

regulations. The agency has fully considered all of the comments on benefits. These estimates are more fully explained in the full RIA. What follows is FDA's conclusion as to how these benefits should be valued.

#### 1. Safety Benefits

In the tables below, FDA presents revised estimates of the benefits of mandatory HACCP for seafood processors. Several changes from the preamble to the proposal are noteworthy. First, based on the comment that said that FDA had underestimated the number of cases, FDA has reestimated the baseline numbers of cases for certain illnesses (Ref. 226). Next, some changes were made to the valuations of particular cases, as better information was obtained concerning the probabilities of death per type of illness. Finally, as mentioned above, some changes have been made to the estimates of the percentages of the illnesses reduced.

Although Canada, for example, has mandatory HACCP for its seafood processors, no data exist on the efficacy of HACCP. Therefore, for the percentages of the illnesses reduced, FDA used three different types of its experts (seafood experts, epidemiologists familiar with microbial hazards, and microbiologists) to address the efficacy of seafood HACCP. Each of these experts reviewed the literature on each type of hazard as well as the requirements of HACCP. The ranges reflect likely upper and lower bounds on how effective HACCP will be at controlling production deficiencies by processors, including indirect controls exerted by processors on the owners of harvesting vessels. In addition, the tables reflect the fact that some of the cases of illness are not addressable by this rule as they are caused by either consumer or restaurant mishandling or

poor fishing practices by recreational fishermen.

In order to calculate the number of cases (annual cases resulting from exposure to hazards associated with seafood consumption) that would be reduced by HACCP, each of the four experts followed a series of methodical steps. The first was to determine the types of seafood associated with each hazard. The second step consisted of reviewing the various aspects of the rule to determine the areas of seafood harvesting and processing that the rule could affect. The third step was to eliminate those cases that could not be affected by the rule.

These would be cases that seafood processors could neither eliminate through processing nor prevent from being introduced, either by their own staff or by control over raw materials. Cases caused or controlled by factors outside of the HACCP system include recreational harvest (approximately 20 percent of all seafood harvested) that does not pass through processing plants and problems caused by restaurant, supermarket or consumer improper cooking or mishandling. In addition, there will be some types of hazards that will not, for the foreseeable future, be controllable by means other than avoiding contaminated waters, which will not be 100 percent effective (ciguatera, for example). Until rapid, inexpensive tests are developed, HACCP cannot be 100% effective at controlling these hazards.

Once each expert had accounted for those cases that could not potentially be reached by this rule, the experts then assessed the likely effectiveness of control steps associated with broad sanitation improvements and mandatory controls on specific hazards and specific species.

*Ciguatera*: Both the lower and upper bound reductions in illness are

relatively small in the near term because there does not yet exist a rapid, inexpensive test for this toxin. Processors and commercial fishermen must rely on information about whether geographic areas are ciguatoxic. Moreover, many illnesses are attributable to recreational harvest.

*Hepatitis A virus*: This illness derives mostly from molluscan shellfish. For molluscan shellfish, the controls are harvesting from approved waters and good sanitation in the plant. These regulations specifically involve both types of controls. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish.

*Norwalk virus*: This illness derives from raw molluscan shellfish that are contaminated from human pollution in harvesting areas. Control involves harvesting from approved waters. These regulations include this kind of control. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish and because of the uncertainty of the control of sewage from harvesting and recreational vessels.

*Vibrio vulnificus*: This illness essentially derives from eating raw molluscan shellfish from the Gulf of Mexico. *Vibrio vulnificus* is a naturally occurring, ubiquitous, marine organism. The lower and upper bound numbers reflect the fact that controls are newly emerging for this organism and still have uncertainties associated with them.

Table 6a sets out the new estimates of baseline cases of foodborne disease related to HACCP and the range of cases averted by HACCP.

TABLE 6a.—ESTIMATE OF ANNUAL CASES AVERTED

Hazard	Estimated number of cases <sup>1</sup>	Number of cases averted (lower) <sup>2</sup>	Number of cases averted (upper) <sup>1</sup>
Anasakis .....	100	25	60
Campylobacter jejuni .....	200	100	150
Ciguatera .....	1,600	96	200
Clostridium botulinum .....	10	3	5
Clostridium perfringens .....	200	100	150
Diphyllobothrium latum .....	1,000	250	600
Giardia .....	30	15	23
Hepatitis A Virus .....	1,000	150	500
Other Marine Toxins .....	20	.....	1
Norwalk Virus .....	100,000	15,000	50,000
Other Vibrio's .....	1,000	200	500
Paralytic Shellfish Poisoning .....	10	.....	1
Salmonella non typhi .....	200	100	150
Scombrotoxin .....	8,000	4,000	6,000