

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and
- Exports.

The issues listed in the bullets are covered in detail in the cost benefit analysis of the preceding sections, with the exception of the trade effects of this interim final rule, which we will discuss here.

Although most of the information required for prior notice is already supplied to CBP when importing food products, this new notice requirement may cause a reduction of imports of certain food products into the United States. For example, food manufacturers, processors, or growers may choose to stop exporting food products to the United States if the additional costs of complying with the prior notice increase the price of the imported product (or perhaps decrease the quality of the product) to the point where they cannot compete with a domestically-grown or produced product. This may be the case for food products that are grown or produced in the United States with an elastic enough supply to meet consumer demand without large increases in price. For example, if Florida-grown and California-grown oranges meet the demand for the fruit in this country at or close to current prices, then it is unlikely that the United States will import many oranges from other countries, if the price of the imported product rises (or the product quality is lowered) because of the prior notice requirement.

On the other hand, for example, there are products for which substitutes, and more specifically, U.S. grown or produced substitutes, are not available. In these cases, and in cases where U.S. demand for the product greatly exceeds domestic supply, importers will pass along to the consumer any increase in price for the product brought about by the prior notice requirement (as long as the quality and other attributes of the product remain intact). For example, exotic fruits such as coconuts, mangoes,

and papayas are not grown in significant quantities in the United States; if the demands for those fruits are relatively inelastic, there will not be a significant decrease in quantity demanded in the United States when the importers raise the price of the fruit to cover the costs of submitting prior notice.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this interim final rule is a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This interim final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information, *i.e.*, each prior notice.

Title: Prior Notice of Imported Food.

A. Description

Section 801(m) of the FD&C Act (21 U.S.C. 381(m)) requires prior notice to the Secretary of Health and Human Services (the Secretary) of an article of food that is being imported or offered for import into the United States. Section 801(m)(1) of the FD&C Act states that the Secretary shall require submission of notice providing the identity of each of the following: The article of food; the manufacturer; the

shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of arrival. Section 801(m)(2)(A) of the FD&C Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. FDA's prior notification of imported food shipments interim final rule implements these statutory provisions.

1. Comments on the Burden of Information Collection

Some comments on the proposed burden of information collection stated that the information collection would not be necessary if ABI/ACS could be used to submit the required information. Other comments stated that the information collection was unproductive and unduly burdensome for the benefits it would provide. Still other comments stated that FDA had underestimated the hours associated with the reporting burden.

FDA's agreement with CBP to allow most prior notices to be submitted through ABI/ACS will greatly reduce the burden of this new collection of information.

A few comments were concerned that FDA had underestimated the proposed burden because they did not understand that FDA had calculated the submitting burden based on import entries, not entry lines. For each import entry, the prior notice or notices are expected to take about an hour to file. The prior notice or notices for each import entry would cover approximately 2.6 lines, with each line representing a different article of food to be imported. For this interim final rule burden of information analysis, FDA has clarified how the estimates were calculated to allay the comments' concerns.

2. Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows: