

March 16, 2009

Office of Information and Regulatory Affairs
Attn: Mabel Echols
Office of Management and Budget
Room 10102, New Executive Office Building
725 17th Street, NW
Washington, DC 20503

Docket: E9-4080, *Federal Register*: February 26, 2009 (Volume 74, Number 37)

Dear Sir/Madam:

Thank you for the opportunity to comment on the principles and procedures governing regulatory review. The biotechnology industry is regulated by multiple agencies and therefore has a keen interest in regulatory developments that may affect the continued ability of the industry to provide innovative products.

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. BIO also represents state and regional biotechnology-derived associations, service providers to the industry and academic centers.

BIO's members are regulated by or are affected by regulatory programs at most U.S. government departments and agencies, including but not limited to: U.S. Department of Health and Human Services, U.S. Department of Agriculture, U.S. Department of Commerce, U.S. Department of Energy, U.S. Environmental Protection Agency, U.S. Department of the Interior, U.S. Department of Justice, U.S. Department of the Treasury, Office of the U.S. Trade Representative, and the Small Business Administration. Therefore, the regulatory process across the federal government can have significant impact on the ability of the industry to research and develop innovative products to heal, feed and fuel the world.

In its *Federal Register* notice, the Office of Information and Regulatory Affairs (OIRA) in particular requested comments in eight areas: 1) The relationship between OIRA and the agencies; 2) Disclosure and transparency; 3) Encouraging public participation in agency regulatory processes; 4) The role of cost-benefit analysis; 5) The role of distributional considerations, fairness, and concern for the interests of future generations; 6) Methods of ensuring that regulatory review does not produce undue delay; 7) The role of behavioral sciences in formulating regulatory policy; and 8) The best tools for achieving public goals through the regulatory process. BIO provides the following comments on these areas and other general principles important for the U.S. government regulatory process.



Relationship between OIRA and Agencies

OIRA has an important role in the coordination of agencies' proposed regulations to be consistent with policies that cross agencies' jurisdictional boundaries. For example, agricultural plant biotechnology is regulated by three government agencies, and it is essential to our members that the regulatory activities of these agencies do not conflict. That being said, the expertise of the regulating agencies and their differing statutory mandates must be recognized and accepted, particularly on matters related to science or safety.

OIRA also can play a useful role in coordinating the review of proposed regulations to ensure that they are consistent with U.S. international obligations.

In its review capacity, OIRA should ensure that alternatives to regulations have been examined and that agencies have identified the least burdensome approach to regulations that may effectuate the same outcome as a more burdensome regulatory approach. Particularly in the current economic climate, OIRA can also facilitate agencies' consideration of mechanisms to promote job growth and economic activity.

Disclosure and Transparency

BIO fully supports a transparent regulatory process that provides appropriate protection for trade secrets and other confidential business information. We support a transparent interagency review process under OIRA's oversight, in which appropriate restrictions are placed on ex parte communications and guidance is provided to agencies and the regulated community.

Encouraging Public Participation

One of the strengths of the U.S. regulatory system is its process for encouraging public participation through public comments. Generally, the current system and policies balance the need for public participation and avoidance of undue delay in promulgating regulations. We note that all agencies should consistently collect public comments via the Regulations.gov web portal so that all interested parties have an opportunity to review comments as they are received by the agency. In addition, new initiatives could further benefit from public dialogue meetings and workshops to explain the intent of the proposed initiative and to collect experience and input from related activities to make the proposed initiative as practical and workable as possible.

Role of Cost-Benefit Analysis

Cost-benefit analysis may sometimes inform regulatory decision-making processes, but should not necessarily be the determinant analysis, and in some cases may not be necessary. For example, use of cost-benefit analyses to develop regulations, or incorporation into regulations of requirements to conduct cost-benefit analyses, may be inappropriate either when it conflicts with an agency's statutory mandate or when it is impossible to define and assess benefits in a way that allows science-based comparison to costs. In addition, the use of cost-benefit analysis by regulating agencies may be inappropriate when the role of government should instead be

restricted to providing information that can subsequently be used by the private sector in cost-containment efforts.

OIRA can play an important role in ensuring that cost-benefit analysis is not misused to pursue the goal of cost containment to the detriment of other public goals. Among other things, OIRA should verify the methodology used by an agency to assess costs and benefits, and determine whether cost benefit analysis is a necessary part of a regulatory approach. OIRA itself may conduct cost-benefit analysis to help identify less burdensome approaches to regulations that can achieve comparable outcomes.

Distribution, Fairness, and Interests of Future Generations

As part of the review process of public comments, agencies are already required and expected to consider all comments submitted, including those related to fairness, distribution of costs or benefits, and the interests of future generations. Furthermore, agencies are specifically directed by Executive Order to consider the distribution of impacts. For example, agencies must consider disproportionate impacts on specific groups, such as children, minorities, and low-income populations. Agencies also necessarily need to consider how regulations will impact or promote U.S. interests.

It is difficult to envision how additional analysis in these three areas would enhance or facilitate the regulatory process, particularly as it relates to the interests of future generations. Clarification of the phrase “interests of future generations”, as intended by OIRA, is needed before BIO could comment further on its place in regulatory decisionmaking. For example, by “interests of future generations,” is OIRA referring to sustainability? We note that the “interests” of generations far in the future are likely to be very difficult or impossible to define and evaluate.

In view of OIRA’s next consideration, “Undue Delay,” BIO requests to know how OIRA would implement any additional analyses without causing undue delay.

Undue Delay

The Office of Management and Budget, of which OIRA is a part, currently has a 90 day limit to provide interagency review of an agency’s non-emergency regulations. This is an appropriate time period. Any shorter time frame would provide insufficient opportunity for interagency review, and any longer period of time would cause unnecessary delays. BIO believes that the absence of predictable time frames for regulatory decisions (or established time frames that are not consistently met) can lead to unacceptable uncertainties that discourage and inhibit technological innovation, particularly for small businesses.

Behavioral Science

BIO believes that regulatory decisions should be based on objective scientific data and, where an agency’s statute permits, an evaluation of the balance between risks and benefits, including the ability to promote economic activity. Without better definition around the term “behavioral

science” and its place in the regulatory process, it is difficult to comment with any specificity on the appropriate role of behavioral science in such critical areas as risk assessment and risk management (for example, does it include neuroscience? Does it include public opinion research?). Furthermore, inclusion of a new area of science and determinations of the relevance of particular scientific findings to an agency’s statutory mandate should reside with scientific experts within the agency during development of regulations.

Tools for Public Goals

Regulations are important tools to achieve public goals, particularly in providing for safety and promotion of economic activity. However, regulations must be grounded in statutory authority and sound science and should not be created without the legal and scientific basis to support them.

Thank you for the opportunity to provide comments on principles and procedures governing regulatory review.

Sincerely,



Tom DiLenge
General Counsel and Vice President
Legal & Intellectual Property