

to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as a significant regulatory action if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also considers a regulatory action significant if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Need for Regulation

Section 303 of the Bioterrorism Act (Public Law 107-188), gives FDA expanded authority to prevent the distribution of any article of food for which we have credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. Previously, if we received credible evidence or information indicating that an article of food presented a threat of serious adverse health consequences or death to humans or animals, we would typically have taken one of the following actions: (1) Requested a voluntary recall of the suspected product; (2) developed enough evidence to move directly to seize the food; or (3) referred the matter to the appropriate State authority for most cases involving purely intrastate commerce. Thus, Congress' expansion of our authority to allow administrative detention of food permits us to immediately detain food in commerce, which provides an added measure to ensure the safety of the nation's food supply.

Reason for Regulation

FDA is proposing this regulation to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant—particularly if the plant is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to

avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of foodborne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The economic incentives for firms to engage in food safety activities largely hinges on the ability of consumers to identify and avoid products associated with the responsible party. However, firms can change both their own names and the names of their products, and can also change owners and managers. Therefore, it may be quite costly for consumers to obtain the information that would allow them to avoid products associated with the responsible party. Moreover, some firms might be infiltrated by those who wish to launch attacks on food safety, or might even have been formed by those having that end in mind. Such firms would not be responsive to normal economic incentives to provide food safety.

The events of September 11, 2001, led Congress to conclude that there should be a regulatory mechanism to temporarily remove from commerce potentially violative food that presents a threat of serious adverse health consequences or death to humans or animals, and store it under an appropriate level of security until we can investigate the potential threat and evaluate whether to initiate judicial enforcement action and, if appropriate, initiate such action. This proposed regulation implements this mechanism.

Regulatory Options

We considered several regulatory options or alternatives as follows in developing this proposal:

Option One: Establish a regulatory framework for administratively detaining food, with expedited procedures for instituting certain enforcement actions involving perishable food (i.e. take the proposed action);

Option Two: Take the proposed action, but change the definition of perishable food, the maximum timeframe for administrative detention of perishable food, or both;

Option Three: Take the proposed action, but define the level of security we require for transportation and storage;

Option Four: Issue regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e. limit the action to the regulations required by section 303 of the Bioterrorism Act).

We request comments on these options, as well as suggestions on other regulatory options that we should consider. We will address comments on this analysis in the analysis of the final rule.

Baseline: The situation before Congress passed the Bioterrorism Act

Usually, we designate the option of taking no regulatory action as the baseline. We then compare the costs and benefits of the various regulatory options to the current regulatory state of affairs. However, for this rule, we chose the situation that existed before Congress enacted the Bioterrorism Act as the baseline. We chose this baseline rather than the current regulatory state of affairs because our authority to administratively detain food under the Bioterrorism Act already exists, regardless of whether we now promulgate regulations setting out the procedures we will follow when we detain food.

Therefore, in order to analyze the impact of Congress giving us the authority to administratively detain food, we needed to specify a baseline that predated our having received that authority. By convention, we do not attribute costs or benefits to the baseline, per se, but instead capture the impacts of the regulation by comparing the costs and benefits of the other options to the baseline. Prior to Congress passing the Bioterrorism Act, we had other enforcement options available to us in those situations in which we can now use administrative detention, that is, in which we receive credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals. We will discuss those enforcement actions as part of the baseline in the following analysis.

In addition, we do not discuss the option of taking no regulatory action as one of the non-baseline options, because that option is not legally feasible. Option Four (establish expedited procedures for instituting certain enforcement actions involving perishable food only) most closely resembles the option of taking no regulatory action, because in that option we would limit ourselves to only the regulatory action that Congress required us to take in the Bioterrorism Act.

Option One: Establish a regulatory framework for administratively