and standards, policy recommendations, and guidance for the procurement, operation, safety, and disposal of civilian agency aircraft; (ii) operating a government-wide aircraft management information system; (iii) identifying and advising agencies and OMB of opportunities to share, transfer, or dispose of underutilized aircraft; to reduce excessive aircraft operations and maintenance costs; and to replace obsolete aircraft; (iv) providing other technical assistance to agencies in establishing their own automated aircraft information and cost accounting systems and conducting the cost analyses required by this Circular; (v) reviewing proposed agency internal aircraft policies for compliance with OMB guidance and notifying OMB of any discrepancies; and (vi) conducting an annual study of the variable and fixed costs of operating the different categories of government aircraft and disseminating the results for use in making the cost comparisons required in Section 8.a.(ii) and reporting the trip costs as required in Section 10.c.

In order to carry out these responsibilities, the Administrator of General Services shall maintain an interagency aviation policy working group to advise him in developing or changing aircraft policies and information requirements.

d. Except for provisions of this Circular which specify their own implementation dates, each agency head shall issue internal agency directives to implement this Circular no later than 180 days from the date of the Circular. These internal agency directives must include all policies contained in this Circular, but may also contain additional policies unique to the agency. Responsibility for these policies shall be assigned to a senior management official who has the agency-wide authority and resources to implement them.

13. *Accounting for Aircraft Costs.* Agencies must maintain systems for their aircraft operations which will permit them to: (i) justify the use of government aircraft in lieu of commercially available aircraft, or the use of one government aircraft in lieu of another; (ii) recover the costs of operating government aircraft when appropriate; (iii) determine the cost effectiveness of various aspects of their aircraft programs; and (iv) conduct the cost comparisons required by OMB Circular A–76 to justify in-house operation of government aircraft versus procurement of commercially available aircraft services. Although agency accounting systems do not have to be uniform in their design or operation to comply with this Circular, they must accumulate costs which can be summarized into the standard Aircraft Program Cost Elements defined in Attachment B. The use of these elements to account for aircraft costs is discussed in Attachment A.

14. *Effective Date.* This Circular is effective on publication.

15. *Information Contact.* All inquires should be addressed to the General Management Division, Office of Management and Budget, telephone number (202) 395–5090.

Richard Darman,

Director.

[FR Doc. 92–4268 Filed 2–26–92; 8:45 am]

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OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Announcement of policy.

SUMMARY: Biotechnology is the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components. Because these diverse processes, products and services may find application in many areas, such as medicine and pharmaceuticals, agriculture, energy, manufacturing, and environmental protection, the attendant planned introduction of biotechnology products into the environment may be subject to federal oversight under the federal statute(s) relating to each such area. The statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight..

In 1986 the "Coordinated Framework" was issued to explain the proper allocation and coordination of oversight responsibilities under the several relevant statutes and among the several relevant federal agencies. The Coordinated Framework thus addressed who shall have oversight authority in each instance, but did not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion.

To fill that need, the Federal Register notice sets forth the proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute. It describes a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique.

In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.

These principles recognize the desirability of appropriate oversight of unreasonable risks, such as current restrictions on the introduction of dangerous pathogens; the principles also confirm the limited extent of current oversight of low-risk activities, such as the traditional breeding of farm animals and plants.

Means for implementing these principles are illustrated; specific implementation must be developed in the context of each agency's statutory programs. Because this Final Statement on Scope addresses the exercise of oversight discretion within the scope of statutory authority, nothing herein displaces agencies' duties under applicable statutes, nor provides additional authority not available under applicable law.

Dated: February 24, 1992.

D. Allan Bromley,

Director, Office of Science and Technology Policy.

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I. Background

A. Statutes Pertaining to Biotechnology Products

Biotechnology is the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components. See Report on National Biotechnology Policy (President's Council on Competitiveness: Feb. 1991), p. 1. Because these diverse processes, products and services may find application in many areas, such as medicine and pharmaceuticals, agriculture, industry, and environmental protection, the attendant planned introduction of organisms or other biotechnology products into the environment may be subject to federal oversight under the one or more federal statutes relating to each such area. The **Federal Register** of November 14, 1985 (50 FR 47174) contains a matrix of the many federal authorities related to biotechnology products. There is no single, unified statute governing all introductions of biotechnology products into the environment, just as there is no single, unified statute governing the use of any other basic, multipurpose technology such as chemical engineering, civil engineering, or the use of fire or electricity. A single statute would quickly become obsolete, or an excessive constraint on innovation, as people devised new and useful ways to employ the technology, and would fail to address the important differences in the potential impacts of the technology when used in different ways.

Introductions into the environment of biotechnology products are therefore subject to government oversight pursuant to statutory authority corresponding to the particular type of introduction in question. The Federal Plant Pest Act governs the importation and movement of plant pests; the Federal Food, Drug and Cosmetic Act (FFDCA) governs foods, food additives, cosmetics, human and veterinary drugs, and medical devices; the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) governs pesticides; the Toxic Substances Control Act (TSCA) governs chemicals; several statutes (the Clean Air Act, Clean Water Act, Oil Pollution Act, "Superfund" law, and Resource Conservation & Recovery Act) govern the use of pollution control techniques; and certain statutes govern projects that are federally funded. One or more of these laws may apply to introductions of biotechnology products for research or commercial purposes.

Each of these laws is administered by a Federal agency. For example, the Food & Drug Administration (FDA) administers FFDCA; the Environmental Protection Agency (EPA) administers FIFRA, TSCA, and the pollution-control statutes; and the Department of Agriculture (USDA) administers the Federal Plant Pest Act while also funding many research projects involving biotechnology.

Each statute directs the implementing executive branch agency to carry out certain responsibilities. The statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight. Typically each statute leaves the agency discretion within those bounds in exercising oversight.

B. The "Coordinated Framework" and the Need for a Scope Document

In view of the diversity of Federal statutes pertaining to biotechnology products, in 1986 the Coordinated Framework for the Regulation of Biotechnology was issued to describe the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It explained that existing statutes provide a basic network of agency jurisdiction over both research and products, assuring reasonable safeguards for the public and the environment. It also explained the coordination among Federal agencies to ensure that such safeguards would be generated by a smooth, understandable regulatory oversight process. The Coordinated Framework stated that "to the extent possible, responsibility for a product use will lie with a single agency." (51 FR 23363). The Framework was expected to evolve in light of experience, and modifications to the framework were anticipated. The Coordinated Framework for the Regulation of Biotechnology continues to be Federal Government policy today for the allocation of oversight responsibilities—which agencies shall have oversight responsibility for which biotechnology products.

But the Coordinated Framework did not fully address how oversight should be exercised within the scope of discretionary authority afforded by statute. The Coordinated Framework recognized that while the statutory bases for regulation among the involved agencies may differ, common principles should govern decisions on how to exercise discretionary oversight over introductions of biotechnology products.

C. Proposed Statement on Scope

In order to fill that need, the Federal agencies worked closely to devise such a common statement of the basis for exercising oversight within the scope of discretionary authority afforded by statute. This statement has commonly come to be called the "Scope" document. In July 1990, OSTP published a proposed version of the Scope document prepared through the Interagency Biotechnology Working Group of the President's Council on Competitiveness, which had been asked to review the scope issues by the Director of OSTP after prior attempts to develop a scope had not reached consensus and because the Director observed the need for attention by an interagency group concerned with policy implications as well as scientific issues. This history of this effort is detailed in the Proposed Scope document published by OSTP. See "Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms with Modified Hereditary Traits," 55 FR 31118 (July 31, 1990). The Proposed Scope set forth a risk-based approach to the scope of oversight: "To the extent permitted by law, planned introductions into the environment of organisms with modified hereditary traits should not be subject to oversight * * * unless information concerning the risk posed by the introduction indicates that oversight is necessary." 55 FR at 31120. This statement expresses a risk-based approach that focuses on the properties of products introduced into the environment, the characteristics of

the target environment, and the confinement measures employed, rather than on the process or technique by which the product was created. Information on the process could provide evidence of likely risk and of quality control in production, but the nature of the process could not be the sole or dispositive criterion for triggering oversight. The Proposed Scope delineated possible criteria for evaluating risk, pertaining to both the organism and the target environment into which it was introduced.

The Proposed Scope also suggested six examples of categories for exclusion from oversight. Five of these categories were defined by modifications such as selective breeding, transformation, deletions and use of noncoding marker genes. The sixth category consisted of modified organisms that present no greater risk than their unmodified parental strains.

D. Public Comments on the Proposed Scope and Subsequent Policy Developments

The Proposed Scope was issued for public comment. A summary of the public comments received is provided in the appendix below.

In addition, several important policy developments have occurred since the issuance of the Proposed Scope, which have been taken into account in developing the current final statement on Scope. These developments include a decision by the President to approve Principles for Regulatory Review for Biotechnology, and an EPA report endorsing the risk-based approach to environmental policy. These policy. These policy developments are also summarized in the appendix.

Agency proposals that address the introduction of organisms into the environment have also been issued since the Proposed Scope. On February 1, 1991, USDA proposed guidelines (56 FR 4134) which set out points-to-consider for scientists in designing field trials and were intended to provide quality assurance for federally-funded agricultural research.

EPA is considering proposed regulations under FIFRA for small-scale release of microbial pesticides titled: Microbial Pesticides; Experimental Use Permits and Notifications, and proposed regulations under TSCA titled: Microbial Products of Biotechnology; Proposed Regulations under the Toxic Substances Control Act.

The present final statement of principles for the exercise of oversight within the scope of statutory authority is based on interagency deliberations since July 1990 and careful consideration of all the items set forth at greater length in the Appendix, including consideration of comments from public and subsequent policy developments. As indicated below, the fundamental risk-based approach in the Proposed Scope received widespread endorsement and has been retained and strengthened in today's final statement.

II. Rationale for Risk-Based Approach

The propose of this statement is to guide the exercise of agencies' oversight, within the scope of authority afforded by statute, to ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions. This approach therefore focuses on the characteristics and risk posed by an introduction, rather than on the process by which a product is created. This is the same fundamental, risk-based approach enunciated in the Proposed Scope in July 1990 (see 55 FR at 31119), and endorsed by the great majority of public comments on the Proposed Scope (see appendix below). The risk-based approach is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations. Citing these rationales, the first Principle of Regulatory Review for Biotechnology approved by President Bush in August 1990 requires the federal government to adhere to a risk-based approach. Likewise, the EPA Report on Risk Priorities issued in September 1990 and the Competitiveness Council Fact Sheet on Critical Technologies issued in April 1991 explain the imperative of following a risk-based approach. (See excerpts in appendix, below.) This section briefly explains the reasoning behind this risk-based approach.

A. Scientific Principles for the Risk-Based Approach

Introductions of organisms into the environment may pose hazards to humans, wild or domesticated plants and animals, or to the environment generally (for example, algal blooms in ponds or disruptions of natural cycles). The risk posed by an introduction of biotechnology products into the environment is a function of the characteristics of the organisms or other products, the particular application (including confinement measures), and the environment itself. As stated in the Coordinated Framework, "Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval." (51 FR 23303). Even many organisms that are pathogenic are routinely used with practices or under conditions that mitigate risk; much of the research within the discipline of plant pathology is in this category. Meanwhile, certain unmodified organisms are of such great risk that they are not allowed into the United States, such as the Foot and Mouth Disease Virus (FMDV).

Just as with traditional breeding techniques, the production of organisms using new molecular techniques of genetic manipulation may or may not pose risk, depending on the characteristics of the organism, the target environment, and the type of application. The National Research Council's extensive review of the potential risks of introductions of organisms made from new biotechnology processes (NRC, Field Testing Genetically Modified Organisms (1989)) reached the conclusion that organisms that have been genetically modified are not *per se* of inherently greater risk than unmodified organisms.

It elaborated:

1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods. (p. 15)

2. Information about the process used to produce a genetically modified organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight. (pp. 14 and 15.)

3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes. (p. 14)

4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits. As the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants. (p. 3)

5. In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganisms, but many of the new methods have two features that make them even more useful than the classical methods.

Precision allows scientists to make genetic modifications in microbial strains that can be characterized more fully, in some cases to the level of DNA sequence. This reduces the degree of uncertainty associated with any intended application. The new methods

have greater power because they enable scientists to isolate genes and transfer them across natural barriers. (p. 123)

The process of modification is thus independent of the safety of the organism. Although the new biotechnology processes can be used to produce risky organisms, so can traditional techniques; it is the characteristics of the organism, the environment, and the application that determine risk (or lack thereof) of the introduction, not the technique used to produce the organism. Indeed, the new technologies of molecular modification may increase the potential for safe, planned introductions because they employ techniques that are more precise and more efficient than traditional cross-breeding, and that therefore yield a better-characterized and more predictable organism. On the other hand, their great power allows us to transfer genes more readily, thus resulting in organisms with new traits or combinations of traits.

From these scientific observations derive the following fundamental Scope principles:

1. A determination to exercise oversight within the scope of discretion afforded by statute should not turn on the fact that an organism has been modified or modified by a particular process or technique, because such fact is not alone a sufficient indication of risk.

2. A determination to exercise oversight in the cope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism in a particular environment used for a particular type of application is unreasonable.

3. Organisms with new phenotypic trait(s) conferring no greater risk to the target environment than the parental organisms should be subject to a level of oversight no greater than that associated with the unmodified organisms.

B. Risk-Based Approach Ensures Safety

A purpose of government regulation of biotechnology, as with any safety regulation, is to limit unreasonable risks faced by the public and the environment. Yet agency resources are scarce, and cannot be applied to every possible problem; responsible officials must choose carefully the risks of highest concern and find the best way to combat them. In order to protect the public and the environment, the scope of oversight should help focus agency efforts at reduction of the most important risks (and at least cost, so that society's resources are kept available to combat the next highest risks). As the US Environmental Protection Agency (EPA) recently stated.

There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks. (US EPA, SAB, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," Sept. 1990, Exec. Sum., (p. 2.))

C. Risk-Based Approach Avoids Discouraging Useful Innovation

Determining the scope of oversight on grounds other than risk would also tend to discourage useful innovations. The potential benefits of biotechnology are enormous; as described in the February 1991 Report on National Biotechnology Policy, innovation in biotechnology has begun to make possible great improvements in our ability to grow food, protect the environment, and produce medications, among other applications. Triggering the exercise of oversight based on the use of a specific innovative technology, such as recombinant DNA, will tend to discourage the use of that technology by industry and researchers.

The distribution of oversight burden across technologies is in many ways as important as the total amount of burden: If oversight is aimed only at one type of technology, the burden will be skewed against that technology and hinder its development. New regulations often place greater restrictions on new products or technologies while grandfathering in older, and sometimes more risky, products or technologies. This uneven regulation encourages the continued use of older products and technologies, while discouraging innovation and potential risk reduction.

Similarly, special oversight directed at "new techniques" in biotechnology could discourage innovations using those techniques.

III. Final Statement on Scope

Statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight. Within the scope of authority provided by statute, federal agencies shall exercise oversight of planned introductions of biotechnology products into the environment only upon evidence that the risk posed by the introduction is unreasonable. A risk is unreasonable where the full value of the reduction in risk obtained by oversight exceeds the full cost of the oversight measure. This formulation ensures that limited federal oversight resources will be applied where they will accomplish the most net beneficial protection of public health and the environment while allowing useful, safe innovations to proceed. Evidence of risk must incorporate information about the chacteristics of the organism or other biotechnology product, the target environment, and the type of application.

Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product—not the process by which it is created. Products developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Where oversight is warranted, the extent and type of oversight measure(s) must be commensurate with the gravity and type of risk being addressed, must maximize the net benefits of oversight by choosing the oversight measure that achieves the greatest risk reduction benefit at the least cost, and must consider the effect that additional oversight could have on existing safety incentives.

The risk-based approach taken in this Final Statement on Scope is the same as the approach enunciated in the July 1990 Proposed Scope, which provided that "To the extent permitted by law, planned introductions into the environment * * * should not be subject to oversight * * * unless information concerning the risk posed by the introduction indicates that oversight is necessary." 55 FR at 31120. As detailed below, the Final Statement on Scope also retains the "criteria for evaluating risk" suggested in the Proposed Scope. The principal differences between today's Final Statement on Scope and the Proposed Scope are (i) the recognition that there are a variety of oversight measures that agencies might employ, not simply a binary choice between "oversight" and "no oversight," and therefore the provision that agencies choose from among the menu of measures those oversight measures that achieve risk reduction at net benefit and least cost; (ii) the removal of the examples of "categories for exclusion" in the Proposed Scope, because, as described below under "Implementation," those categories were not explained in the basis of risk and ignored the need for each agency to have the flexibility to fashion its implementation in the context of its statutory program. These differences are warranted in the interest of sound public policy, and reflect the numerous public

comments (summarized in the appendix) recommending such revisions.

IV. Implementation

A. Exercising Discretion Within the Scope of Statutory Authority

As described above, this Final Statement on Scope guides agencies' exercise of oversight within the scope of discretion provided by statute. Nothing in this document displaces agencies' duties under applicable statutes, nor does this document provide the basis for additional authority not available to agencies under applicable law. Rather, this document guides the exercise of discretion within the range of authority left to agencies under their statutes. Each agency will need to implement these guidelines in a manner appropriate to each statutory framework, and to exercise its oversight authority consistent with the risk-based principles of this Final Statement on Scope.

This Final Statement on Scope governs all oversight within the scope of agency discretion afforded by statute of planned introductions of biotechnology products into the environment. It does not relate only to new regulatory initiatives or new categories of organisms introduced into the environment. In addition, the term "planned introduction" as used here includes introductions in the course of research and in commercial and other applications. It is not limited to initial small-scale field trials.

In applying the risk-based approach there will of course be areas in which regulatory interventions are frequent, and areas in which such interventions are legally authorized but are less common because the industry operates safely and the occasions for regulation and enforcement are fewer. Such safety could be the result of longstanding industry practices, and of industry's pragmatic understanding that government intervention—whether through federal or state law or otherwise—would occur if safety rules were violated. Although federal oversight for such activities may be legally available, it may be observed that where an industry operates in a safe manner, little or no oversight is commonly exercised. One example of such a safe equilibrium may be traditional agriculture operating with safe organisms following accepted practices and precautions. This is consistent with recommendations made by the National Research Council in the publication, Field Testing Genetically Modified Organisms, 1989, p. 66.

B. Evaluating Risks

Products developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Such determinations should be based on risk factors or criteria like the ones listed below pertaining to the organism's ecological niche, potential for gene exchange, ability to monitor and to mitigate persistence and spread and potential consequences of dissemination into the greater environment. These factors for evaluation of risk are largely derived form the work of the Ecological Society of America. (See J. Tiedje, R. Colwell, Y. Grossman, et al., 70 *Ecology* 298 (April 1989).)

For the Organism: Fitness; infectivity, virulence, pathogenicity, toxicity; host range; the type of substrate or resources utilized; the purity of the formulation; environmental limits to growth or reproduction (habitat, microhabitat); susceptibility to control by antibiotics, biocides, by substrate, or by mechanical means; whether and how introduced traits are expressed.

For the Target Environment: Selection pressure for the introduced trait; presence of wild, weedy or feral relatives within dispersal capability of the organism or its genes; presence of vectors or agents of dissemination or dispersal (e.g., mites, insects, rodents, birds, humans, machines, wind, water); direct involvement in basic ecosystem process (e.g., nutrients cycling); whether there are alternative hosts or partners (e.g., the organism is involved in symbiosis or mutualism); range of environments for testing or use in light of potential geographic range; effectiveness of confinement, monitoring and mitigation plans.

The scope principles do not dictate precisely how information on risk should be evaluated. Different ways of making the risk determination are possible. One means of judging the risk posed by an introduction is to compare its risk to an introduction of a comparable organism or biotechnology product previously used in introductions in a comparable target environment. An organism or other biotechnology product can be comparable to a previously used organism or product regardless of the process by which that organism has been modified or product produced. An introduction should be subject to no greater degree of oversight than was a comparable organism or product previously used in past safe introductions in a comparable target environment. Effective confinement techniques in appropriate cases can also reduce the potential risk of an introduction, and accordingly, the need for oversight.

Unreasonable risk is the threshold for exercising oversight within the scope of discretion afforded by statute. The term does not denote a fixed absolute number. Rather, a risk is "unreasonable" where the environmental benefits achieved by oversight measures to reduce the risk are greater than the social cost of those oversight measures. This definition enables, and requires, agencies to choose from among the range of oversight options those measures that obtain net benefits. Thus, a more demanding oversight option may be warranted when the risk reduction to be gained from government intervention is large. If the risk reduction to be gained is small, as will usually be the case with low-level risks, less costly oversight options will need to apply. As described above under "Rationale for Risk-Based Approach," this formulation ensures that oversight resources will be allocated to address priority risks. "If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks." (US EPA, SAB, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," Sept. 1990, Exec. Sum. (p. 2.) It should also be noted that "unreasonable risk" is already a criterion used by federal agencies, such as in exercising oversight under provisions of TSCA and FIFRA.

Of course, in some cases an agency may not have sufficient information to determine whether the introductions of organisms would pose unreasonable risk, and whether additional oversight therefore would be warranted. In cases in which an agency has reason to believe that introductions could pose risk but lacks adequate information to determine if that risk is unreasonable, agencies may need to collect information. Any information requests should be designed to maximize their benefits and minimize their costs by soliciting only the most useful information in the least costly manner.

Certain terms used to characterize risk evaluation in the Proposed Scope, 55 FR 31118, have been dropped because they were ambiguous and raised concerns among the public commenters. Several comments noted the confusing language and potential circularity of the term "similar organism" or "similar introduction." That usage has therefore been removed and, where appropriate, replaced by the more precise idea of an introduction posing comparable risk to a

previous introduction. The term "organism with deliberately modified hereditary traits" was intended to encompass any organism with changed hereditary traits, regardless of the technique or process used to effect the change. This term was intentionally broader than terms such as "genetically modified organism" which have come to imply a specific technique of genetic manipulation (namely, use of recombinant DNA methods). Yet, "deliberately modified hereditary traits" might not have encompassed exotic organisms introduced by humans into a vulnerable target environment. Thus, the term has been omitted and the focus is now placed on the risk of an introduction, not the genesis of the organism.

C. Assessing Oversight Options

Agencies have a wide variety of oversight options with which to fashion their oversight programs consistent with the risk-based approach enunciated here. The term "federal oversight" includes a range of possible Federal activities related to planned introductions: Issuance of suggested industry practices, development of guidelines for certain introductions, and requirements for notification, labelling, prior review or approval of certain introductions. This range of federal oversight activity might be undertaken by a Federal agency or by a local entity as directed by or under guidance from a Federal agency. It could involve, for example, a research institution establishing an "institutional safety committee" for review of certain planned introduction experiments.

This menu of oversight options means that agencies can choose oversight measures to be commensurate with the gravity and type of risk being addressed, and fashioned to maximize the net benefits to society and the environment, taking into account the costs of oversight.

In determining the risk reduction that may be achieved by a contemplated oversight measure, it is important to recognize that persons introducing biotechnology products into the environment often face other institutional incentives to ensure that such introductions are safe. Such existing safety incentives may include oversight already being exercised under another regulatory authority, state laws, and marketplace incentives for safety created by the interests of workers and consumers in obtaining products that are safe. Safety can also be promoted by generally accepted research practices, professional and industrial association standards, and other safety-oriented guidelines and procedures. It is important to take account of the interplay between the new oversight measure and the pre-existing incentive systems. In some circumstances the effect of a new oversight measure may complement existing safety incentives, but in others its effect may be dampened or undercut by its (unintended) displacement of existing safety incentives. For example, imposing new safety standards may in certain circumstances simply displace existing safety incentives provided by state law or by market price differentials for accepting risk. Agencies should account for these potential incentive effects in their calculation of the net benefits of potential oversight measures. Further, agencies should affirmatively design oversight measures to work in concert with pre-existing safety systems, such as by strengthening the information base on which marketplace incentives depend. In appropriate cases agencies might forgo additional oversight where existing incentives adequately address the risks posed.

D. Use of "Categories of Exclusion/ Inclusion"

1. Treatment of Former Exclusion Examples

The six examples of "categories for exclusion" provided in the Proposed Statement on Scope (55 FR at 31121) have been deleted from the Final Statement on Scope. As these examples were set forth without the context provided by the statutes under which regulations were to be implemented, no rationales were provided in the Proposed Scope relating them to risk. Thus, a certain amount of confusion arose concerning their relationship to risk. Indeed, several commenters suggested that the exclusions were inconsistent with a risk-based approach because they were "process-based." For instance, the first proposed exclusion category contained plants and animals that result from natural reproduction or the use of traditional breeding techniques. Traditional breeding activities, however, are typically of low or trivial risk because the plants and animals chosen for breeding by traditional agricultural breeders are typically of low or negligible risk in their applications and target environments, not because the techniques are themselves intrinsically safe. Because this Final Statement is to be a guidance document to the agencies, it is not meant to provide the risk rationales for these examples. Any agency that wishes to use any of these categories in the context of a specific statute would provide a rationale based on risk.

The five examples of categories for exclusion addressed only various aspects of the introduced organism, whereas the present Final Statement on Scope addresses the entire introduction, necessarily including the characteristics of the target environment and the particular application as well as the nature of the biotechnology product. The five examples for exclusion gave no insight into the critical issue of the potential interactions between an organism's traits and its ecological context. An organism may pose risk in one target environment but be relatively harmless, or beneficial, in another. It is fundamental that the present Final Statement on Scope requires oversight decisions to be made within the scope of discretion afforded by statute based on information about the organism or other product, the target environment and the type of application, not about the organism alone.

The simple binary choice between "oversight" and "no oversight," implied by the notion of a single scope with a single set of exclusions, does not accurately characterize the range of choices open to an agency within the scope of discretion afforded by statute. Oversight measures may include the option of no oversight, or no further oversight in cases where statutes require initial oversight, as well as a range of other measures.

A single list of "exclusions" (or, for that matter, "inclusions") cannot pragmatically be written to apply uniformly to all agencies and all statutes. The specific mechanisms of implementation of the risk-based principles will of course depend on the statute at issue, and accordingly no single list of "categories" can be promulgated for use by all agencies under all statutes. Agencies could, for instance, develop categorical risk-based exclusions from a statute's oversight net, such as where a statute begins by encompassing all of a certain set of activities and then exempts low-risk elements of that set. Or agencies could develop categorical risk-based inclusions in a statute's oversight net, such as where a statute attaches oversight only when an activity creates an unreasonable risk. Or agencies could employ a stratified hierarchy, providing several levels or types of oversight that correspond to levels of risk. The choice of these or other means will depend on the statute and the nature of the activity subject to oversight. Not every statute may be open to all of these options. Indeed, by listing specific "examples of

categories for exclusion," the Proposed Scope issued in July 1990 may have given the incorrect impression that some exclusion-oriented approach was mandatory for all agencies, or that the specific categories listed in that proposed document were mandatory, or that an extra burden of persuasion would be borne by agencies seeking to craft a different approach or set of exclusions; none of these was intended.

2. Developing Categories of Exclusion

The concept of categories for exclusion may nonetheless retain usefulness in appropriate statutory circumstances. Where a statute initially casts a wide net over a field of activity, the agency may retain or be delegated authority to exclude some subcategories of activity from oversight on the ground that the potential risks they pose are too low to justify oversight or that such risks are already adequately overseen by another agency.

For example, under TSCA, EPA must receive notice of all "new chemicals"; those that pose "unreasonable risk" are subject to further regulatory restrictions. But TSCA enables EPA to exclude products from review, in at least four ways. First, EPA may determine that certain products are not "new" and thus do not require premanufacturing notice to the agency. For instance, where small changes in genetic or molecular structure are involved, it may be a matter of judgment whether the product is "new." In exercising such judgment, the agency may determine that certain categories of products are not "new" under TSCA because they possess no "new" properties. Second, under TSCA section 5(h)(3), EPA may exclude microorganisms used in small quantities (defined by rule) for research and development. Third, the agency can decline to act during the 90-day period after a notice is filed. Unless the agency acts, after 90 days the product may be produced without further restriction. EPA could develop guidance to its TSCA program to decline action with respect to certain low-risk categories of introductions of organisms. Fourth, under TSCA 5(h)(4), the agency has the authority to exclude broad categories of products by rulemaking where those products do not pose "unreasonable risk." EPA could propose risk-based 5(h)(4) exclusions for certain categories of introductions, simultaneous with proposing any regulations applying TSCA to organisms.

Similarly, under FFDCA, no "food additive" may be marketed unless it is in compliance with an authorizing regulation promulgated by FDA. However, substances that are "generally recognized as safe," as defined in the statute, are excluded from the definition of "food additive," and therefore from the premarket clearance requirements. For organisms to be used as or to make food ingredients, FDA could describe the criteria by which it will determine the organisms or their products will fall into the "generally recognized as safe" exclusion, or will be subject to premarket regulation.

Thus, agencies exercising oversight pursuant to this document should consider employing risk-based exclusions. For example, an exclusion could be fashioned (if its risk basis is appropriately explained in the context of the particular oversight measure) for organisms whose introductions pose low or negligible risk, e.g. domesticated animal and crop varities used in agriculture.

3. Developing Categories of Inclusion

A different approach could be employed where a statute bases the exercise of oversight on risk and gives the agency the task of affirmatively identifying which particular activities out of a larger universe pose risks sufficient to justify oversight. Agencies could therefore develop risk-based categories of inclusion to define the area of oversight.

For example, the Federal Plant Pest Act governs the movement of plant pests regardless of the process by which the organisms were produced. The Act defines "plant pests" as any organisms "which can directly or indirectly injure or cause disease or damage in any plants or parts thereof * * *" In order to implement the Act, USDA has identified specific organisms with these properties and placed them on a published list. Movement or importation of organisms on the list requires an advance permission from the agency. The list is expanded as new plant pests are identified; also, items can be removed from the list when they are believed to no longer present a plant pest risk.

4. Developing Combined Approaches

In some areas, an agency might use both "exclusion" and "inclusion" approaches. It might identify categories of activities for inclusion on the ground that they pose a sufficient risk to justify oversight, and simultaneously exclude other activities on the ground that they do not present risk justifying oversight. Any activities not included in either category could be dealt with on a case-by-case basis, and perhaps addressed explicitly in categorical exclusions or inclusions at a later date. For example, the guidelines on recombinant DNA organisms developed by NIH use both approaches. An appendix to the guidelines list microorganisms on the basis of likely hazard, an example of the "inclusion" approach. The guidelines also specifically exclude certain organisms, such as *E. coli* K–12, *B. subtilis* and *Saccharomyces*. As another example, an agency might implement a statute requiring public disclosure of all hazardous introductions by explicitly excluding some trivial-risk activities from the duty to disclose, specifically including some categories of introductions that typically pose a potential hazard, and announcing criteria for deciding whether the remaining introductions are risky enough to require disclosure.

Finally, agencies could employ a "hierarchy" of oversight options to correspond to degrees and types of risk. Some statutes arm that agency with an array of oversight instruments to deploy as the circumstances warrant. In such cases, agencies must decide not only whether or not to exercise oversight but also the appropriate level and type of oversight when it is exercised. Agencies could develop categories of criteria for exercise of varying degrees of oversight, based on the degree of risk posed by an introduction, and the costs of oversight options. For example, oversight options might include: guidance on sound practices, simple notification to a local review committee, application for prior approval by a local review committee, notification to a federal agency, considered deference to another agency already overseeing such introduction, or application for prior approval by a federal agency. Or under its statutory authority an agency might impose (as a requirement of all introductions of a certain risk level or as a condition of prior approval in a specific case) disclosure of information, restrictions on a planned introduction, appropriate prophylactic measures (confinement or containment), or prohibition of certain kinds of activities. Other options could also be available under various statutory programs.

One example of such a hierarchical approach to the degree of oversight is contained in USDA's proposed guidelines for federally-funded researchers (56 FR 4134 (Feb. 1, 1991)). The guidelines calculate the likely risk of an introduction of a modified organism according to the likely risk to health and environment posed by introducing the parental strain, and the change in that risk (increase or decrease) effected by modification of the parental strain. For each of five risk levels, they suggest levels of confinement measures to be applied,

and degrees of review by a disinterested party (such as a local safety committee).

Appendix: Comments on Proposed Statement on Scope and Subsequent Policy Developments

Several important statements of government policy on risk and new technology have been published since July 1990. Because these policy guidelines have played a formative role in the development of the current Final Statement on Scope, they are excerpted briefly below. In addition, public comments on the Proposed Statement on Scope were received. The discussion in the present document relies on and refers to the concepts and recommendations contained in these policy guidelines and the views expressed in the public comment letters. The items below are presented in chronological order.

1. President's Principles of Regulatory Review

In August 1990 President Bush approved Four Principles of Regulatory Review for Biotechnology, as follows:

(1) Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product—not the process by which it is created.

Products developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Biotechnology products that pose little or no risk should not be subject to unnecessary regulatory review during testing and commercialization. This allows agencies to concentrate resources in areas that may pose substantial risks and leaves relatively unfettered the development of biotechnology products posing little or no risk.

(2) For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare.

Expedited review procedures should be adopted for products likely to pose lesser risk. The jurisdiction of the several regulatory agencies should be clarified to avoid unnecessary confusion and delay and agencies should use the same standards and apply them consistently. This is especially important where a product could be regulated by several agencies. For example, pest-resistant plants may be subject to regulation by both the Environmental Protection Agency (for pesticidal properties) and by the Food and Drug Administration (for food safety).

(3) Regulatory programs should be designed to accommodate the rapid advances in biotechnology. Performance-based standards are, therefore, generally preferred over design standards.

A performance standard sets the ends or goals to be achieved, rather than specifying the means to achieve it (e.g., through a design standard). This provides firms and researchers with flexibility in choosing the best means of compliance. A performance-based standard for containment, for example, would permit alternative biological approaches for assuring containment in place of a design-based standard requiring specific physical barriers.

The adoption of performance criteria in developing regulations reduces the need to rely on a lengthy and contentious regulatory process to revise regulations. Such unwieldly regulatory procedures inevitably inhibit the changes in regulatory structure needed to accommodate advances in science knowledge. Procedures should be adopted to provide agency decision-makers with up-to-date scientific opinion and knowledge—for example, through the use of science advisory panels.

(4) In order to create opportunities for the application of innovative new biotechnology products, all regulation in environmental and health areas—whether or not they address biotechnology—should use performance standards rather than specifying rigid controls or specific designs for compliance.

"Design-based" requirements may preclude use of biotechnology products even when such approaches may be both less costly and more effective. For example, a requirement to employ specific pollution control equipment would prevent use of innovative biotechnology pollution remediation or control techniques.

2. EPA Report on Risk Priorities

In September 1990 the U.S. Environmental Protection Agency's Science Advisory Board released its report, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection." The report stated (Exec. Sum. p. 2):

> There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks.

Setting regulatory policy based on the process used to modify an organism rather than on the relative risk of its introduction, or based on type of technology (e.g., biotechnology verses other technologies) rather than the relative risk of an activity, would be inconsistent with this risk-based approach; it would misallocate oversight resources and thereby burden low-risk activities while exposing society to higher-risk activities.

3. Summary of Public Comments on the Proposed Statement on Scope

By October 1990, the deadline for submissions, forty-four letters of comment on the OSTP Proposed Statement on Scope (55 FR 31118 (July 1, 1990)) were received. The following is a brief summary of these comments.

(A) Overview

- The general response to the "Scope Document" and the Administration's effort to define a common approach to oversight of planned introductions was positive.
- Commentators strongly supported those principles outlined in the body of the document which emphasized a risk-based approach to regulation.
- The majority of criticisms focused on the "Examples of Potential Exclusion Categories" while other comments related to ensuring implementation of the principles through the regulatory process. Particular words or phrases were cited as vague or otherwise problematic.

(B) Specific Issues

(i) Risk-based Approach

- Thirty-two letters specifically noted the wisdom of a risk-based approach, particularly if the level of oversight is commensurate with the degree of potential risk.
- The "Criteria for Evaluating Risk" were deemed adequate and appropriate in that they focused on characteristics of the organism and the environment into which it is being released, rather than on the process by which the organism is produced.
- Several respondents stated that there is a sufficient body of scientific experience to support risk evaluation as a means for determining need for oversight.

(ii) Examples of Potential Exclusion Categories

- Several respondents supported the use of categories of introductions that could be excluded from oversight as a move away from case-by-case regulatory review.

• The most frequent objection to the exclusion categories (10 letters) was that categories 1–5 were process-based, in contradiction with the principles contained in the body of the document. Thus, several respondents proposed deleting the "Examples of Potential Exclusion Categories."

• At least 3 commenters opposed any regulatory scheme that did not include *all* of the exclusion categories on the premise that current regulatory inconsistencies and confusion would be retained otherwise.

• Five commenters proposed employing category 6 as the cornerstone for federal policy on exemptions.

• It was pointed out that many organisms produced using methods described in categories 1–5 would be subsumed under category 6 if the resulting product posed no greater risk to the target environment than the parental organism.

• Evidence was offered that organisms produced via methods proposed for possible exclusion under exclusion categories 1–5 may still pose health or environmental hazards and, thus, should not be exempted.

• One commenter felt that category 2 should be modified to cover only those exchanges "known to occur in nature" and another suggested adding viruses.

• There was a proposal to add "organisms resulting from mutagenesis by transposable elements" to category 5.

• A new category was proposed comprised of organisms developed using recombinant techniques (such as PCR, *in vitro* mugagenesis, homologous recombination, or other self-cloning methods) which result in phenotypes identical to those obtainable through traditional techniques.

• One letter suggested adding three organisms to the exempt list indicating interest in a process similar to that used by the National Institutes of Health (NIH) whereby conditions under which certain experiments may be performed are considered by petition to the Recombinant DNA Advisory Committee.

(iii) Implementation

• A recurring theme was the need for consistent implementation across agencies. It was suggested that OSTP remain visible and involved in order to ensure interagency consistency.

• Three letters noted the past delays in proposing agency regulations and encouraged rapid implementation of the "Scope Document."

• Four commenters predicted that it would be difficult or impossible to implement this scheme because it was not clear who was responsible for determining the need for oversight.

• Local Industrial Biosafety Committees (IBCs) or similar institutions were proposed as a venue for determination of risk and need for further oversight.

• Two commentators suggested that notification be deleted from the description of oversight methods in order to allow for categories of exemption from other, more burdensome forms of oversight.

• Several respondents stated that a system of licenses or permits was not appropriate for research activities.

(iv) Definitions

• The most problematic word was "similar" when used to describe the situation in which "the level of risk of an introduction is the same as or less than a previous safe introduction." Suggested alternative language in 3 letters was "comparable to or less than."

• Two letters questioned the adoption of the term "modified hereditary traits" as opposed to "genetically modified organisms," which implies that modified traits are heritable, regardless of how the modification was achieved.

• There was a question as to whether or not contained field tests would be included under "planned introductions into the environment."

(v) Additional Issues

• Four respondents proposed alternate schemes, three of which involved the development of lists of exempt organisms or introductions. Suggested criteria for inclusion on such a list were "familiarity" or inclusion on the list currently maintained by CDC and NIH.

• OSTP was reminded that this document will play an important role in international negotiations and product export.

4. Report on National Biotechnology Policy

In February 1991, the President's Council on Competitiveness published the Report on National Biotechnology Policy. The Report describes the Administration's policy on biotechnology regulations (p. 11)

In biotechnology, as in many other high technology industries, Federal regulation is a critical determinant of the time and cost to bring a product to market. In serving as "gatekeepers" for the development and use of new products, regulatory agencies may create substantial barriers to product development. These barriers result from the costs of testing to meet regulatory requirements, the potential for delay in regulatory approval, and the uncertainty associated with the possible imposition of extensive restrictions or outright disapproval of new biotechnology research or products. In addition, uncertainty related to the extent or effectiveness of Federal regulation may lead to the enactment of a patchwork of conflicting and burdensome state regulations. Delay, cost, and regulatory uncertainty discourage new research in regulated areas and curtail the development of new products, as well as undermine public confidence.

In general, to avoid unnecessary burdens on biotechnology, the Administration has sought to eliminate unneeded regulatory burdens for all phases of the development of new biotechnology products—laboratory and field experiments, products development, and eventual sale and use. Existing regulatory structures for plants, animals, pharmaceuticals, chemicals and toxic substances provide an adequate framework for regulation of biotechnology in those limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment. In these instances, regulation also can help shield industry from avoidable incidents that could tarnish its image and impair its development.

5. Competitiveness Council Fact Sheet on Critical Technologies

In April 1991 the President's Council on Competitiveness issued a Fact Sheet concurrently with the OSTP publication of the Report of the National Critical Technologies Panel. The Fact Sheet stated:

Because technological innovation holds the promise of providing new and better ways to meet the very objectives of particular health, safety, or environmental regulations, those regulations that discourage or penalize innovation are self-perpetuating burdens of American industry.

While appropriate regulation in response to market failures can serve valuable social and economic functions, it may also impose significant costs that particularly affect the ability and incentive of firms to develop new high technology products. Some regulatory regimes are no longer appropriate to new technologies, while others were developed without adequate consideration of the burdens placed on international competition, and many regulations explicitly impose greater burdens on new facilities and products.

Regulation inhibits innovation most when the regulatory agency takes on the task of specifying which technologies or designs industry must employ. Further, once a technology is enshrined in regulation, firms have little incentive to invest in better techniques.

The following principles were offered to minimize disincentives to innovation:

• Regulations should be issued only on evidence that their potential benefits exceed their potential costs. Regulatory objectives, and the methods for achieving these objectives, should be chosen to maximize the net benefits to society.

• Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.

• Voluntary private standards and disclosure should be relied on where possible instead of inflexible regulation.

• Health, safety and environmental regulations should address ends rather than means. They should employ performance-based incentives that harness the creativity of market actors to design and continually innovate better ways of reducing excess risks. They should not specify technologies or designs that firms must employ.

• Licensing and permitting decisions and review of new products should be made swiftly and should be based on standards that are clearly defined in advance.

[FR Doc. 92-4603 Filed 2-26-92; 8:45am]
BILLING CODE 6560-50-M

Meeting of the President's Council of Advisors on Science and Technology

The President's Council of Advisors on Science and Technology will meet on March 5-6, 1992. The meeting will begin at 9 a.m. on Thursday, March 5, 1992 in the Conference Room, Council on Environmental Quality, 722 Jackson Place, NW., Washington, DC. The meeting will conclude at approximately 12 noon on Friday, March 6, 1992.

The purpose of the Council is to advise the President on matters involving science and technology.

Proposed Agenda

1. Briefing of the Council on the current activities of the Office of Science and Technology Policy.
2. Briefing of the Council on current federal activities and policies in science and technology.
3. Discussion of progress of working group panels.

Portions of the March 5-6 meeting will be closed to the public.

A portion of the briefings on current federal activities and policies in science and technology will require discussion of budget preparation procedures of the Executive Office of the President and other federal agencies which, if prematurely disclosed, would significantly frustrate the implementation of decisions made requiring agency action. Also, a portion of the discussion of panel progress will necessitate discussion of information which is formally classified in the interest of national security. Accordingly, these portions of the meeting will be closed to the public pursuant to 5 U.S.C. 552b(c)(1), (2), and (9)(B).

Because of the security requirements, persons wishing to attend the open portion of the meeting should contact Ms. Ann Barnett (202) 395-4692, prior to 3 p.m. on March 4, 1992. Ms. Barnett is available to provide specific information regarding time, place, and agenda.

Dated: February 20, 1992.

Damar W. Hawkins,

Executive Assistant, Office of Science and Technology Policy.

[FR Doc. 92-4485 Filed 2-26-92; 8:45 am]
BILLING CODE 3170-01-M

DEPARTMENT OF STATE

Office of the Secretary

[Public Notice 1577]

Extension of the Restriction on the Use of the United States Passport for Travel to, in, or Through Iraq

On February 1, 1991, pursuant to the authority of 22 U.S.C. 211a and Executive Order 11295 (31 FR 10603), and in accordance with 22 CFR 51.73 (a)(2) and (a)(3), all United States passports, with the following exceptions, were declared invalid for travel to, in, or through Iraq and Kuwait unless specifically validated for such travel. The restriction was not applicable to those American citizens then residing in Iraq and Kuwait nor to American professional reporters and journalists on assignment there. The restriction was required by the fact that armed hostilities then were taking place in Iraq and Kuwait, and the safety of any American citizens travelling to those countries no longer could be guaranteed.

With cessation of armed hostilities, the restrictions on use of the United States passport for travel to, in, or through Kuwait was revoked on March 6, 1991. The restriction on use of the passport for travel to, in, or through Iraq was continued because the Secretary concluded that conditions in that country continued to present an imminent danger to the public health or physical safety of American citizens.

Although armed hostilities have ended, the Government of Iraq continues to direct hostile acts against United States citizens and nationals. There have been numerous incidents over the past year in which American citizens, including some who entered Iraq inadvertently, were detained by Iraqi authorities for extended periods of time without notification to the U.S. Interest Section of the Polish Embassy in Baghdad. Several of these Americans were subjected to harsh and inhumane treatment during their detention.

In light of these circumstances, I have determined that Iraq continues to be a country "* * * where there is imminent danger to the public health or physical safety of United States travelers."

Accordingly, United States passports shall be invalid for use in travel to, in, or through Iraq unless specifically validated for such travel under the authority of the Secretary of State. The restriction shall not apply to American citizens who were residing in Iraq on February 1, 1991 who continue to reside there nor to American professional reporters and journalists on assignment there.

The Public Notice shall be effective upon publication in the **Federal Register** and shall expire at the end of one year unless sooner extended or revoked by Public Notice.

Dated: February 18, 1992.

Lawrence S. Eagleburger,

Acting Secretary of State.

[FR Doc. 92-4494 Filed 2-26-92; 8:45 am]
BILLING CODE 4710-10-M

THRIFT DEPOSITOR PROTECTION OVERSIGHT BOARD

National Advisory Board Meeting

AGENCY: Thrift Depositor Protection Oversight Board.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app., announcement is hereby published for a meeting of the National Advisory Board The meeting is open to the public. Please note that elsewhere in this issue of the **Federal Register** is a meeting notice for the newly established National Housing Advisory Board which will meet in the afternoon following the National Advisory Board meeting.

DATES: The meeting is scheduled for Wednesday, March 11, 9 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the Federal Deposit Insurance Corporation, Board Room, 6th floor, 550 17th Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jill Nevius, Committee Management Officer, Thrift Depositor Protection Oversight Board, 1777 F Street, NW., Washington, DC 20232, 202/786-9675.

SUPPLEMENTARY INFORMATION: Pursuant to section 21A(d) of the Federal Home Loan Bank Act, the Thrift Depositor