

## **The Need for Centralized Regulatory Review**

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ANVISA, the Civil House and their fellow ministries are to be complimented for addressing a timely topic, oversight of Brazilian regulatory agencies.

Brazil's growing and dynamic economy can be hindered by a lethargic regulatory system. In fact a number of international organizations have ranked Brazil's regulatory system considerably lower than a number of its neighboring South American countries.

Brazil is a major player on the world economic stage. It has the fifth largest population in the world; its GDP exceeds that of Russia not to mention India. An improvement in its regulatory system will allow Brazil to maintain its dynamic growth.

I am with CRE Brasil, an NGO located in Sao Paulo. We monitor and report on the activities of Brazilian regulatory agencies through the CRE Brasil website, <http://cre.org.br/>.

Based upon our work as of this date, we believe Brazil's continued economic growth is dependent upon a steady stream of investment from foreign multinational corporations. We also believe it is questionable whether the past level of foreign investment will continue in the absence of regulatory reforms. In particular we believe Brazil must place

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a high priority on honoring commitments to outside parties made during the regulatory process, it must diminish conflicting decisions among regulatory agencies and it must make regulatory decisions transparent.

The regulatory regime in Brazil started in a manner similar to the evolution in many countries, from the “bottom-up”. However as governments grow and regulatory agencies mature, additional oversight is in order.

In my opinion, Brazil is in need of a central authority to direct its regulatory structure, and the faster this is done, the faster international investors will respond in a favorable manner. In a like manner, the Inter-American Development Bank should continue to support research and development aimed at making structural improvements in the regulatory process in addition to its existing, and occasionally over emphasis on geographic-specific improvements.

Regulatory improvement is a function of oversight from groups within the government as well as groups from outside the government. The IDB should institute a program to assist outside groups in reporting on the transparency of Brazilian regulatory agencies.

I am not in a position to state that the events and actions taken in one country will necessarily work in another country, but since I was instrumental in establishing regulatory review in the US White House Office of Management and Budget, I would like to share those experiences with you with the intent of providing you an additional input into your deliberations.

## Establishment of the Federal Information Triangle

Centralized review authority in the US White House Office of Management and Budget evolved into what might be called the Federal Information Triangle. After all, timely, accurate and transparent information is the heart of a sound regulatory structure.

The “Federal Information Triangle” consists of three key components. At its apex stands the Office of Information & Regulatory Affairs in the White House Office of Management and Budget (OMB). Its base is supported by the Paperwork Reduction Act on one end and the Data Quality Act on the other. Basically, the Paperwork Reduction Act controls the information that the government collects; the Data Quality Act controls the information that the government disseminates, and OMB administers these two statutes and the attendant Executive Orders needed to discharge the totality of the functions set forth in the Paperwork Reduction Act. Consequently, the flow of scientific and technical information among agencies to support science policy efforts such as the release of risk assessments will be impacted by these statutes and related guidance.

### **OMB's Office of Information and Regulatory Affairs (OIRA)**

OMB's OIRA has overall responsibility for the review of federal regulations and the establishment of federal information policy. The office had its genesis in the Quality of Life Review originated by the Nixon Administration.

#### *Nixon/Ford Administrations*

The Quality of Life Review was established to analyze federal regulations in the

environmental, health and safety areas. Consequently, it focused on EPA, OSHA, NOAA, portions of the Department of Interior, and the Army Corps of Engineers. It was not mandated by an Executive Order, but simply by a memorandum to the heads of agencies from then head of OMB, George Shultz.

OMB's role in the Quality of Life Review differed in a major way from the process OMB currently uses under its Executive Order for Regulatory Planning and Review (E.O. 12866). More specifically, OMB would send proposed regulations out to the affected agencies, receive their comments, resolve differences among agencies and then develop an Administration position. The process used for the review of regulations paralleled that used for the formulation of an Administration position on legislation. Comparatively, there is little interagency review under the current OMB review process. In essence OMB served as judge not the initial reviewer of regulations.

In that the Quality of Life Review was the first explicit Presidential review of regulations in a systematic fashion, it was very controversial and subject to considerable litigation, Congressional oversight and publicity in the press. Without the experiences gained from the Quality of Life Review, actions by subsequent Administrations would have either failed or would have occurred at a much slower pace.

The Quality of Life Review continued through the Ford Administration. However, on the last day of the Ford Administration, a high-ranking EPA official unilaterally canceled the agency's participation in the Quality of Life Review.

### *Carter Administration.*

The Carter Administration, although not commonly viewed as an agent of regulatory reform, had a major impact on centralized regulatory review.

Many people are not aware of the fact that it was the Carter Administration who established the first OMB-wide office on regulatory review; it was called the Office of Regulatory and Information Policy. In establishing this office although the Carter Administration did not require OMB review of individual regulations, it did Issue Executive Order 12044, which for the first time established government-wide principles for the development of federal regulations. The Carter Administration also set up a review process co-chaired by the Council of Economic Advisors and OMB to give a detailed review to a select number of regulations; this group review group was called the Regulatory Analysis Review Group.

At the same time, OMB had been reviewing paperwork requirements under the old Federal Reports Act. This Act did not grant OMB overly significant review powers. Consequently, OMB initiated a legislative proposal to improve this system. In doing so, Administration officials had the foresight, nearly three decades ago, to move to improve federal information policy. As a result of the diligence of the Carter Administration, the apex and foundation of US regulatory policy emanated from the passage of the Paperwork Reduction Act in 1980. President Carter signed this seminal

measure in his last days in office, notwithstanding opposition from a majority of his Cabinet.

The Act gave unchallengeable authority to OMB to review paperwork burdens imposed by agencies. The Act also established by statute, the Office of Information and Regulatory Affairs in the White House Office of Management and Budget. The establishment of this office received the majority of the attention. However, a complete reading of the Act clearly demonstrates that the PRA itself was equally significant in establishing a framework for federal regulatory and information policy.

### *Reagan Administration*

The Reagan Administration, whose leadership campaigned on a theme of reducing the burden that federal regulations impose on the public and private sectors, issued the landmark Executive Order 12991. Executive Order 12291 which required regulations issued by all Executive Branch agencies to go through OMB for analysis and comment. OMB would have not been able to discharge this responsibility, had it not had experience under the Quality of Life Review and under the then- operating Office of Regulatory and Information Policy established by President Carter. In particular, OMB would not have had the hands on experience to establish a government-wide , timely regulatory review system which worked---critics would have had the prevailing hand.

It should be noted that although the Reagan Executive Order applied only to Executive Branch agencies, the independent agencies agreed to comply with its principles on a

voluntary basis, but not to submit their regulations to OMB. Although there was an exemption from OMB review of the activities of independent agencies in the Executive Order, there was no such exemption in the Paperwork Reduction Act.

#### *Clinton and Bush Administrations*

With the arrival of the Clinton Administration, they also issued an Executive Order and were instrumental in improving the Paperwork Reduction Act by passing amendments to the Act in 1995. Clinton support for centralized regulatory review was a critical event because it gave the process the needed bipartisan support without which the system could have vanished. Both Bush Administrations were very supportive of central review; Bush II expanded the scope of regulatory review; for a complete history of the evolution of central review, see <http://www.thecre.com/ombpapers/centralrev.html>

Consequently, one can readily conclude that the role of OMB in Information policy and regulatory review has been supported on a bipartisan basis for nearly three decades.

#### **Paperwork Reduction Act (PRA)**

The Paperwork Reduction Act is well established, and there is reasonably good compliance with the Act, although one can find a number of violations at any given time. Basically, the PRA controls all information coming into the government. It is important to note that it not only controls information submitted to the government (i.e., reporting requirements), but it also controls information that the federal government requires outside parties to maintain (i.e., record keeping requirements). It even applies to the labeling that federal agencies mandate on products.

Since so many regulations include recordkeeping or reporting requirements, virtually all regulations have to go to OMB under the Paperwork Reduction Act for review, even in the absence of an Executive Order. However, in the absence of an Executive Order, OMB's range of review *might* be constrained. The Paperwork Reduction Act, coupled with OMB's oversight and implementation of the Act worked well for a number of years.

However, as will be explained in the next section, notwithstanding legislative passage of statutes designed to “regulate the regulators” – “good government” statutes – technological advances such as the Internet and the proliferation of agency websites required that the vanguard of “good government” statutes, the Paperwork Reduction Act, be reinforced notwithstanding the presence of OMB as the overseer of the federal regulatory process.

### **Data Quality Act**

As a result of the passage of the “good government” statutes, including the Paperwork Reduction Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and the Congressional Review Act, agencies began to look at ways to bypass OMB review. They found the superhighway of all bypasses in the Internet. More specifically, by placing a study, a risk assessment, or a statement about a product or a production process on the Internet, agencies had immediate impact throughout the world on the thinking of federal agencies and state and local governments, including potential litigants. In essence, the agencies began to use the dissemination of information

through the Internet as a “backdoor *Federal Register*.” Acting in this manner agencies were able to bypass OMB review; the Paperwork Reduction Act and the Executive Order on Regulatory Review; reinforcing actions had to be taken to ensure that the regulatory review process was not going to be compromised by the publication of non-rules (reports) in the *Federal Register*.

The Center for Regulatory Effectiveness (CRE) was founded in 1996 at the request of House and Senate leadership to aid them in the implementation of the Congressional Review Act. The Center soon expanded its mission to include the development of mechanisms to improve the federal regulatory process.

CRE concluded that there was a need for “standards of care” which would govern the release of information by federal agencies. More specifically, CRE concluded that there was a need for: (1) OMB issuance of guidance setting minimum standards that data must meet before it is disseminated by the federal government; (2) agency issuance of guidance that not only conforms to OMB’s guidance, but tailors such guidance to the unique circumstances and programs of the particular agency or components thereof, and (3) the establishment of a petition process where the public could request a change in information disseminated by federal agencies. CRE presented its proposals to the general public, to the regulated industry and to interest groups through its website. After considerable discussion, CRE refined its proposal and disseminated its findings and conclusions to the Congress. Congress enacted Data Quality legislation in the FY 2001 Consolidated Appropriations Act (P.L. 106-554). That legislation incorporated

many of the suggestions proposed by CRE. The passage of the Data Quality (Information Quality) Act completed construction of the Federal Information Triangle, consisting of OIRA at its apex, and the Paperwork Reduction Act and the Data Quality Act as the two corners in its base.

*Consequently, Brazilian authorities should recognize that in the US the establishment and refinement of centralized regulatory review took place over nearly four decades and eight Presidential Administrations.*

### **Concluding Observations**

- The development of sound analytical techniques is a necessary, but not a sufficient, condition for regulatory review; without a central regulatory authority it doubtful that serious attention will be given to regulatory impact analyses.
- The most critical component of instituting a regulatory review system is to establish a central regulatory authority responsible for issuing “good government” rules which “regulate the regulators” and having the authority and resources to enforce the rules.
- The central regulatory authority must:
  - demand and enforce commitments made by regulatory agencies to outside parties.
  - implement a conflict resolution process for resolving conflicting directives issued by regulatory agencies.
  - Insist that the activities of regulatory agencies be transparent.