

actually the result of poor manufacturing practices, making recourse to the courts sometimes impractical.

In the absence of the proposed CGMP regulations, the burden of monitoring manufacturing practices would fall more heavily on consumers, despite the difficulties consumers face in monitoring manufacturers. Moreover, the proposed CGMP regulations are preventative and should ensure that problems are identified and dealt with during manufacturing, packaging, and holding, rather than after someone has consumed an unsafe product and experienced an adverse effect.

b. *Fewer requirements for vitamins and minerals.* FDA could require more controls from establishments that manufacture, package, or hold plant or animal derived dietary ingredients such as amino acids, proteins, herbals, botanicals and other products not classified as vitamin and mineral manufacturers, packagers, or holders. The plant or animal derived dietary ingredients are probably characterized by greater variation in product quality than synthetically derived dietary ingredients. Under this option, the segment of the industry that manufacture, package, or hold products that are the most likely to have difficulty manufacturing or maintaining uniform product quality dietary ingredients would be required to follow the proposed testing and other production and process control requirements. Manufacturers of vitamins and minerals would be required to follow the sanitation, holding, and consumer complaint provisions only, they would not have to adopt manufacturing controls to ensure that products did not contain too much or too little of a vitamin or mineral.

Plant or animal ingredients are likely to experience greater natural variation in product quality than synthetic compounds, so they may require the higher minimum standard of regulation contained in the proposed regulation. The advantage of this option is that fewer establishments will be affected as much; approximately 723 establishments classified as manufacturers, packagers or holders of products other than vitamins and minerals, rather than the 1,566 establishments estimated to be covered by the proposed regulation (see table 2 of this document). The compliance costs would therefore be lower. The disadvantage is that vitamin and mineral manufacturers also potentially manufacture products of variable quality, so the expected benefits from more consistent product quality would

be reduced. Moreover, if dietary supplements contain too little of a vitamin or mineral consumers may not receive the intended health benefits, and if the dietary supplements contain too much of a vitamin or mineral they may experience illness or injury.

We estimate that the benefits of this option would be approximately proportional to the ratio of recalled products that were classified as vitamins and minerals to all recalled dietary supplements products. Approximately 50 percent of the recalled products were vitamins and minerals so we estimate that this option would generate no more than \$109 million in benefits. We assumed that the costs of this option would be proportional to the fraction of establishments that would be required to follow all of the proposed provisions and those that follow the reduced requirements with the total costs estimated for this proposal as shown in table 17 of this document. The estimated mean cost of the proposed regulation is \$86 million (see table 19 of this document). The fraction of establishments required to follow all the provisions is .46 (= 723/1566). The fraction of establishments that would have reduced testing is .54 (= 843/1566). Testing is approximately 36 percent of the total costs. We estimate the total costs from this option to be \$69 million ( $\$86 \text{ million} \times .46 + \$86 \text{ million} \times .54 \times (1 - .36)$ ).

c. *More restrictive CGMP regulations than the proposed regulations.* One option is to propose (or finalize) more restrictive rules than the proposed CGMP regulations. Under this option, CGMP regulations could provide consumers with additional safeguards. Several of the largest manufacturers of dietary supplements now voluntarily comply with some of these additional safeguards (Ref. E2). The most significant additional provisions that would be required under this option are product quality testing for each incoming shipment lot of components and dietary ingredients, inprocess testing for contaminants at critical control points and mandatory written procedures for all of the various provisions of the proposed regulation.

The advantage of this option is that the additional requirements provide safeguards that the essential safety and quality provisions are being followed. The disadvantage of this option is that it is more costly than the proposed rule, and we are not aware of any information that would show any additional verifiable health benefits.

d. *HACCP without the other elements of CGMP regulations.* The agency could

propose a requirement that manufacturers implement a HACCP (or HACCP like) system for the manufacturing of dietary supplements without the other elements of the proposed CGMP regulations. A critical control point is where production controls can be applied to reduce or eliminate hazards (including biological, chemical, or physical contamination) that may make dietary supplements unsafe.

The advantage of an industry-wide HACCP program is that HACCP does not require manufacturers to follow detailed uniform requirements in order to achieve desirable outcomes. Manufacturers themselves determine for their specific products and processes how they will best eliminate, reduce, or control hazards in the manufacturing of dietary supplements.

We have not designed a hypothetical HACCP system for the dietary supplement industry. For the purpose of generating estimates of costs and benefits, we assumed that a HACCP regulation for a dietary supplement manufacturer would be likely to encompass sanitation prerequisites that are met, writing a HACCP plan, and monitoring critical control points. The benefits and costs of the HACCP plan would be generated by controls for a narrower set of hazards in the manufacturing, packaging, and holding processes than those covered by this proposal, and would not include the other benefits and costs generated by the proposed rule especially the reduced consumer search costs, because uniform product quality would not necessarily be assured. The advantage of HACCP as an option to prevent product contamination is that it does not specify detailed manufacturing requirements. The disadvantage is that in the absence of uniform controls there would not be uniform minimum product quality across the industry and consumers would not derive the same benefits from lower search costs.

e. *Require final product testing only.* FDA could propose that manufacturers test their finished products for identity, purity, quality, strength, and composition but not include any of the other mandatory provisions of the proposed regulation. The advantage of this option is that it would be the least costly option of those considered. Many firms already test some of their finished products, reducing the impact of this option. Approximately 69 percent of manufacturing plants conduct finished product testing and almost 65 percent of all finished batches in the industry are already tested using physical, chemical, microbiological, visual or organoleptic