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Third-Party Programs to Assess Regulatory Compliance

In recent years, federal agencies have increasingly turned to private third parties to assess whether regulated entities and products are in compliance with federal standards and other requirements. In regulatory programs, third parties are authorized to carry out product testing, facility inspections, and other regulatory compliance activities in the place of regulatory agencies. Regulatory agencies take on new roles in approving, coordinating, and overseeing these private actors.

There are many reasons for the use of regulatory third-party programs. Some regulatory objectives are difficult to achieve using traditional regulatory approaches such as ensuring the safety or correct labeling of food and other products manufactured in complex international chains of production. Third-party programs may extend the reach of regulators by enabling third parties around the globe to participate in compliance assessment. Another motivating factor is that agency resources may be inadequate to address the ever-growing number of problems and entities subject to regulation. Third-party programs may have the effect of shifting some costs associated with compliance assessment to private parties and thereby conserving governmental resources.

Regulatory third-party programs raise a host of important questions. Representing a partial privatization of the public function of implementing and enforcing regulatory law, they are a form of "public-private governance," in which private actors play roles that are traditionally viewed as governmental in nature. While they may enable innovation, efficiency, and quality in the provision of governmental services, third-party programs may also jeopardize the fulfillment of public purposes and commitments. Difficult issues are presented regarding considerations such as the competence and independence of third-party actors, the extent of governmental control and oversight, and the management and coverage of third-party program costs.

Recognizing the growing use of third parties and the issues it raises, the Administrative Conference is issuing this Recommendation to assist federal agencies in determining whether and how to establish third-party programs to assess regulatory compliance. This

Recommendation suggests that when considering a third-party program, agencies should consult relevant governmental and nongovernmental resources and compare the costs and benefits of a third-party approach to a more traditional approach of direct governmental compliance assessment. Also, if agencies are considering a program in which regulated entities could choose whether to contract with third parties for regulatory compliance assessment, they should evaluate whether regulated entities will have adequate incentives to do so.

The Recommendation also sets forth considerations for agencies after they have decided to establish a third-party program. Agencies should design third-party programs that are calibrated to the risks associated with regulatory noncompliance. When these risks are higher, a more robust third-party program is appropriate. When possible, agencies should incorporate relevant existing governmental or private-sector standards and activities, which may avoid unnecessary duplication and otherwise create efficiencies for both agencies and private parties. Agencies that rely on third-party programs should also ensure that the agency and the public have appropriate access to information about program operation and they should commit to undertaking appropriate oversight activities.

Frequently, regulatory third-party programs use the practices and terminology of an international conformity assessment framework developed by private-sector standards organizations. Conformity assessment is broadly defined in international standards as the "demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled." [1] As federal agencies have recognized that verifying compliance with regulatory requirements can be viewed as a form of conformity assessment, they have developed third-party programs that incorporate international conformity assessment standards. Agencies have also tapped into the international networks of private actors that seek to operate in accordance with these standards and carry out the activities related to conformity assessment.

[1] American National Standards Institute (ANSI), National Conformity Assessment Principles for the United States, 3, *available at* http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf.

In this way, the worlds of public regulatory compliance and private conformity assessment are merging in regulatory third-party programs. To understand regulatory third-party programs, the language of conformity assessment must be understood. Yet it is also important to recognize that the two worlds are not fully merged. The federal statutes, regulations, and policy documents that establish third-party programs each have their own sets of practices and terms, which are at times inconsistent with international conformity assessment standards or otherwise forbid their use. Federal third-party programs sometimes predate relevant international standards or, for other reasons, do not rely on or make reference to them.

The following recommendations adopt the vocabulary of both regulatory compliance and conformity assessment. The goal of third-party programs, as understood herein, is to enable regulatory agencies to rely on the strengths of the private sector for an assessment of the compliance of a regulated entity or product. The third parties are often referred to as conformity assessment bodies, a broad term that encompasses various types of private parties that conduct conformity assessment activities (*e.g*. testing bodies, certification bodies, etc.). Regulatory agencies may directly approve conformity assessment bodies for participation in third-party programs, or they may rely on private accreditation bodies to approve conformity assessment bodies. Specific international standards have been published for the operation of various types of conformity assessment bodies, as well as accreditation bodies.

Recommendations

A. Determinations by Federal Agencies Whether to Use a Third-Party Program: Resources & Considerations

Regulatory agencies that have the discretion to develop a third-party program to assess regulatory compliance should consider whether such an approach may be beneficial. In so doing, they should avail themselves of available resources, compare the benefits and drawbacks of third-party programs with direct compliance assessment, and consider whether regulated entities will have sufficient incentives to participate if the use of third parties would be optional.

1. Consult Available Resources

(a) Agencies considering whether to establish a third-party program should consult the variety of governmental and non-governmental resources relating to third-party conformity assessment. These include, but are not limited to:

(i) The National Institute of Standards and Technology (NIST), which has the responsibility under the National Technology Transfer and Advancement Act of 1995 to coordinate conformity assessment activities of governmental and private-sector entities with the goal of avoiding unnecessary duplication and complexity; and

(ii) Private standards and related organizations, in particular, the conformity assessment standards of the International Organization for Standardization (ISO) and the private-sector organizations that guide their development and use, such as the American National Standards Institute (ANSI).

2. Compare a Third-Party Approach with Direct Governmental Compliance Assessment

(a) Agencies considering a third-party program should compare such an approach with direct governmental assessment of compliance. In choosing between them, an agency should consider their respective costs and benefits, including:

(i) the costs that would be incurred by the agency in developing a third-party program, including the costs of setting up the program and performing ongoing oversight;

(ii) the potential delay in implementation of a regulatory program resulting from the activities necessary to set up a third-party program;

(iii) the potential cost savings or benefits generated by the need to hire fewer agency staff for direct regulatory activities;

(iv) the costs that would be incurred by regulated entities paying third parties to perform the compliance assessment activities, which are likely to be of particular concern to small businesses; and

(v) the benefits that may accrue to regulated entities by, for example, receiving regulatory approval to market their products more quickly or simultaneously satisfying the requirements of other regulatory entities, such as state agencies or agencies in other countries. (*See* Administrative Conference of the United States, Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg. 2,257, 2,259 (Jan. 17, 2012); *see also* Exec. Order 13,609 (May 1, 2012); Exec. Order 13,563 (Jan. 18, 2011)).

(b) An agency should also consider the characteristics of the regulatory standards and the regulated products or activities at issue. The risks or rewards of relying on third parties may vary depending on the type of regulatory program. For example:

(i) The regulatory standards to be applied in a third-party program should be clearly written and contain requirements whose absence or presence can be objectively assessed. Without clear and objective standards, the risk of unreliability and inconsistency in the determinations of third parties is higher;

(ii) Where an agency's program involves mandatory standards designed to protect public health and safety and the risks associated with noncompliance by regulated entities are high, a more complete and costly third-party program is likely to be warranted;

(iii) When a program simply confers a marketing label showing compliance with voluntary regulatory standards, a failure in the compliance assessment system has a more limited impact, and therefore may be suited to a less costly third-party program; and

(iv) When the regulated product or activity is international in scope because of international trade, it may be better suited to a third-party program because:

(A) such programs enable regulatory agencies to extend their reach outside national borders by incorporating private actors around the globe; and (B) if the standard to be applied in the program is an international standard, it becomes more likely that regulated entities will be able to utilize a single third-party conformity assessment process to satisfy multiple regulatory jurisdictions. However, the agency should take into account the degree of difficulty overseeing the private actors operating in other countries. (*See* Administrative Conference of the United States, Recommendation 2011-6).

3. Evaluate Incentives for Participation in the Optional Use of Third Parties

(a) If an agency is contemplating a third-party program in which regulated entities would have the choice of either contracting with third parties or being assessed directly by the agency, the agency should evaluate whether sufficient incentives exist or can be created to attract the participation of regulated entities. Incentives for regulated parties to participation in third-party programs may include:

(i) avoidance of a fee for direct governmental assessment when choosing to contract with a third party; or

(ii) satisfaction of regulatory requirements of other jurisdictions in which regulated entities operate or sell products.

B. Considerations for Federal Agencies When Establishing a Third-Party Program

Agencies that have decided to establish a third-party program to assess regulatory compliance, or which are directed by statute or other provision of law to do so, should undertake the four enumerated steps listed below.

1. Calibrate the Third-Party Program to the Level of Risks Associated with Noncompliance

(a) A basic principle of conformity assessment is that the design of a conformity assessment system should be driven by the degree of assurance its users need. If the

risks associated with regulatory noncompliance are high, a third-party program should require rigorous assessment, ensure the competence and independence of third parties, and facilitate agency oversight. Such a program could include:

(i) accreditation rules that set high standards for third parties to be accredited;

(ii) selection rules that, for example, prevent regulated entities from using third parties with conflicts of interest or minimize the third party's reliance on subcontractors;

(iii) performance rules that require a well-specified and appropriately complete set of assessment activities;

(iv) reporting rules that furnish ample information about the outcomes of assessment activities; and

(v) a full array of governmental oversight activities and enforcement powers.

(b) Where the risks associated with noncompliance are low, such rules may, in some cases, represent a degree of "over-design" that adds costs to the system, and potentially to the products or processes assessed, without compensating benefits. In those situations, the regulatory objective may be achievable with less intensive conformity assessment activities, third parties whose qualifications are not subject to as demanding standards, and lower levels of government oversight.

2. Incorporate Existing Conformity Assessment Standards and Activities When Possible

(a) In order to reduce the costs of the program for both the regulatory agency and regulated entities, agencies should strongly consider relying on existing conformity assessment standards (such as ISO standards setting forth how testing bodies, certification bodies, and accreditation bodies should function) when they establish third-party programs. Using international standards of conformity assessment enhances the possibility that the same conformity assessment might serve to demonstrate

compliance with regulatory requirements in other countries. (*See* Administrative Conference of the United States, Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg. 2,257, 2,259 (Jan. 17, 2012)).

(b) A significant way in which an agency can rely on existing conformity assessment standards is by recognizing private sector accreditation bodies that operate in accordance with the relevant ISO standard to accredit third-party conformity assessment bodies, rather than accrediting them directly. An agency that decides to accredit third parties directly may still use international standards as a guide for its own accreditation activities.

(c) Agency programs that anticipate reliance on conformity assessment bodies in other countries may be particularly well-served by relying on private accreditation bodies. Such accreditation bodies may have more institutional competence than the agency in dealing with the foreign conformity assessment bodies and may be located in the same country or region of the world. However, the agency should address the issue of how to provide for oversight of the foreign activities of private accreditation bodies and the foreign conformity assessment bodies they accredit.

(d) When an agency incorporates international standards into its requirements for accreditation bodies or conformity assessment bodies, it can supplement those standards in various ways. An agency, for example, may require that a certification body be accredited by a private accreditation body to the relevant ISO standard and also meet a certain set of requirements specific to the agency's own third-party program. The accreditation body could be given responsibility for assessing conformity with the program-specific requirements as part of its accreditation, or the agency could do its own assessment as part of recognizing an accredited certification body for participation in the program. Through program-specific requirements, the agency could also require certification bodies to undertake particular types of surveillance activities at particular times.

3. Ensure that the Agency and the Public Have Appropriate Access to Information

(a) The responsible agency and the public should have access to a variety of types of information about the operation of third-party programs used to assess regulatory compliance. In particular:

(i) The development of third-party program rules and guidance should include public notice and an opportunity for public participation;

(ii) The public should have access to and input into the procedures by which a regulatory third-party program is run. When agencies incorporate international conformity assessment standards into their regulatory processes, important concerns arise about the public availability of those standards due to the costs of obtaining copyrighted materials. The Administrative Conference has recommended that when an agency considers "incorporating copyrighted material by reference, the agency should work with the copyright owner to ensure the material will be reasonably available to regulated and other interested parties both during rulemaking and following promulgation." (Administrative Conference of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg. 2,257 (Jan. 17, 2011));

(iii) The public should have access to certain types of information about the compliance of regulated entities and products. If a third-party program replaces another regulatory compliance program, the same types of information that were accessible to the public before the implementation of the third-party program should remain available. It may also be appropriate and desirable to provide additional compliance information to the public that was not available before the third-party program came into effect;

(iv) The public should have access to certain types of information about the third parties that participate in the regulatory program. The agency should make clear the roles and identities of the various third-party actors, and where

mandated by legislation and otherwise appropriate, maintain a public list of the private bodies associated with the program, and their characteristics and activities;

(v) For effective oversight, the government agency will also need certain types of information from conformity assessment bodies and accreditation bodies. For example, certification bodies might be required to report potential conflicts of interest before performing a certification, or the dates of their assessment activities so that agency officials can conduct site visits for oversight purposes. Certification bodies could also be required to submit documents gathered or generated during the process that explain and support the ultimate outcome of the conformity assessment process. To the extent that information required of third parties constitutes or includes confidential business information, it can be protected from disclosure in accordance with the Freedom of Information Act and other applicable laws;

(vi) Agencies should also consider structuring information disclosure requirements so that they have the effect of enhancing the degree to which third-party conformity assessment bodies answer directly to the regulatory agency rather than just the regulated entity that has contracted with it. For example, a testing body can be required to send its test results directly to the agency. Information technology can play an important role in enabling the transfer of information in a third-party program. Regulated entities, third-party conformity assessment bodies, and accreditation bodies can be required to report certain types of information electronically, thereby also allowing information that should be public to be made public more promptly; and

(vii) Agencies should be attentive to the possibility that international conformity assessment standards include confidentiality provisions that may prevent the transfer of information in a regulatory third-party program. Program-specific accreditation or certification requirements may be needed to

ensure governmental or public access to information that might otherwise be considered confidential.

4. Commit to Undertaking Appropriate Oversight Activities

(a) When an agency establishes a regulatory third-party program, its role changes from being the guardian to guarding the guardians. Governmental oversight of third-party programs is essential to ensuring that the program is fulfilling its regulatory purpose. In addition to exercising direct oversight, an agency can also require third parties to conduct surveillance activities that provide additional information to the agency about program operation.

(b) For a successful third-party program, a regulatory agency must implement and enforce the rules it establishes for program actors. In principle, the same enforcement strategies and tools would apply in enforcing third-party program rules as apply in enforcing other regulatory rules. The agency can require certain types of reporting by third parties, conduct audits or inspections to verify that third parties are operating in accordance with programs rules, and respond to instances of noncompliance through removing third parties from the program and possibly other sanctions. In this context, the agency's third-party program rules apply to the private bodies that form the third-party system rather than the regulated entities themselves. (*See also* Administrative Conference of the United States, Recommendation 94-1, The Use of Audited Self-Regulation as a Regulatory Technique, 59 Fed. Reg. 44,701 (Aug. 30, 1994)).

(c) An agency that establishes a third-party program should set forth, to the extent possible, how it intends to conduct such oversight of third-party participants. The agency may determine, for example, that it will assess the performance of accreditation bodies every few years; that it will conduct a certain number of audits of accreditations or certifications; or that it will carry out a market surveillance program that will test a certain number of products off the shelf each year. Special rules may be necessary to ensure that agencies are able to conduct desired oversight activities, such as requiring,

as a condition for accreditation, that certification bodies maintain agreements with entities they certify to allow the agency to observe certification audits.

(d) The agency should retain backstop enforcement authority over regulated entities, which could be used when the agency discovers through the third-party program or otherwise that a regulated entity is out of compliance.

(e) As in traditional regulatory programs, agencies should be equipped to receive and respond to information from the public about potential or actual noncompliance. When third parties have played a role in assessing compliance, the agency should provide for the option of directing a public complaint to the relevant third-party body for an initial investigation. The agency, however, must remain responsible for ensuring that the complaint is resolved. The agency could also require that employees of accreditation bodies and conformity assessment bodies be given information about how to contact an official within the regulatory agency anonymously to report any potential problems.

(f) The agency may require accreditation bodies and conformity assessment bodies to undertake certain activities that provide information for oversight purposes. Accreditation bodies may be required, for example, to conduct periodic audits of the certification bodies they accredit. Certification bodies may be required to conduct surveillance audits of the entities and products they certify. In both cases, the agency might also require that some or all of the audits be unannounced rather than announced. Without unannounced audits, accreditation and conformity assessment bodies may lack the incentive to do them for fear of offending existing clients. Agencies can make unannounced audits of facilities mandatory by ensuring that regulated entities agree to such audits as a condition of certification.