GUIDELINES FOR REGULATORY IMPACT ANALYSIS

Supplement:

Addressing International Effects

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As is the case with the 2016 *Guidelines*, this supplement represents HHS' current thinking on the conduct of regulatory impact analysis. It does not establish any requirements for any person and is not binding on HHS, any HHS agencies, or the public. Analysts may use an alternative approach if it satisfies the requirements of the applicable Executive Orders and regulations. To discuss an alternative approach, contact the Office of the Assistant Secretary for Planning and Evaluation.

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ADDRESS INTERNATIONAL EFFECTS

In 2016, the U.S. Department of Health and Human Services (HHS) completed its *Guidelines for Regulatory Impact Analysis* (hereafter *Guidelines*) under the leadership of its Assistant Secretary for Planning and Evaluation (ASPE) and Analytics team. Section 7.3 of the *Guidelines* briefly addresses the analysis of international effects. The purpose of this supplement is to expand that discussion and provide more detailed information on conducting such assessments.

As noted in the *Guidelines*, the regulatory analysis should focus on benefits and costs that accrue to U.S. citizens and residents. These domestic benefits and costs may result in part from the actions of foreign-owned entities or others outside of the United States. Regardless of whether these costs and benefits result directly from the regulation, or indirectly from the regulation's impact on foreign entities, they should be reported as part of the main analysis.[1] For some rules, it may also be appropriate to perform a supplementary analysis addressing costs and benefits borne by foreign individuals and entities. To enhance transparency, these impacts should be reported separately in the regulatory analysis.

> Analysts should comprehensively consider all potentially important consequences of the regulation. To enhance transparency, report impacts accruing to U.S. citizens and residents separately from impacts accruing to foreign entities.

In this supplement, we assume that readers are familiar with the HHS *Guidelines*. In particular, this supplement builds on the discussion in Chapter 4, *Assess Costs*, to include international impacts. That chapter describes the basic concepts and approach, discusses how to assess compliance and government implementation costs, and provides an overview of approaches for estimating market impacts. Assessing international impacts applies the same concepts and general approaches as assessing domestic impacts, extending them to include issues that arise in the international context.[2]

We begin by providing a working definition of international effects and briefly reviewing the concepts discussed in more detail in Section 4.1 of the *Guidelines*. We then characterize the range of potential impacts and discuss their estimation, suggesting useful data sources.

S.1 Basic Concepts and Context

In the context of HHS regulatory analysis, the term "international effects" refers to the impacts of changes in behavior by foreign individuals and entities attributable to the regulation. Often these changes in behavior manifest as changes in international trade. These international effects may be directly associated with the impacts on entities subject to the regulation. For example, a regulation that increases the cost of selling a good in the United States may lead foreign firms to exit the domestic market. International effects may also be indirect; they may be associated with the impacts on entities and individuals not subject to the regulation. To continue the example, if a foreign firm stops selling to the U.S. market, U.S. producers may benefit by increasing their market share. U.S. consumers would also be positively or negatively affected if these responses lead to changes in the quality or price of the affected goods or services.

[1] For example, the Interagency Working Group on Social Cost of Greenhouse Gases (2021) indicates that a global perspective is needed when estimating the benefits of reducing greenhouse gas emissions, because "climate impacts occurring outside the U.S. borders can directly and indirectly affect the welfare of U.S. citizens and residents".

[2] Examples of tools and data sources that can be used to conduct analyses of international impacts are discussed later in this supplement.

As noted earlier, regulatory analyses should focus on the domestic effects of the regulation. This means that both direct and indirect effects on U.S. entities should be included in the main analysis. Effects on foreign entities, whether direct or indirect, should be reported separately if they are expected to be substantial.

One challenge is determining whether a firm should be considered "foreign" or "domestic." For example, it is often difficult to separate the impacts of a regulation on U.S. subsidiaries of foreign entities from the impacts on U.S.-owned businesses. In such cases, cost and other impacts on U.S. subsidiaries should be included in the main analysis rather than reported separately as international effects. Where this is the case, analysts should clearly document the approach and assumptions and discuss the implications.

As discussed in detail in the *Guidelines*, the goal of regulatory analysis is to assess changes in social welfare. Chapter 4 of the *Guidelines* describes three economic concepts that are of particular importance when assessing costs within this context, regardless of whether the impacts are domestic or international. The first is the distinction between opportunity costs and other types of reported changes in revenue, sales, or spending. Opportunity costs are the appropriate measure of changes in welfare, i.e., costs are incurred when resources such as labor and materials are used for one purpose and hence cannot be used for another purpose. For review by decisionmakers and others, it is often useful to accompany the estimates of opportunity costs with information on accompanying effects, such as changes in import and export quantities and prices.

The second important economic concept is the distinction between resource costs and transfers. Transfers are monetary payments between persons or groups that do not affect the total resources available to society. Transfers between domestic entities do not affect whether the net benefits (benefits minus costs) of the regulation are negative or positive as long as they do not lead to behavioral changes. Information on domestic transfers is needed, however, to assess the distribution of costs and benefits as discussed in Chapter 7 of the *Guidelines*. Transfers between domestic and international entities are handled differently. OMB *Circular A-4* (2003) indicates that "transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits."

The third important concept is the difference between compliance costs and changes in producer and consumer surplus. As introduced in Chapters 3 and 4 and discussed in Appendix B of the *Guidelines*, consumer surplus is the benefit that consumers receive when they are able to purchase products for less than they are willing to pay; producer surplus is the difference between the revenue producers receive and their cost of production. Estimating changes in consumer or producer surplus requires understanding likely changes in costs and prices and in quantities supplied and demanded. As noted earlier, these changes may result from the direct or indirect impacts of the regulation. Regardless, the main analysis should report the net change in U.S. social welfare, measured as changes in U.S. consumer surplus and U.S. producer surplus. The international effects section should report the benefits and costs that accrue to entities beyond the borders of the United States.

Note that in addition to the effects on international trade that are the primary focus of this supplement, regulations may impose costs on international visitors entering the United States. These costs may include, for example, pre-arrival out-of-pocket expenses (e.g., fees for medical exams); screening or testing products or people prior to entry into the United States; or delay at the port of entry due to additional processing requirements. Analysts should estimate and present the potential effects of the regulation on nonimmigrant visa holders and report these effects in the main analysis. Estimation of related costs should follow the guidance in Chapter 4 of the *Guidelines*, taking care to avoid double-counting of impacts included elsewhere in the analysis.

S.2 Characterizing International Effects

As illustrated in Figure 1.1 and discussed in more detail in Chapter 2 of the *Guidelines*, likely responses to the regulation must be identified to support estimation of associated impacts on social welfare. In this section, we discuss examples of responses to the regulation that are international in scope, focusing on trade impacts. These include

changes in imports and exports, in domestic production and consumption of directly affected goods, in domestic production and consumption of complements or substitutes, and in prices. We recognize that many rules may have insignificant effects along some or all of these dimensions. Section S.3 then discusses how to identify and assess the impacts of concern for a particular regulation, including the use of screening analysis to target the assessment.

Throughout this section we use the term "regulated goods" as shorthand to refer to those goods and services directly affected by the regulation. While the regulation may relate to the good itself (e.g., what it contains), it may also or instead affect its labelling, manufacturing process, or other factors.

S.2.1 Changes in Imports and Exports

HHS regulations may affect U.S. imports and exports for a variety reasons, such as the following.

- The costs (or cost-savings) associated with a rule may encourage or discourage some foreign producers from exporting their goods to the United States.
- Regulatory compliance may lead to differences in production costs depending on where the good is produced, changing the costs of U.S. production relative to non-U.S. production.
- Technical standards or other rule provisions may restrict or prohibit imports from individual countries, decreasing imports.
- Regulatory compliance may influence the competitiveness of U.S. firms in foreign markets, leading to changes in exports.

Changes in imports and exports are useful metrics for gauging the market response to HHS regulations and are likely to be of interest to decisionmakers. However, such changes are not a welfare measure. As noted earlier, to assess the effects of the regulation on social welfare, the associated changes in consumer and producer surplus must be estimated.

S.2.2 Changes in Domestic Production or Consumption of Regulated Goods

Understanding the effects of changes in imports or exports of regulated goods also requires understanding their domestic production and consumption. Although the behavioral responses of domestic producers and consumers, in conjunction with the estimated changes in imports and exports, are not alone sufficient to estimate the effects on social welfare, they may provide important insights into the sign and magnitude of a rule's international effects.

Responses to the regulation may involve changes in the quantities and prices of imported or exported goods, due to the costs of compliance or other provisions that encourage or discourage international trade.

As a simple example, assume that a good can only be manufactured outside of the United States. If the regulation causes imports to decline and the U.S. population consumes less of the good as a result, then consumer welfare may decline.[3] If instead the good can be manufactured both within and outside of the United States and the regulation leads to a decrease in imports, U.S. producers may respond by increasing their production. In this case, U.S. producers will likely realize an increase in welfare. To understand the welfare effects on consumers, we also need to know whether this shift in production changes the price of the good. If increasing domestic production leads to price increases, the welfare of U.S. consumers may decline.

The ability of U.S. firms to increase production in this case depends on many factors, some of which are unique to the specific markets affected and specific periods. For example, for food products, domestic producers may have limited ability to increase production if the U.S. climate is unsuitable for cultivation. A lack of access to raw materials (e.g., a mineral component of a drug) may also limit the extent to which U.S. firms are able to increase production.

[3] Potential welfare gains associated with improvements in health or safety are measured separately (see Chapter 3 of the *Guidelines*).

S.2.3 Changes in Domestic Production or Consumption of Substitutes

Changes in U.S. imports or exports may also contribute to changes in the domestic production or consumption of substitute goods. The welfare implications differ for consumption versus production in this case. While the availability of substitutes affects consumer surplus, options for substitution are reflected in the demand function for the regulated good (Boardman et al. 2018). This means that the welfare loss associated with reduced consumption of the regulated good includes the net welfare effect of consuming more of the substitute good. In addition, while price changes for substitutes may affect demand and lead to changes in welfare, these price effects are usually insignificant.

In contrast, estimating substitution in production may be important for understanding the change in domestic producer surplus. To the degree that domestic production of substitutes displaces the production of goods imported into the U.S. from foreign producers, surplus for U.S. producers will increase. These and related issues are discussed in Section 4.3 of the *Guidelines*, which describes the use of partial and general equilibrium models to estimate market impacts.

S.2.4 Changes in Prices

The changes in market quantities described above (i.e., in imports, exports, demand, and supply) are intertwined with changes in prices. Price information is needed both to aid in predicting these impacts and to estimate the welfare effects that result, measured as changes in consumer and producer surplus as described in Appendix B of the *Guidelines*.

For example, if a rulemaking leads to a price increase for a good that is produced domestically as well as imported, U.S. consumer surplus will likely decline, but U.S. producer surplus may increase. The extent to which these positive and negative consequences are counterbalancing will depend on the characteristics of the market. In contrast, if the good is produced outside of the United States and the regulation increases its import price, the welfare of U.S. consumers will likely decline without a potentially offsetting increase for U.S. producers. Whether the regulation will lead to change in prices depends on several factors, including producer decisions to adjust returns to capital rather than passing the costs of regulatory compliance on to consumers (see Section 7.1 as well as Section 4.3 of the *Guidelines*). These decisions also depend on the characteristics of the affected markets and the relative market power of the affected firms.

S.3 Quantifying International Effects

The most appropriate approach for estimating the international effects of HHS rulemakings varies from one regulation to the next. Some regulations will have negligible international effects and no analysis will be needed. If quantitative analysis is feasible, several approaches are possible that vary in their suitability for application to particular types of markets and direct or indirect impacts. As is the case with other components of the regulatory analysis, determining the most appropriate approach involves: (1) conducting screening analysis to determine the scope of future work, including the international effects to be considered and the extent to which quantification is desirable, and (2) if quantitative analysis is appropriate and feasible, selecting the most suitable modelling approach. Chapter 6 of the *Guidelines* provides related information on assessing uncertainty and nonquantifiable effects.

S.3.1 Screening Analysis

As discussed in Section 2.4 of the *Guidelines*, screening analysis should be used to inform decisions about the scope of the analysis. Analysts should generally begin by reviewing the literature and talking to industry experts to explore previous assessments of similar policies and better understand related issues. This step is necessary to understanding the rule's domestic costs and benefits as well as its international effects.

Some simple comparisons may be helpful in the international context. In particular, analysts should consider the extent to which the affected market involves imports and exports. If production and consumption are largely domestic

now and expected to remain so in the foreseeable future, international effects are likely to be minimal. As part of this assessment, analysts will need to consider whether the rule provides a competitive advantage to foreign producers who may enter the U.S. market as a result, or raises or lowers other existing trade barriers.

Conversely, if trade represents a more substantial portion of the market, significant international effects may be more likely. Determining "significance" requires case-by-case consideration. Factors to consider include whether the compliance costs or savings of a rule are likely to accrue disproportionately to either importers or exporters. However, in general, trade volume representing 10 percent or more of the U.S. market is likely to be significant, whereas trade volume constituting 1 percent of the market is likely to be insignificant.[4] In addition to the magnitude of the impacts, analysts should also consider the extent to which decision-makers or other stakeholders are likely to raise related questions.

In addition, analysts should consider the relative magnitude of compliance costs. When such costs are low relative to the size of the market, the regulation is unlikely to result in significant international effects. Conversely, rules with relatively high compliance costs may have more significant international effects. In this latter case, additional screening may be needed to determine the importance of the effects.

S.3.2 Quantifying International Effects

When estimating international effects, analysts should first use screening analysis to target future work and determine the extent to which quantitative analysis is desirable and/or feasible. Quantification requires selecting among a variety of approaches. It may involve using existing models or creating new models tailored to the issues of concern.

If quantitative analysis is deemed appropriate, the next step is to select an approach. This decision is often not straightforward, as the choice between approaches depends on several factors, such as the extent of involvement of domestic versus foreign producers and the characteristics of the products. Below, we discuss the factors to consider in determining whether to use an existing model or to develop a new model tailored to the regulation. We then discuss two special cases: niche products produced solely outside of the United States, and goods that are highly sensitive to changes in transit time such as those that are perishable. Note that in this discussion we use the term "model" to encompass a variety of quantitative approaches, ranging from relatively simple spreadsheet calculations to substantially more complex simulation models. Sources of related data are described in Section S.3.3.

Use existing models: Using or adapting an existing model has several advantages, if available models are suitable for the products, firms, and markets affected by the regulation. Perhaps most importantly, applying the same model across analyses saves time and resources and leads to comparable results. It also can ease communication with decision-makers and other stakeholders who gain familiarity with the approach as a result of its repeated use.

The most suitable approach often may be to use a partial equilibrium model that focuses on individual markets. At times, when the effects are substantial and likely to affect multiple markets throughout the economy, general equilibrium models (such as the Global Trade Analysis Project (GTAP) model) may be useful.[5]

Deciding whether to use an existing model requires comparison of the regulatory context to the markets and scenarios included in the model. Related information will likely be collected during the screening process and is generally needed to understand domestic as well as international effects. Although many issues need to be considered on a case-by-case basis, three considerations are likely to be common across rulemakings.

[4] Analysts might also consider the significance of the project for consumer welfare (e.g., low-volume drugs or devices may not represent a significant market share, but the availability of these products may be critical for certain subpopulations).

[5] For information on GTAP, see: https://www.gtap.agecon.purdue.edu/.

- Does the model represent the structure of the market and consumer and producer behavior with sufficient accuracy on an international level? While no model perfectly reflects all the intricacies of a given market, the model should reflect the structural and behavioral characteristics that drive the functioning of the market (such as its competitiveness) and determine the likely magnitude of the welfare implications of the regulation.
- Does the model provide a sufficiently detailed representation of the market for the product(s) of interest? For example, a model that aggregates products into large categories is unlikely to be sufficient to estimate the effects of a regulation that addresses only one product in a category.
- Does the model require data that are accessible for the market in question? If detailed representation of the structure, conditions, and other characteristics of the market are not available, analysts may be able to develop reasonable assumptions. Otherwise, a more tailored approach may be necessary.

The FDA Regulation and Enforcement Policy Trade Impact Model (the FDA Trade Impact Model) is an example of an existing model that may often be useful (see Wood et al. 2015). Derived from the Global Simulation Model (GSIM) developed by Francois and Hall (2003), it is a partial equilibrium model representing international trade in individual markets for commodities including cosmetics, dietary supplements, foods, pet foods and animal feeds, pharmaceutical preparations, and tobacco products.[6] For each market, the model estimates import demand, import supply, domestic prices for domestic products, and the export price in response to certain simulated policy options. It also computes changes in quantities produced and producer and consumer surplus for the United States and its affected trading partners.

Develop a rule-specific model: When existing models are not available or appropriate, analysts will need to develop an approach suitable for the regulation or regulations of concern. As noted earlier, a partial equilibrium model will be suitable in most cases where quantitative assessment is desirable. A defining characteristic of partial equilibrium models is that they represent supply and demand within a single market (see *Guidelines* Section 4.3).

Within this framework, a model that assumes the market is perfectly competitive will generally provide a reasonable approach for estimating international trade effects. Such a model typically assumes that the good is homogeneous and that there are no barriers to market entry, multiple producers, no transaction costs, and perfect information. While many markets do not strictly adhere to these assumptions, the dynamics represented in such a model are generally consistent with the responses of producers and consumers across a wide range of markets. For this reason, the perfectly competitive model is the standard approach for many partial equilibrium analyses of trade effects.

One question is whether the model needs to explicitly represent international trade. If U.S. and non-U.S. producers are likely to be equally sensitive to the impacts of the regulation, such a distinction may not be necessary. In this case, changes in imports as a fraction of the overall change in the quantity supplied will be proportional to non-U.S. producers' share of the U.S. market under baseline conditions. In this relatively straightforward case, the data needed for the analysis include supply and demand elasticities, baseline quantities and prices, and the relative market share of U.S. and non-U.S. producers.

When U.S. and non-U.S. producers differ in their sensitivity to regulatory changes, analysis of international effects becomes more complicated. Under these conditions, analysts must separately estimate supply responses for U.S. and non-U.S. producers, as well as the relationship to consumption. While such models would apply many of the same assumptions as the simple partial equilibrium model discussed above, they require more complex calculations as well as additional data. These data include (1) baseline data on U.S. production and consumption of the good(s) in question, (2) baseline data for non-U.S. consumption and production, (3) demand and supply elasticities for U.S. consumers and producers, (4) demand and supply elasticities for the rest of the world, and (5) imports and/or exports of the affected good(s).

[6] GSIM and associated documentation are available at https://wits.worldbank.org/simulationtool.html.

Special case 1: Niche products produced exclusively outside the U.S.: Some rulemakings affect niche products produced exclusively outside the United States. Analysis of these rules generally require a tailored approach. A key difficulty is predicting the response of foreign producers to a U.S. rulemaking. In addition, while substitutes may exist (and may be produced in the United States), they are by definition not identical to the niche product. The degree to which consumers would switch to the substitutes is therefore often difficult to predict.

In this case, analysts may wish to develop upper bound estimates of the loss in consumer surplus (see Appendix B of the *Guidelines*) by assuming that the supply of the niche product drops to zero. In other words, with the regulation, the product is no longer imported and there is no counterbalancing change in the domestic production or consumption of substitutes. Under this scenario, analysts require information on the elasticity of demand. If elasticity data are not available for the product of concern, analysts may consider applying the demand elasticity for a similar product.

Special case 2: Changes in transit time: Some regulations will increase or decrease the transit time for goods imported into the United States. In these cases, the responses of foreign producers will likely depend largely on the extent to which the goods are perishable, the magnitude of the change in transit time, and the options for adjusting to or mitigating the effects of these changes. For example, a regulation that significantly increases transit time for perishable goods such as fresh fruit and vegetables will likely lead to more significant international effects than a rule that results in a modest increase for non-perishable items, especially if technological responses such as increased refrigeration are expensive or unavailable. Other factors, such as demand and pricing in associated markets and opportunities to make offsetting changes in transportation practices, are also likely to affect foreign producers' decisions to continue exporting to the United States as well as any associated change in price.

As noted earlier, screening analysis can be used to determine the importance of these as well as other effects. Estimating the welfare effects of regulatory provisions that change transit time is likely to be difficult; it may often be most feasible to estimate these effects as a range. For example, one approach to estimating this effect is to assume no change in imports or product prices but use producers' willingness to pay (WTP) for quicker transit as an indicator of the associated loss. For example, Hummels and Schaur (2013) estimate WTP for shorter transit time across approximately 1,000 product categories as an *ad valorem* premium (i.e., the percentage over the base price or value).[7] The Hummels and Schaur estimates reflect differences in transit time and costs for air cargo versus ocean cargo over individual routes. To apply this approach, data are needed on (1) the types of affected products (e.g., food and beverages, medical devices, etc.), (2) the baseline market value of those products, and (3) the change in transit time associated with the regulation.

A second approach is to consider a change in imports, e.g., to reflect the risk of spoilage for perishable goods. In this case, if transit time increases, analysts may assume that the change in imports is equal to the portion of perishable products that would likely spoil prior to reaching the market. The potential spoilage loss (and producer response) would vary for different combinations of products (produce, seafood, meats, dairy, grains), regions of origin (Asia-Pacific, Europe/Africa, and the Americas), and U.S. destinations (eastern U.S. and western U.S.). The consumer surplus loss associated with this reduction in imports would depend on the elasticity of demand for the affected product(s), the baseline price of these products, and the extent of the reduction in imports. To estimate the consumer surplus loss associated with the time delay for products that are still imported, analysts could apply the Hummels and Schaur (2013) WTP parameters referenced above to these products.

Developing estimates using this second method requires information on the transit time for affected goods under baseline conditions, the transit time at which spoilage or other impacts are likely for each product category, and the change in transit time associated with the rulemaking. As described in Hummels and Schaur (2013), baseline ocean

[7] These product categories are defined according to the Harmonized Tariff Schedule (HTS) maintained by the U.S. International Trade Commission. The HTS is based on the international Harmonized System (HS), which is an internationally standardized coding system developed and maintained by the World Customs Organization for classifying traded products.

shipping time data may be obtained from a master schedule of all vessel movements included in the Port2Port Evaluation Tool.

S.3.3 Data Sources

Data sources to support the screening analysis and quantitative methods described above include the following.

- *Imports and Exports:* The U.S. Census Bureau publishes annual and monthly statistics on U.S. imports and exports using the Harmonized Commodity Description and Coding Systems (HS). The UN Comtrade Database also includes detailed global trade data organized according to the HS.[8] UN Comtrade is the largest depository of international trade data with more than 3 billion data records since 1962. In terms of prices, the U.S. Bureau of Labor Statistics also provides Import/Expert Price Indexes (MXP) containing data on changes in the prices of goods and services traded between the United States and other countries.[9]

- *U.S. and Foreign Production:* Domestic production data by industry are available from the U.S. Census Bureau's Annual Survey of Manufacturers' Industry Product Analysis series. In addition, the United Nations publishes annual production statistics by commodity in its Industrial Commodity Statistics Yearbook for more than 600 industrial products (United Nations 2019).

  Focusing on agricultural products, the Food and Agriculture Organization (FAO) of the United Nations Statistics Division (FAOSTAT) publishes country-specific data on the production of agricultural products. In addition, the U.S. Department of Agriculture's Production, Supply, and Distribution Online Database (PS&D Online) includes country-specific production data, by year, for several varieties of cotton, oilseeds, other seeds, tobacco, dairy, livestock, poultry, grain and feed, and horticultural and tropical products.

- *U.S. and Foreign Demand:* Depending on the specific product(s) examined, demand data may be available from a variety of sources. The U.S. Bureau of Labor Statistics publishes annual data from the U.S. Consumer Expenditure Survey, which includes highly disaggregated data on the spending patterns of U.S. households. Demand data for both the United States and foreign countries may also be available from industry associations or market research firms that track specific product markets.

- *Demand and Supply Elasticities:* Application of the methods described above requires estimates of the elasticity of supply and elasticity of demand for directly regulated industries. Unfortunately, empirical support for supply elasticities is often fairly limited. One potentially useful source for supply elasticities is Broda *et al*. (2008), which reports import demand elasticities for several thousand HTS codes, including inverse supply elasticities.

  Relative to supply elasticities, more information is available on demand elasticities. For example, Taylor and Houthakker (2010) includes own-price elasticity values for 107 product categories. Another potential source is Kee *et al.* (2008), who use data for the 1988-2001 period across 117 countries to estimate import demand elasticities for goods defined according to 6-digit HTS codes. When elasticity values aren't readily available, analysts should consider seeking input from experts in the market of interest.

In sum, assessing international impacts generally applies the same concepts and approaches as other components of the regulatory analysis. The key differences are the need to separately report domestic and international impacts, and to collect data on trade to support screening analysis and quantitative assessment as needed.

[8] The database is available at https://comtrade.un.org/.

[9] The indexes are available at https://www.bls.gov/mxp/home.htm.

REFERENCES

Boardman, A. E., D. H. Greenberg, A. R. Vining, and D. L. Weimer. (2018). *Cost-Benefit Analysis: Concepts and Practice*, Fifth Edition. Cambridge University Press.

Broda, C., N. Limao, and D.E. Weinstein. (2008). "Optimal Tariffs and Market Power: The Evidence." *American Economic Review* 98(5):2032-2065, and the website of David E. Weinstein at Columbia University, Department of Economics, accessed at http://www.columbia.edu/~dew35/TradeElasticities/TradeElasticities.html on June 6, 2017.

Francois, J.F., and H.K. Hall. (2003). *Global Simulation Analysis of Industry-Level Trade Policy.* Technical Report, Institute for International and Development Economics, Rotterdam, The Netherlands.

Hummels, D. L. and G. Schaur. (2013). "Time as a Trade Barrier," *American Economic Review* 103(7):2935-2959.

Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. (2021). Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide: Interim Estimates Under Executive Order 13990. February. https://www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf

Kee, H.L., A. Nicita, and M. Olarreaga. (2008). "Import Demand Elasticities and Trade Distortions." *Review of Economics and Statistics* 90(4):666–682.

Taylor, L.D. and H.S. Houthakker (2010). *Consumer Demand in the United States: Prices, Income, and Consumption Behavior*. Springer-Verlag New York.

United Nations, Department of Economic and Social Affairs. (2019). Industrial Commodity Statistics Yearbook: Production Statistics (2007-2016) - Volume 1 Physical Quantity Data.

U.S. Department of Health and Human Services. 2016. *Guidelines for Regulatory Impact Analysis* https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis

United States Office of Management and Budget (OMB). (2003). *Circular A-4: Regulatory Analysis.* http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

Wood, D. W., D. K. Birur, S. R. Bradley, J. E. Brophy, S. A. Karns, M. K. Muth, and Y. Zheng. (2015). *FDA Regulation and Enforcement Policy Trade Impact Model* prepared for the U.S. Food and Drug Administration.