

Opportunity Cost Analysis Framework

from

ROADMAP FOR IMPEMENTING BIOSECURITY AND BIODEFENSE POLICY IN THE UNITED STATES

Project Partners

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Development of the Opportunity Cost Framework

Biosecurity policies, such as the BSAT regulations and export controls, promote national security by preventing theft, diversion, and deliberate malicious use of biological knowledge, skills, technologies, materials, and/or pathogens and toxins. At the same time, the restrictions imposed by these policies may have indirect effects on biodefense and health security activities (e.g., research, medical countermeasure development, and biosurveillance), which inadvertently could present barriers to achieving U.S. biodefense objectives.

The authors developed an analytic framework for analyzing the opportunity costs of new or changing biosecurity policies. The framework is based on historical case studies on the opportunity costs of two existing biosecurity policies: (1) the Biological Select Agent and Toxin Regulations, and (2) the U.S. government dual use research of concern (DURC) policies, including the policy for federal agency review and oversight of DURC, which was released in 2012, and the policy for institutional oversight of DURC, which was released in 2014. The case study findings revealed a set of data needs/parameters for assessing the opportunity costs of biosecurity policies. These data needs enable: 1) identification of the types of direct and opportunity costs arising from policy compliance and implementation activities; and 2) full and accurate determination of these costs. These parameters were ordered into a structured analytic framework for assessing the opportunity costs of policy, including direct costs, the indirect effects resulting from these costs, and their downstream consequences (Figure 1). By evaluating new policies using this framework, policy-makers can evaluate potential opportunity costs and identify policy strategies that could mitigate anticipated costs before they unintentionally counteract investments. This framework also can guide the collection of data for evaluating implemented policies to understand fully the effects of a given policy.

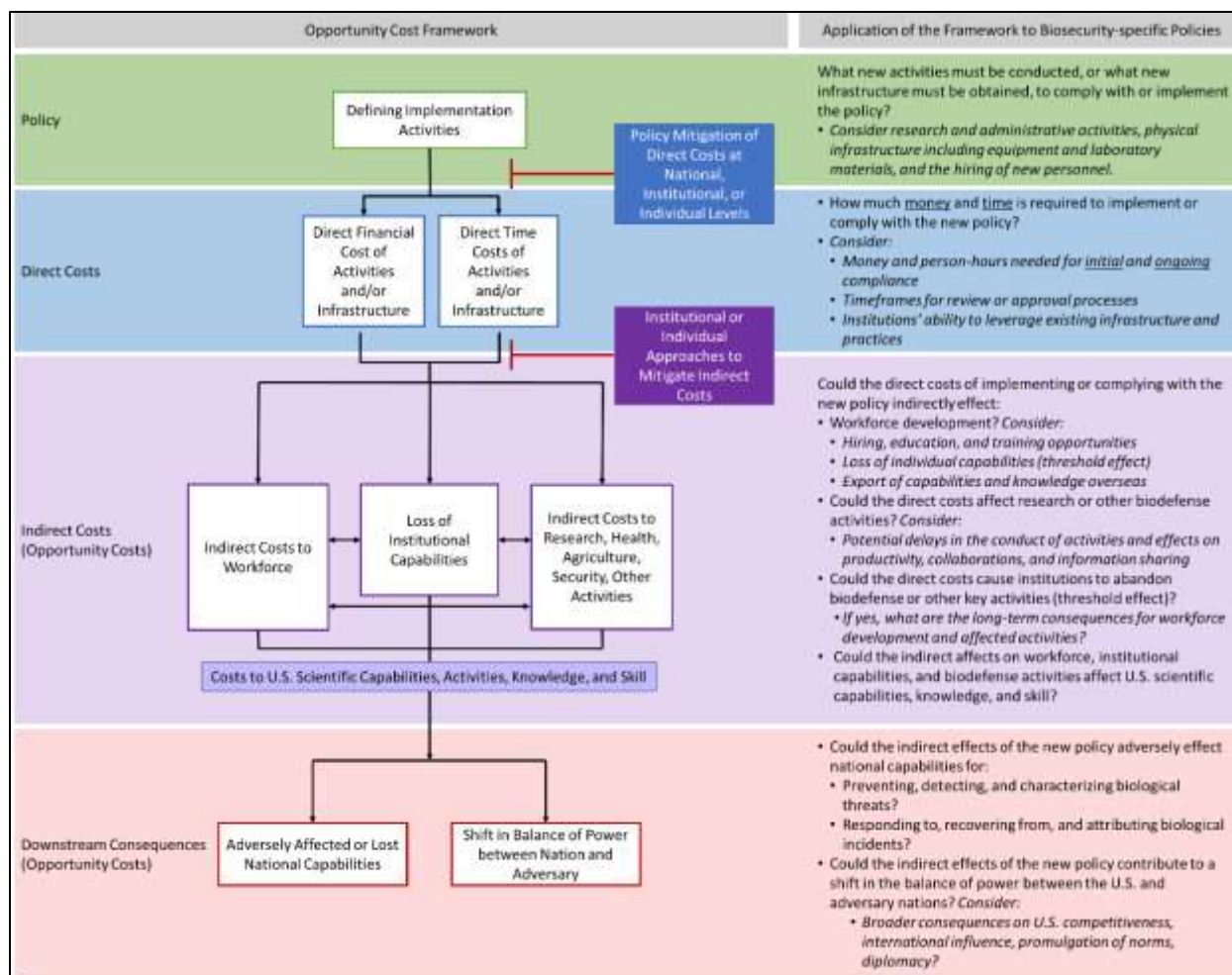


Figure 1. Opportunity Cost Framework.

A key principle underlying the framework is that the direct costs of policy implementation or compliance can lead affected stakeholders to make trade-offs that, collectively, may compromise U.S. workforce, infrastructure, capabilities, and activities in the policy area (in this case, biodefense). Seemingly small financial or time costs can limit the ability and/or desire of an individual or institution to conduct regulated work because of strains on or conflicts with their mission, responsibilities, and resources. Summing up direct costs across all affected stakeholders, as is done for a regulatory impact assessment, obscures the indirect costs on individuals and institutions, thereby underestimating the potential consequences of a policy on U.S. national objectives. To address this issue, application of the framework to new or changing policies involves sequential assessment of the direct costs, indirect costs, and downstream consequences.

Although this framework was developed based on historical case studies of biosecurity policies, the authors propose that it could be used broadly for the assessment of policies related to research, health, agriculture, and security. Therefore, the generalized framework is described in the left-hand side of the figure and its application to

biosecurity policies is described in the right-hand side. Details about each step are provided below.

Step 1: Defining Implementation Activities

The first step involves defining the activities that must be conducted and the infrastructure that must be obtained to implement or comply with the policy. Examples of these activities include: research and administrative activities, hiring of new personnel, and purchase of equipment or laboratory materials. To determine whether and how policy implementation involves changes to the infrastructure or operation of affected institutions, two factors should be considered: 1) overlapping requirements of guidelines established by other policies, which may have led institutions to implement the changes already; and 2) existing laboratory architectures, workflows, and procedures. Additionally, the personnel responsible for conducting the activities and the source of funding for compliance activities or infrastructure needs should be identified because both can influence the indirect effects arising from the direct costs.

Opportunity costs should be evaluated separately for different types of institutions and sectors. Institutions to consider when evaluating implementation or compliance costs of biosecurity policy include: academic research institutions, government research institutions, public health laboratories, veterinary diagnostic laboratories, contract research organizations, and companies developing medical countermeasures or other biodefense products. The opportunity costs of historical biosecurity policies varied across these institutions, all of which have different missions, levels of resources, and roles and responsibilities in biodefense.

Step 2: Assessing Direct Costs

The second step involves determining how much money and/or time is required to conduct the implementation activities. Considering the funds and person-hours that are required for upfront *and* ongoing compliance is critical for accurately assessing these costs. Direct time costs should include both ‘active’ time (i.e., when affected stakeholders actively are engaged in compliance activities) and ‘passive’ time (i.e., when affected stakeholders are waiting for compliance review or completion of an approval process).

Step 3: Assessing Indirect Costs

The third step involves determining how the funds and time that institutions dedicate to compliance activities lead to indirect costs. The ‘threshold effect’ may be a useful concept for evaluating the relationship between the direct costs and the indirect costs. (Figure 2) Below the threshold level, direct time or financial costs may *limit* or cause *delays* in regulated activities. Above some threshold level, the direct costs of compliance become high enough that an individual or institution chooses to cease conducting or supporting the regulated activity.

The threshold level of direct costs is specific to and varies between individuals and institutions. The historical case studies highlighted individual and institutional stakeholders who chose to cease work with BSAT or research with dual use potential

because the direct costs of compliance exceeded their threshold levels, whereas other stakeholders' threshold levels were higher resulting in their continued support of BSAT activities. The level of cost tolerance of different individual and institutional stakeholders can be used for proactive evaluation of indirect costs. Therefore, this threshold concept serves to bridge between direct and indirect costs.

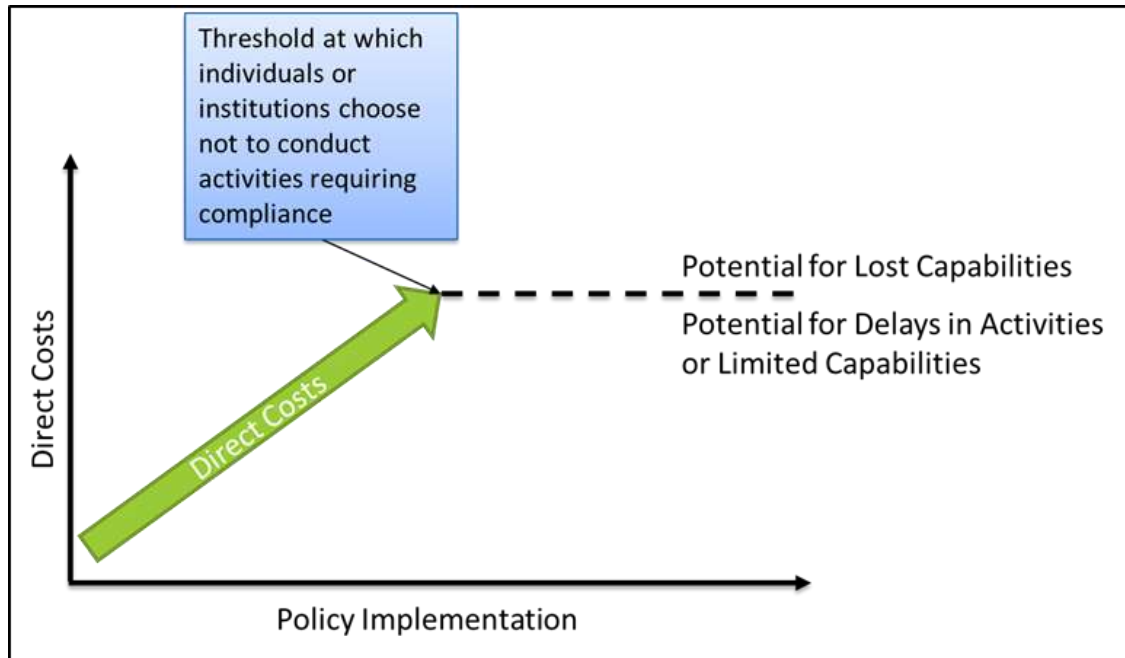


Figure 2. Applying the threshold effect to understand the indirect costs arising from the direct costs of policy compliance or implementation. Low-to-moderate direct costs may limit or cause delays in regulated activities. Above a threshold level, direct costs become high enough that individuals or institutions choose not to conduct or support the regulated activities.

Indirect costs in three key areas should be considered: research and other regulated activities, workforce, and institutional capabilities. Costs to regulated activities could arise from delays in the conduct of the activities and indirect effects on productivity, collaborations, and information-sharing. Costs to workforce could arise through several different mechanisms, including: 1) the loss of hiring, education, or training opportunities, which adversely affects workforce development; and 2) individual choice to not conduct the regulated activity. When evaluating the loss of individual capabilities, the assessment should consider whether those individuals likely would continue working in the regulated profession abroad, an outcome that could contribute to the shifting of power between U.S. and adversary nations. The loss of institutional capabilities occurs when institutions cease to support regulated activities because of high direct costs of policy implementation or compliance. In addition to immediate effects on the regulated activities conducted at the institution, the loss of training opportunities may adversely affect workforce development, and the loss of infrastructure may adversely affect research and development activities that support national objectives.

Collectively, the indirect costs to regulated activities, workforce, and institutional capabilities may lower U.S. scientific and technical capabilities and/or cause the U.S. to abandon or significantly curtail certain lines of research and development.

Step 4: Assessing Downstream Consequences

The fourth step involves assessing the downstream consequences of the indirect costs to U.S. national objectives. Costs to U.S. scientific and technical capabilities and/or to U.S. research and development activities may adversely affect national capabilities. At the same time, the export of knowledge and capabilities abroad and the continued advancement of research in adversary nations in areas that have been abandoned or limited in the U.S. could reduce U.S. global competitiveness. These consequences could contribute to a shift in the balance of power between the U.S. and adversary nations, limiting U.S. influence within the international science and technology community.

One caveat of any analysis of downstream consequences is the recognition that declines in national capabilities or global competitiveness arise from a complex interplay of scientific and technical, political, economic, and socioeconomic factors. This complexity poses challenges for forecasting or retrospectively evaluating the extent to which the indirect effects of policy implementation or compliance contribute to these consequences. Individuals using this framework to assess opportunity costs should consider when downstream consequence may be influenced heavily by such factors.

Step 5: Identifying Mitigation Strategies

The final, optional step involves identifying strategies for mitigating the opportunity costs. Mitigation measures could be applied to the direct costs to prevent or reduce the indirect costs, or to the indirect effects to minimize the downstream consequences. Solutions for alleviating direct costs could be implemented at the national, institutional, or laboratory levels. For example, policy-makers could provide funding options to off-set the direct costs of implementation and compliance, institutions could centralize administrative work to minimize individual administrative burdens, or laboratories could distribute administrative work among multiple individuals to reduce overall burden on any one individual. Solutions to mitigate indirect costs often are specific to individuals or institutions and thus, tailored approaches could be identified based on specific needs. Proactive or retrospective implementation of the mitigation measures may reduce the long-term opportunity costs of a policy.