



September 23, 2015

Ms. Yvonne Jamison
Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20006

RE: China's WTO Compliance (Docket No. USTR-2015-0010)

Dear Ms. Jamison,

The American Chemistry Council (ACC)¹ is pleased to provide the following submission in response to the Federal Register notice published on August 15, 2014 requesting public comments on China's compliance with the commitments made in connection with its accession to the World Trade Organization (WTO). ACC greatly appreciates the efforts of the U.S. Trade Representative (USTR) in helping to ensure that China's WTO commitments are upheld.

The business of chemistry is an \$801 billion enterprise and a key element of the U.S. economy supporting nearly 25% of U.S. GDP. It is one of the nation's largest exporters, accounting for twelve cents out of every dollar in U.S. exports. U.S. chemical exports to China have risen steadily from \$5.3 billion in 2005 to \$13.54 billion in 2014. According to ACC's Global Chemical Production Regional Index (Global CPRI), China has demonstrated the most significant growth in the volume of chemical output and is one of the world's largest markets for chemicals, currently making up around 25% of global chemical production. Due to its heavy demand for chemicals, China is a net chemical importer, with a trade deficit in chemicals of \$373 million. As a result of China's significance to the global chemical industry and global chemicals trade, the implementation of its trading regime has important implications for the U.S. chemical industry.

ACC has long been a supporter of trade liberalization worldwide and of the multilateral rules-based trading system of the WTO. ACC and its member companies supported China's accession to the WTO in 2001 and for Permanent Normal Trade Relations status with China, in order to further encourage China's integration into the global trading system. A key benefit to China's continued engagement in the WTO is ensuring predictability in business transactions and conformity with global regulatory norms.

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.



In the comments attached (Attachment 1), ACC highlights four areas of ongoing concern regarding China's implementation of its WTO obligations: New Chemical Substance Regulations; Customs Restrictions; implementation of the Globally Harmonized System for Classification and Labelling (GHS); and overall transparency in the regulatory process. In addition, ACC supports the broader comments submitted by the U.S. Council for International Business (USCIB), of which ACC is a member.

Again, ACC appreciates this opportunity to provide the Trade Policy Staff Committee with these views. Please do not hesitate to contact me (alexa_burr@americanchemistry.com, 202-249-6425) should you have any questions or comments, or require additional information.

Sincerely,

Alexa Burr
Manager, Regulatory & Technical Affairs



Attachment 1 – American Chemistry Council Comments on China's WTO Compliance (Docket No. USTR-2015-0010)

New Chemical Substance Regulations

Chemical control legislation addresses the safety, health, and environmental aspects of the manufacture, import, and supply of industrial chemicals. ACC and its member companies support national legislation around the world that aims to protect humans and the environment and promotes the safe handling of chemicals.

The implementing regulation to accompany China's *Regulation on the Environmental Management of New Chemical Substances* (MEP Decree No. 7), which entered into force in October 2010, has had a negative impact on exports of chemicals and chemical products into China. Lack of clarity and consistency in the development of guidance for the interpretation of this Regulation, and four years of practical experience with the legislation and guidance, has led to significant difficulties for U.S. companies throughout the New Chemical Notification process. This has hindered efforts to bring new technologies to the market in a timely manner. U.S. exporters are still waiting for China to resolve a number of inconsistencies with this Regulation and its guidance.

With these provisions, China established a new chemical notification scheme based on an inventory of existing chemicals ("old" chemical substances) that was developed over nine years. Any substance or component of a product within the scope of the regulations that is not listed on the inventory is defined as "new." A new chemical notification requires submission of chemical identity, physical properties, toxicity and ecotoxicity data for approval before manufacture or import can be undertaken. This process is very burdensome due to the significant amount of data that must be submitted to register a chemical. Furthermore, the process for approvals is uncertain and is often delayed without notification to the registrant, despite MEP describing the review process and timeline in its Guidance.

In June 2015, the Chinese Ministry of Environmental Protection's Solid Waste and Chemical Management Technology Center (SCC-MEP) issued updated Draft Guidance for the Notification and Registration of New Chemicals, hereafter referred to as the Guidance. ACC is concerned with the new language in the Guidance as it refers to articles exempted from the NCN Guidance. The new language implies that **any** "new" chemical substance in an article that could potentially result in exposure to humans or the environment will be subject to the full NCN obligations under Order Number 7. As written, this requirement will be applicable to all articles and their subcomponents, even if there is extremely low risk of hazard or exposure to humans or the environment.

Such a requirement would impose significant administrative and compliance burdens for industry, especially for U.S. companies that import articles into China. To ACC's knowledge, no other government has such a requirement for articles. As written, the provision will impact all articles manufacturers and importers in China since merely any chemical in an article will



need to be notified, even if it is not released. Global suppliers to Chinese importers will be required to proactively inform their Chinese customers of substance new to China that may be contained/released from their manufactured articles. This will be a significant burden on exporters to China since they will have to ensure substances are notified, resulting in amplified implications throughout the global supply chain. The decisions of U.S. suppliers' to export substances and articles to China will be impacted due to the increased administrative burden and possibility of disclosing sensitive Confidential Business Information (CBI) to customers.

In alignment with international practice, ACC recommends SCC-MEP maintain the previous version of the Article Exemption, under which articles, and substances used in or released by articles, were exempt as they pose negligible risk to human health or the environment. ACC provided detailed comments on the Guidelines submitted to SCC-MEP on July 30, 2015, which included suggestions and recommendations for improving the Guidelines.

Mutual Acceptance of Data: The Chinese regulations differ from other similar regulations in other countries, in several significant respects. There is no specified exemption for low volume imports or production. Some 20-50% of potential new notifications in China would be exempt elsewhere. One of the few exceptions available, for research and development, is more restrictive in duration and volume than in other countries. Ecotoxicity testing in a Chinese laboratory is required, even if similar tests have been conducted elsewhere according to international standards. This requirement is inconsistent with the Organization for Economic Co-operation and Development (OECD) principle of Mutual Acceptance of Data (MAD). It also is contrary to the spirit of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) agreement, in which China is a full member.

Furthermore, to fully participate in the world trading system, China should readily accept test data generated in other countries under international guidelines for the mutual acceptance of data. All scientifically valid information that enables one to assess a chemical should be sufficient and acceptable to meet the provisions of the Regulation. Moreover, the Regulation should allow for the use of alternative sources of information (e.g., QSARs, read-across, category approaches, waivers, in vitro methods, expert judgment, modeling, etc.) that can be used to fulfill the data requirements. All of these restrictions create delays in imports, duplication of testing, and an increased burden on foreign manufacturers.

Confidentiality and Data Protection: ACC also has serious concerns over the protection of confidential business information (CBI), which is an important and fundamental element in any chemical control program. China's Ministry of Environmental Protection (MEP) has made general statements that officials should protect confidential business information. Transparent administrative processes when handling, storing and communicating new chemical information are needed when this information is transferred to other government agencies, or the provinces, as required as part of the supervisory process.

Moreover, the Regulation Guidelines state MEP will publicly disclose the names, notifier, notification class and administration class of new chemical substances on its website. Disclosure of some of the content information on the MEP website is not appropriate and can jeopardize



confidential business information for all of industry in China – domestic and importers. The information required by the users (customers) of the new chemical can be found on the Material Safety Data Sheets (MSDS) and label for the new chemical or the product containing the new chemical.

The content that China proposes to make available globally on the Internet is not appropriate or necessary. It has the potential to give competitors easy access to information not only on the chemical, but also about the potential market and use of new technologies. ACC has requested that MEP consider reducing the requirements for the use of Generic names to protect CBI appropriately. This is necessary to ensure the protection of substance identity and allow registrants to maintain their competitiveness.

Non-Discrimination and National Treatment: Although the new chemical regulations apply to domestically manufactured substances as well as imports, the requirements have not been widely communicated and are virtually unknown to local industry. Along with the severely inadequate testing facilities, this calls into question the expectation for compliance by domestic companies. In addition, there appear to be domestically-produced chemicals advertised for sale in China that do not appear on the inventory of existing chemicals, and should therefore have already undergone the required notification and registration as new chemicals. Currently, these chemicals are not known to have been registered by MEP.

Customs Restrictions

U.S. chemical companies have been subject to port inspections for GHS labeling of chemical products. Our members continue to be impacted by this newly enforced requirement which does not align with current international practice.

Technical Barriers to Trade: On January 20, 2012, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issued Quality Inspection Letter [2012] No.16², outlining new inspection requirements for the 160 chemicals listed in the “Legal Inspection Catalogue”. As a result, on February 1, 2012, China's Entry-Exit Inspection and Quarantine Administrations (CIQ) started compulsory inspections of imports/exports of these chemicals and their packaging.

The listed chemicals (defined by tariff code) must have a Chinese Globally Harmonized System (GHS) compliant Safety Data Sheet (SDS) in the package and must be labeled according to GHS prior to arrival in China. The product label must be in Chinese; a product label must be included on the outer package, and applied to individual containers on inner packages, where applicable. AQSIQ has indicated that, although only 160 chemicals are listed in the “Legal Inspection Catalogue”, inspection can cover the entire “List of Dangerous Chemicals” (2002), which currently contains over 3,800 entries. We have ongoing concerns with mandatory classification lists and the source/quality of many of the classifications.

² Quality Inspection Letter [2012] No.16 was superseded by Quality Inspection Letter [2012] No.30, issued February 29, 2012.



The implementation of this new inspection scheme is causing significant delays of exports to China and does not align with international practice. The situation is expected to worsen noticeably when 1) the focus of inspection moves beyond the 160 chemicals; and 2) the List is supplemented.

Member companies have found that these inspections are not being confined to chemicals listed in the catalogue or included on the Dangerous Chemicals list. In Shanghai Port, over-zealous inspection has been especially prevalent. In addition to Shanghai Customs, members have also encountered inspection delays in Dalian, Dongguan, Guangdong, Nanjing, Ningbo, Pudong, and Tianjin.

GHS Implementation

ACC supports efficient implementation of the GHS for workplace chemicals and has been an active participant in the development and implementation of GHS in many countries. Several member companies have expressed concern about China's implementation of GHS due to its overly burdensome requirements and lack of alignment with international standards.

Confidentiality and Data Protection: Under State Decree 591 (Regulations on Safe Management of Hazardous Chemicals in China) and GHS standards, labels are required to disclose hazardous ingredients above a "cut off" range. They are not required to provide descriptions of all ingredients, where the information is proprietary. For GHS labels, label standard GB15258 states:

For mixtures, the chemical or generic names of the main ingredients contributing to the hazardous classification and their concentration or concentration ranges should be indicated. There should be no more than five ingredients indicated when multiple ingredients are present. Ingredients which are considered confidential business information do not have to be indicated, however, their hazards should be listed."

In addition, the Certificate of Conformity requires disclosure of stabilizers and inhibitors (with percentages). This is above and beyond the requirements of GHS.

U.S. chemical companies have expressed concerns about additional disclosure of ingredient information in proprietary compositions. They have also cited a number of examples where it appears the regulatory authorities do not have sufficient training to understand the GHS regulations and are delaying shipments unnecessarily.

One company reports that they are now having products held up by Dongguan CIQ for label and SDS issues identified by a 3rd party (a non-governmental consulting agency). The company does not agree with these alleged deficiencies and is planning a meeting with CIQ for clarification. Shortcomings in inspection processes are disrupting business and costing companies time and money to address.

Another company reported that the Shanghai Import/Export Inspection Bureau said their Chinese GHS labels did not meet the regulatory requirement, and lacked main hazard ingredients information. While the requirement is to disclose ingredients that contribute to the hazard (with provisions for trade secrets), the inspection officers interpret that a label is incorrect unless there



is a large percentage of ingredients disclosed. The company was required to change the label disclosure.

Technical Barrier to Trade – Voluntary SDS Standard: In addition to requiring disclosure of valuable ingredient information, the Chinese Voluntary SDS Guidance Standard, GB/T 17519-2013 *Guidance on Compilation of Safety Data Sheet for Chemical Products* entered into force January 31, 2014. Even though the GB/T standard is voluntary, it is understood that the new information requirements must be met when supplying SDS in support of hazardous material registration applications.

Prior to GB/T 17519-2013 going into effect, China did not give appropriate advance notice or opportunity for stakeholders to comment, as is required under the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement. The new standard is different from current international practice and the implementation of GHS. It requires significant expansion of the information required in Section 2 of the current SDS, including duplication of all the information from Sections 11 and 12.

The new standard has also not been legally codified under State Decree 591. Mandatory implementation of the voluntary standard will lead to additional discrepancies between imports and will slow down the inspection process at ports. It is currently understood by industry that if the new SDS does not meet GB/T 17519-2013 requirements, the hazardous material registration may be denied on that basis. Therefore, it will also lead to discrepancies within the inspection process depending on the CIQ inspector's interpretation and enforcement. There are already many differences in customs procedures depending on the entry point in China and this standard is leading to additional complications.

Mandatory implementation of the new voluntary standard would also result in companies having to reformat their entire SDS template as well as the process for creating the SDS for China alone, since it does not allow for the numbering of sub-sections and requires duplicative information. For one company alone, this means over 750 individual SDS forms will need to be reformatted and updated with new information. Across all of industry, thousands of SDS would be required to be reformatted, which is a non-value added activity for information that is already included in the SDS.

Technical Barrier to Trade – Packaging: The requirement to include an SDS in the package is problematic. Per the UN Transport Regulations, there are box closure standards for regulated materials. If the Chinese SDS is put in the box as part of the manufacturing process, then the Packaging Standard must be followed to ensure the closure is in compliance with the transport regulations. If the Packaging Standard is followed then this procedure should be okay. Clarification is needed on whether every box must have a SDS or provide one SDS per shipment of the same product number. It would be far less burdensome for both AQSIQ and companies to provide one SDS per shipment of the same product.

The Association of International Chemical Manufacturers (AICM), located in Beijing, has noted that GHS labels are mainly for workplace use, not for transportation safety. Importation is part of transportation, and the transportation rules require "Dangerous Goods" labels instead of GHS



labels. In more practical terms, normally the GHS labels should be put on the inner packaging instead of the outer packaging. The on-site inspection of GHS labels will presumably destroy the outer packaging. This may lead to safety problems as original packaging is disturbed. It is not acceptable to open packages of materials that are regulated for transport in the distribution network as the Distribution Centers and the Freight Forwarders do not have access to the original Packaging Standard. Closure standards vary so it is not possible to issue a "one size fits all" instruction.

Technical Barrier to Trade – GHS Inspections: The inspection regime discussed above is unique to China. Standard international practice is to allow relabeling prior to sale, rather than on import. Few countries/laws have the authority/jurisdiction to mandate labeling at customs or outside their borders. For example, coming into the US, OSHA does not have authority to stop products at Customs. The importer/first workplace is responsible for the US OSHA/GHS label. The rationale behind the argument to require labeling prior to import is that under Chinese law, the government can only enforce regulations against companies operating in China. Technically speaking, it is Chinese companies' obligation to classify and label hazardous chemicals in accordance with China GHS. By reviewing the incoming products, it allows the government to assess if these goods are ultimately likely to comply with regulatory requirements. However, it has become a standard practice for suppliers (including foreign companies) of hazardous chemicals to provide SDS in the languages of destination country; and for multinationals or foreign investments to relabel products on site. That is why a lot of companies who export chemicals to China have already updated their SDSs and labels to the GHS requirements.

While the enforcement action is an attempt to improve compliance rates, the approach adopted has significant ramifications to US and other countries who export to China since:

- Global locations generally do not seem prepared to immediately implement Chinese GHS labeling due to color requirements, print hardware capabilities, translations, etc., and
- Most products are direct shipped to China as "make to stock" products, meaning a new process will need to be implemented in the plants to identify China exports, intercept the inventory, and apply the special labels including sometimes having to open outer packages to overlabel inners and then reseal.
- When purchasing raw materials to be used in products manufactured in China, it can be difficult if not impossible to enforce requirements to provide Chinese compliant documents from vendors in who lack the capability.

The regulation is therefore a barrier to trade for importers. It does not enforce compliance for domestic companies on the GHS regulation, only those that import /export. Chinese GHS SDS and labels must be provided for products with GHS classification and products which contain hazardous ingredients over the cut off limit set by standard G13690-2009. This is same requirement for domestic companies and products, but is not well implemented domestically.

Overall Transparency

ACC stresses the importance of an open and transparent regulatory system in China. The lawmaking process and related activities should ensure that all stakeholders are given appropriate advance notice and ample opportunity to comment on major changes in China's regulatory



system, especially as the chemical regulations continue to develop.³ In our experience, the participation of a broad range of stakeholders in the development and implementation of chemical regulations can make a significant contribution toward the objective of a scientifically robust risk management program.

Furthermore, there should be open communication amongst the regulators in China. There are multiple Chinese agencies responsible for regulating chemicals, resulting in duplicative regulations. This not only creates a burden on industry due to compliance costs and delays in shipments, but also imposes a significant resource burden on the Chinese government. Such duplicative regulations impede the growth and progress of the Chinese economy by hindering growth and innovation in the chemical sector, upon which many other sectors are dependent, including electronics. These regulations remove the flexibility necessary to achieve such innovation and growth since all entities, from large companies to small and medium sized enterprises (SMEs) must comply with the burdensome requirements and restrictions.

Conclusion

China's process for developing and implementing regulations that affect chemicals raises concerns about its intention to adhere to international regulatory standards and to develop effective and equitable regulatory regimes that take into account the interests of all stakeholders. A key objective of China's regulatory structure must be its compliance with all WTO obligations.

ACC and its member companies are eager to see China fully integrated into the world trading system so that its companies and people can achieve the economic and social benefits of globalization. We are committed to engaging both the Chinese government and industry to ensure a sustained competitive and growth dynamic for the chemical industry.

ACC and its members companies welcome all opportunities to engage MEP and other Chinese regulatory bodies on issues relating to the development and implementation of chemical regulations. We are always open to new opportunities to engage with Chinese government officials and regulators and appreciate the past efforts of the U.S. Department of Commerce in organizing a series of digital videoconferences on the new chemical regulation between officials from MEP and the U.S. Environmental Protection Agency. These forums are beneficial for not only ACC, but other affected sectors as well. This cooperative effort is important for improving mutual understanding and trust, and we commend MEP for its commitment to ongoing exchanges with EPA and U.S industry.

³ TBT Article 2.12 requires WTO Members to allow a reasonable interval between the publication of a technical regulation and its entry into force in order to allow importers to adapt.

