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VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

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Re: Comments of the American Chemistry Council on OFR's Announcement of a petition for rulemaking and request for comments relating to Incorporation by Reference (77 FR 11414; February 27, 2012).

Dear Sir or Madam:

The American Chemistry Council (ACC)¹ appreciates the opportunity to submit comments on the petition to amend the Office of the Federal Register (OFR) regulations governing the approval of agency requests for incorporation by reference (IBR) of standards into the Code of Federal Regulations (1 CFR Part 51).

Standards play a very important role in our economy and in the U.S. regulatory system. In addition to helping to ensure health and safety, the U.S. standards system also helps to enable innovation. Standards are of great importance to the chemical industry. Our staff and members participate as stakeholders in a wide range of standard development activities, and our member companies use and rely on a wide range of standards. In addition, ACC is itself the ANSI Secretariat for ANSI Z400.1/Z129.1-2010, the standard for Hazard Evaluation and Safety Data Sheet and Precautionary Labeling Preparation.

We strongly support the review undertaken by OFR, and believe that the process of seeking stakeholder comments is timely and should be helpful to refining regulatory requirements. That said, we believe that any proposed revision to the regulations set out at 1 CFR part 51 should be considered with caution and should be informed by robust analysis and evaluation of the benefits and costs of the proposed changes. The U.S. has the most robust standardization system in the world and regulatory changes may have great

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. The business of chemistry is a \$720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

impact on the business model used by many standards development organizations (SDOs). This in turn could have detrimental impacts on the ability of the U.S. to use and generate many of the standards that help protect health and safety.

We urge the OFR to consider the question of what “reasonably available” means very carefully. On balance, the current system of private standards development and incorporation by reference works effectively. The costs associated with developing a standard are not insignificant, and private standards development organizations must recoup their operational costs in some manner, whether by membership dues, sales of standards, or agency subsidy/license. The vast majority of standards development organizations are able to offer completed standards for a nominal cost of purchase. Income from sales of standards generally helps to keep membership fees and dues affordable to those parties wishing to join standards development activities. This, in turn, allows a wider variety of stakeholders to participate in the standards development process, which helps create a more robust consensus standards development process with a wider range of stakeholder input across industry segments and regardless of the size of company. Changing the way in which private standards development is funded could diminish participation in the standards development process. The end result could be less robust standard development, and ultimately less technically robust standards.

Before it can fully evaluate what is “reasonably available,” OFR should be fully informed about the current cost of standard development and the impact any changes may have on the current business model used by SDOs. This information should be collected for a wide range of standards, across a wide range of industries, by different models of SDOs, including non-consensus consortia. We encourage OFR to conduct such an analysis and evaluation to inform any proposed changes the agency may consider.

We also believe that OMB should play an active role in helping to understand the cost of private standard development in the U.S. and in helping to inform discussions regarding the meaning of “reasonable availability.” In particular, OMB has expertise in working with agencies to ensure that appropriate regulatory analysis, including benefit and cost analysis, is conducted to inform rulemaking. Consistent with Executive Order 13563, OMB helps to ensure that our regulatory system protects “public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation”. As changes to the IBR regulations can have broad impacts, a robust regulatory analysis should be a key component underlying any changes to the regulations.

ACC appreciates the opportunity to comment. For any additional information regarding these comments, please contact me at 202-249-6400 or Michael.Walls@americanchemistry.com.

Sincerely,



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