



September 1, 2008

Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

[Docket No. FDA-2008-N-0354]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Farmers' Understanding and Implementation of Good Agricultural Practices

Western Growers is a trade association that represents growers and handlers of fresh fruits, nuts and vegetables produced in California and Arizona. Our 3000 members grow and handle almost half of the United States total output of fresh produce. As such, our organization and members are fundamentally interested in the development of information that can be utilized to improve food safety in the fresh produce sector and are generally supportive of the Agency's efforts to develop "mental models" that will provide information on the "usability" of good agricultural practices in fresh produce operations. Western Growers has been a vanguard in the development and extension of good agricultural practices having been engaged for decades in writing, refinement and training associated with GAPs. We have done this in close collaboration with the public health community as part of our commitment to work with them to achieve the common goals of reducing food borne illness associated with fresh produce commodities. During this decades long collaboration key questions that have consistently been raised by public health partners such as "What is the depth and breadth voluntary GAPs implementation?" and "What barriers might exist that would prevent or provide disincentive to implement good agricultural practices?" have gone largely unanswered. Western Growers believes that the vast majority of our members employ strong food safety programs including good agricultural practices at the production, harvest, packing and transportation levels and that the current marketplace makes it difficult for any firm to introduce product into commerce that has not been produced utilizing strong gaps and audited as a means of verifying to receivers that this is in fact the case. We hope that this information collection activity will assist in confirming this is the case and we will collaborate with FDA in every way to help facilitate the proposed collection. In the event barriers to implementation of GAPs are identified by models or through the collection of information we additionally will support efforts to break down those barriers and encourage FDA to work directly with us and other produce trade associations committed to improving industry performance.

While the preceding comments are general in nature, we offer the following input on the specific topics raised in the federal register notice on this initiative:

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

Western Growers believes that the collection of this information will assist both FDA and industry in the development of information on the breadth and depth of the use of voluntary good agricultural practices in the produce industry. The information collected and resulting modeling may also provide information on the "usability" of GAPs including the perceived effectiveness, efficiency and satisfaction on the part of users. This information in turn can be utilized to develop strategies and tactics to assist in greater adoption of voluntary GAPs. The project will have practical utility if there is any increased subscription or implementation of GAPs programs on the part of industry resulting from information developed.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

Western Growers perceives that the small scale nature of this project will not place any undue burden on individuals or firms participating in information gathering. We are concerned however that the small sample sizes proposed will not provide sufficient baseline information for model development or use by industry. Limited sampling will provide little information to fill in knowledge gaps necessary to develop strategies for redress as proposed by FDA.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

Recognizing that the small sample sizes being proposed will limit the utility of the data and hence the quality of any associated model parameters and/or any qualitative assumptions Western Growers suggests that FDA collaborate with industry organizations to further develop data that can be utilized. Direct coordination with Western Growers, for example, could provide access to a large portion of the produce industry which in turn could be surveyed under FDA supervision utilizing the proposed telephonic method as well as electronically using email and web-based formats routinely utilized by the association to solicit feedback from members. The increased sample size would provide added strength, utility and enhance the overall quality of data gathered. Because the data would be of value to the industry in terms of analyzing the breadth and scope of education and extension efforts on GAPs these initiatives could be carried out by industry under supervision of FDA investigators.

Western Growers anticipates that our membership and most produce operators affiliated with an organization like WG are largely implementing GAPs under either a market based or regulatory structure. We are concerned however those smaller operators and those in other areas of the country may not be as engaged in food safety related good agricultural practice programs as operators in major produce shipping areas. These smaller entities and regions are now taking on increased importance as buyers look to source closer to the point of service and to reduce transportation costs. This study must sample a diverse set of growers and others to truly determine the breadth and depth of the national implementation of voluntary good agricultural practices. Western Growers strongly recommends that the sample size be increased and that key sub-sets be surveyed to ensure that there is definitive information on the wide diversity of produce operations.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

As mentioned above, collaborating with key trade associations across the country to develop and disseminate electronic surveys utilizing email and/or web based technology could expand the scope of the survey and the sample size dramatically without much cost to FDA. Industry collaborators who are interested in developing information on their own members would likely willingly collaborate to facilitate contact with their members in exchange for access to data points associated with their membership. Western Growers encourage FDA to expand the scope and sample size in this fashion and would volunteer to work with FDA to develop mechanisms to develop data on WG members that would prove useful to the Agency and the Association.

In summary, Western Growers supports the proposed project to collect information for mental models that will enhance our understanding of the implementation of good agricultural practices in the fresh produce industry. We do not perceive that this project would cause undue burden on the Agency or industry but we are concerned that the limited scope of information being developed will not provide sufficient data to correctly characterize the industry or assist with model development. WG suggests that FDA collaborate with industry to expand the scope of collection efforts and volunteers to assist in any way feasible to improve the efforts and to achieve the desired outcomes.

Sincerely,



Hank Giclas, Vice President
Strategic Planning, Science and Technology
Western Growers
17620 Fitch Street
Irvine CA, 992614
949-885-2205 direct line
949-809-6205 fax
hgiclas@wga.com