under-regulated business sectors such as telemedicine, fearing that they might find themselves in violation of new regulations after investing. Some report that the implementation of a [nationwide market access negative list](#) would help them better understand what is off-limits for investment.

## Transparency and Timing

While some companies report clearer, more predictable, and shorter approval timelines because of regulatory reforms, many others continue to flag persistent problems with process transparency and timing.

Timelines are not publically available for some licenses and the approval authority does not always use a set timeline. Despite company efforts to request a full list of documents and requirements for licensing processes, Chinese government officials often go back and forth on requirements. This unpredictability and inefficiency complicates companies' efforts to make short- and long-term business plans. A company in the services sector noted that one outstanding application for a license was under consideration for more than a year without a single update on the application status, despite regular requests.

Approval delays can also negatively affect supplier and buyer relationships. One company noted that it was unable to participate in a local tender because of unforeseen licensing delays. Another company experienced an unexpected suspension of a specific license, which impeded its ability to move forward with a planned investment.

Companies note mixed results from government efforts to accelerate approvals. Localization of approval and testing centers has saved time because there are now more accredited testing agencies near industry clusters. The introduction of "green channel" has expedited approvals for qualified products, but companies note that foreign companies cannot easily qualify to use it. In one healthcare company's experience, in order for innovative medical devices to qualify, clinical physicians must endorse product patents as "breakthroughs," leaving room for interpretation by regulators. More clearly defined requirements are necessary.

Lack of detail in an approval authority's rationale for requirements for specific documents, as well as the companies' inability to challenge such requirements for unobtainable documents, can also create delays. A company's inability to provide these documents can stall licensing applications—even if these documents do not directly relate to the project itself. Regular communication between approval authorities and companies would provide a clearer understanding of the reasoning behind certain document requests, enabling regulators to receive appropriate information more quickly.

## Inconsistencies in Regulatory Implementation and Coordination

A lack of coordination between government departments often causes delays and inefficiencies in the approval process. Working-level officials with whom companies interface sometimes lack the necessary authority to coordinate with counterparts in other agencies in ways that could shorten the licensing process. For example, Department A asks for a document that must be obtained from Department B, but Department B fails to provide it, resulting in a stalemate on the license application.

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<sup>2</sup> See list of ownership restrictions in USCBC's list of [China's Ownership Restrictions on US and Other Foreign Investors](#).

In another example, China's ["3-in-1" approval system](#) – implemented nationwide October 1, 2015 – combines a business license, tax registration certificate, and organization code certificate into one license. The change was intended to improve efficiency by consolidating overlapping processes, cutting down on time and bureaucracy. While implementation was successful in some cities, in other cities slower implementation has created confusion among regulators about division of responsibilities. This has slowed approvals instead of speeding them. Companies note that despite the implementation of the streamlined system, they are still required to go through a similar number of steps and interact with a wide variety of personnel.

## Information Disclosure Concerns

Companies go to great lengths to protect their IP in China, as it is often the key to their global competitiveness. While most companies interviewed indicate moderating concerns regarding the need to provide IP to regulators as a part of common licensing processes, some companies continue to report that regulators request proprietary operational information.

A number of companies raised concerns about disclosure during the environmental impact analysis (EIA) process. According to one, new environmental compliance requirements mandate that government agencies put company and project information on their websites for public viewing. Required information includes project timing and scope, sales by factory, and other information that may be sensitive to a company's business operations and competition considerations.

Companies also coordinate closely with their headquarters to mitigate any concerns about proprietary information submitted during licensing processes. Local China teams check with headquarters if there is any question about the sensitivity of information sought by regulators. This process can be time consuming, requiring two to four weeks to prepare the documents and often significant time for internal discussion regarding what information they can include.

When faced with concerns that disclosure of certain requested information is a threat to proprietary IP, companies often seek to provide alternative information that might satisfy regulatory demands. Third-party licensing consultants—with expertise in specific licensing processes—can help smooth these situations, laying out company-specific IP protection requirements and obligations and coordinating submission of supplementary information. However, given different agency practices, a consolidated list of standard information requirements would be helpful.

## Licensing Challenges with Partners and External Licensing Parties

It is generally beneficial for companies to work with external stakeholders, such as business partners and third-party consultants, to facilitate the licensing process. Partners help communicate and set realistic timetables, identify licensing risks and evolving policy challenges, and temper expectations. A good local partner can be invaluable for navigating disputes and increasing transparency, and can expand a company's business and create opportunities to sell to state-run organizations.

In some cases, companies work directly with Chinese joint venture (JV) partners or trusted supply-chain partners to address licensing issues. In other cases, the local Chinese partner might manage key aspects of the licensing process on behalf of the US company. One company noted that its state-owned JV partner generally handles most licensing issues and local government affairs, an arrangement that increases the speed and likelihood of licensing approvals. Wholly foreign-owned enterprises (WFOEs) more often handle their licensing processes directly, but they too report that that it can be beneficial, or even necessary, to employ outside service providers to assist with part of the proceedings. These companies

report that it is crucial to ensure the services provided are defined and billed to show full compliance with regulations.

## Impact of Administrative Licensing Reforms

In general, the aim of administrative licensing reforms—streamlining processes and cutting red tape—is positive. However, in practice, most companies have yet to see a significant impact on their operations or on the ability to access the market. Improvements have been measurable in some areas. One company noted, for example, that the new “green channel” for quicker approval of innovative medical device products recently enabled the company to get approval for a product that improves the quality of medical procedures. Other reforms have great potential for simplifying the licensing process, but implementation remains challenging. Companies that have used the “3-in-1” licensing scheme, for instance, report that this purportedly streamlined process required intense management by government affairs resources, indicating reforms aren’t yet as efficient as possible.

### Reforms in Filing, Approvals, and Technology

The transition from requiring an explicit government approval to system of filing-for-the-record is expected to streamline licensing processes in the future. However, to date, companies note that this transition has not yet resulted in significant efficiency improvements, as much of the required documentation remains the same. In practice, many local governments reportedly approach the new filing process and the old approval process as interchangeable.

Online “e-approvals” are becoming a more accessible option for companies. Yet, while online approvals are available for domestic products, at least some imported products still require an expert review process.

Central and local authorities continue to work closely with foreign companies to improve the licensing procedures in the Shanghai FTZ and expanded zones in Guangdong, Tianjin, and Fujian. Foreign companies report measurable improvements in some areas, such as logistics and financial services, but say the impact on other industries has been minimal at best.

### Challenges in Government Implementation of Reforms

As reforms progress, there remain concerns on how the government implements licensing procedures, from functional capabilities to internal coordination. Regulatory authorities often lack enough staffing to handle the volume of approval requests they receive. This challenge is frequently compounded by a lack of expertise and professionalism, varying widely from jurisdiction to jurisdiction.

A shortage of experts qualified to conduct approvals is likely a significant factor in prolonged approval times. One company in the healthcare industry believes that the CFDA needs to double its staff qualified to conduct approvals in healthcare.

Companies note that central government agencies generally are more open for consultation and have greater authority than local governments. Local authority and willingness to engage with companies varies widely from office to office. A number of companies said that the local government in first-tier cities is often much more professional and efficient with licensing issues than local governments in lower-tier cities, particularly in central and western jurisdictions. Coastal cities tend to be more efficient because

local regulators are more accustomed to working with multinationals; however, companies indicate that even these experiences vary by industry.

## Problems with the Expert Panel Review Process

Companies may be required to undergo expert panel reviews for various regular licensing processes. These expert reviews can be costly and time-consuming, and arranging expert assessments involves significant work by companies and regulators to coordinate schedules.

China's regulations governing expert panels and their composition are less specific than in some other jurisdictions. As one company noted, expert panels demand understanding of "some serious technical engineering requirements," yet experts on the panels may lack technical knowledge related to projects they assess. In some cases, panel members lack the technical knowledge to formulate meaningful questions, or inquire about technical issues already clarified in the supplied documentation.

This lack of technical knowledge can be costly. For example, some manufacturing companies have found a lack in expertise among environmental authorities to appropriately evaluate required pollution monitoring equipment. One company was required to install excessive, expensive equipment at the behest of local regulators that would not have been necessary if they had a nuanced understanding of technical requirements.

Companies are also concerned about conflicts of interest on expert panels. One company noted that many panel members are from state-owned enterprises (SOEs), prompting worries that they may communicate proprietary information to domestic competitors. Reports regarding conflict of interest concerns vary, however. A company in the pharmaceutical industry noted that this is a less pervasive problem than it used to be, and that it is no longer standard practice to have competitors in the same room.

Fees associated with expert reviews can also create a challenge. US companies noted cases where they had to turn down requests to pay experts' fees or travel expenses in order to comply with requirements under the United States Foreign Corrupt Practices Act (FCPA). One company suggested that the local regulator organizing expert reviews should include all costs and fees together to avoid this problem.

## Interagency Coordination and Communication

Poor interagency communication creates another set of difficulties. Companies report that a lack of communication between departments involved in the licensing process is a recurring issue. One company sought a trial production approval and was directed to first speak with the appropriate public institution before seeking approval. However, the regulator either could not or would not tell the company who to speak with at the institution, resulting in an unnecessary delay.

In another example, a company in the healthcare industry noted the central CFDA has articulated requirements for clinical trials, however, the steps and criteria for approval and conduct of a successful clinical trial can differ in practice. In this example, local jurisdictions require companies to conduct redundant clinical trials, which can be an expensive endeavor given the costs of education, testing, and certification expenses for their product approval. A standard guideline communicated and enforced top-down would help improve efficiency, saving both regulators and companies time and money, and benefitting customers by getting new products on the market more quickly.

Lack of communication can lead to conflict over licensing requirements between the central and local governments and delay improvement in licensing processes. One company in consumer health products noted that local branches are pushing for more local approvals for imports, but the central government is having difficulties moving forward with its proposals. In USCBC's 2015 member company survey, companies noted 77 percent of licensing challenges were at the central government level.

Contradictory requirements can be challenging as well. For example, a local regulator told one manufacturing company that it was required to have a specific industrial waste management system in order to obtain a license, but the area had no such technology available for purchase. Because of this, the company was required by local authorities to ship its waste out of the jurisdiction, an activity not welcome and subject to restriction in other local jurisdictions.

### Impact of the Anti-corruption Campaign on Licensing

The central government's [anti-corruption campaign](#) has significantly affected the licensing process, in ways both good and bad. The campaign has led to greater government attention in certain sectors—such as added scrutiny of consumer-facing healthcare products—and companies noted that it has helped move toward a rules-based and transparent licensing regime.

However, some of the clearest commercial consequences of the anti-corruption campaign include a diminished willingness among local government officials to make decisions and increased difficulties in accessing government officials, resulting in delayed license approvals. Some industry regulators may be more impacted than others.

Sudden changes in regulatory leadership from the campaign also concerns businesses. Arrests and investigations of regulators have caused delays in approvals during transitions. For example, one company noted the arrest of a former senior healthcare regulator led officials in that department to be more reluctant to act or make decisions.

While the anticorruption campaign has made access to government officials more difficult, companies said higher-level officials often provide clarity to the process—when companies have the opportunity to meet with such officials.

In the end, USCBC member companies welcome the move to implement a fair and equal licensing regime. American companies have a strong track record of compliance with local regulations; ensuring that the competition does not gain advantage in the licensing process is positive. The anti-corruption campaign needs to result in a sustainable and durable licensing system that is efficient and treats applicants equally. In the meantime, companies should expect delays.

### Managing Government Affairs in the Licensing Process

The complex nature of obtaining licenses from regulators has required businesses to refine their government affairs strategies. These adjustments result in increased focus on transparency and communication, as well as obstacles stemming from the anticorruption campaign.

In order to best manage the licensing function within an organization, one company with manufacturing operations in China divides its licensing work between a government relations team (responsible for interfacing with relevant government agencies to smooth the licensing process) and an environmental compliance and permitting team (responsible for handling technical issues). The company also maintains

an internal license-tracking database to stay abreast of license renewal schedules and to issue reminders to local managers.

## Conclusion and Recommendations

Companies dedicate significant resources to navigating China's complex licensing system and ensuring full legal compliance. Businesses welcome reforms aimed at streamlining administrative processes and cutting red tape, but still face challenges in efficiently conducting business due to the lack of process transparency; slow, conflicting and unpredictable timelines for approvals; poor interagency communication; and burdensome or problematic intellectual property disclosure requirements.

Best practices for managing the challenges may help companies improve internal policies and practices for acquiring licensing, permits, and certification. However, in order to cultivate a more transparent and efficient licensing apparatus conducive to business, reforms will need to continue.

To successfully improve the licensing system, create more certainty, and facilitate investment, USCBC recommends that the Chinese government continue to enact administrative licensing reforms, adhere to commitments on transparency, and improve interagency coordination—across agencies at the same level, as well as between central and local agencies—to implement a streamlined, predictable licensing system. Alleviating company concerns about licensing procedures and creating and fully implementing expedited channels—such as the “green channel” for innovative products—will facilitate the development of a more modern and innovative Chinese economy.

### Summary of Recommendations

#### Product certifications

- Allow manufacturers to continue business with established suppliers and distributors with a proven safety record while the manufacturer awaits approval for its industrial product manufacturing licenses.

#### Market Access Concerns and Unregulated Segments

- Implement a [nationwide market access negative list](#) to clarify which sectors are open to foreign investment and ensure consistent implementation by local and provincial governments. Ensure that this list is minimized to reduce government interference and open more sectors to foreign investment and competition.

#### Expert Review Panels

- Ensure that expert review panel members have technical knowledge of the products they are expected to evaluate.
- Exclude panelists who may have conflicts of interest in reviewing products from competitors' companies.
- Include all costs and fees associated with expert panel reviews in a single charge to applicants.

#### Information Disclosure

- Allow companies to provide alternate information to satisfy regulatory demands to protect their IP.
- PRC agencies should create a consolidated list of standard information requirements.
- For companies navigating licensing processes, consider hiring third-party licensing consultants to lay out company-specific IP protection requirements and obligations and coordinating submission of supplementary information.

#### Reforms in Filing, Approvals, and Technology

- Continue work to simplify approval processes by moving toward filing and one-stop online platforms.

#### Interagency Coordination and Communication

- Work to improve coordination on licensing processes between agencies so that separate departments and agencies part of a single licensing process are aware of required documentation, timelines, and other requirements.