Sub : New Developments in USFDA- Comments from the Industry

USFDA is proposing to establish science based standards for growing, harvesting, packaging and holding of produce for human consumption and amending previous regulation for current Good Agricultural Practices (GAP) in manufacturing, packaging or holding human food to include modern technologies to implement Hazard analysis and risk based preventive controls for human food.

USFDA has requested interested parties to provide comments on proposed rules by May16, 2013 to prepare future rules. The consultation is accessible at the following Federal e-Rulemaking Portal: http://www.regulations.gov. Stakeholders are suggested to forward their comments to APEDA so that consolidated views of the industry could be forwarded to the Division of Dockets Management (HFA-305), US Food and Drug Administration. For convenience for the stakeholders copy of the letter from USFDA is attached for reference.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

January 10, 2013

Mr. Asit Tripathy, I.A.S.
Chairman
Agricultural & Processed Food Products
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Secretary
AA/n (DP)
Ms Abhilasha
Please circulate
28/1/13

Dear Mr. Tripathy,

I am writing to inform you of important new developments regarding the U.S. Food and Drug Administration's (FDA's) efforts to fully implement the Food Safety Modernization Act (FSMA). As you recall, FSMA is a comprehensive food safety law signed into law two years ago on January 4, 2011 by President Barak Obama to better protect the public health of U.S. consumers by taking additional measures to ensure the safety and security of the food supply.

The legislation embraces the public health principle of prevention as the foundation of a modern, global food safety system and is the first major reform of FDA's food safety authorities in more than 70 years. A modern food safety system is both critical and necessary to reduce foodborne illness, which has taken a great toll on American consumers, killing 3,000 and putting almost 128,000 in the hospital each year. A modern, risk-based food safety system can also help minimize economic costs related to disruptions in the food supply.

On January 4, 2013, FDA published proposed rules on Standards for Produce Safety, and Preventive Controls for Human Food. These two proposed rules are the first of five, key proposed rules that would lay the cornerstone of the prevention-based, modern food safety system we need.

It is important to emphasize that the proposed regulations that FDA has announced are proposals rather than final rules. This means that FDA's many stakeholders, including consumers, associations, public health advocates, the regulated industry, and our international and domestic regulatory counterparts will now have the opportunity to review the proposed rules and submit comments for 120 days before they become final. FDA will review the comments that are received during the comment period and will consider revising the rules based on the comments, before issuing final rules.

Summaries of the Preventive Controls for Human Food and Standards for Produce Safety proposed rules and the rulemaking process are presented below. The proposed rules themselves can be viewed at www.fda.gov/fsma .

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Standards for Produce Safety 16 May, 2013

- Applies to both domestically-produced and imported produce.
- Requires farms that grow, harvest, pack or hold most fruits and vegetables to follow standards that are aimed at preventing contamination of produce when those fruits and vegetables are in their raw or natural (unprocessed) state.
- Focuses on the most commonly identified routes of microbial contamination of produce, e.g., those areas that present the greatest risk, namely, agricultural water, biological soil amendments of animal origin such as cow manure-based fertilizer, worker health and hygiene, domesticated and wild animals in growing areas, and equipment, tools and buildings.

Preventive Controls for Human Food

- Based on state-of-the-art and internationally recognized HACCP principles.
- Applies to domestic and foreign firms that manufacture, process, pack or hold human food.
- Modernizes existing current Good Manufacturing Practices and also requires conducting a hazard analysis and implementing risk-based preventive controls.
- Requires a written plan that evaluates hazards that are reasonably likely to occur in food, such as pathogens and allergens, specifies the steps that will be put in place to minimize or prevent those hazards, specifies how these controls will be monitored, maintains routine records of the monitoring, and specifies what actions will be taken to correct problems that arise.

FDA's proposed, science-based rules are the result of an extensive amount of outreach by FDA to get input from consumers, foreign and domestic governments, industry, researchers, and many others. FDA looks forward to further collaboration with these domestic and international stakeholders to forge flexible and reasonable solutions to foodborne illness in order to better protect global public health.

Rulemaking Process and How to Submit Comments

The Preventive Controls for Human Food and Standards for Produce Safety proposed rules will be published in the Federal Register in the United States and will be accessible at: http://www.regulations.gov . Each has been assigned a "docket" to which the public can submit comments. FDA will also notify the World Trade Organization Committee on Sanitary and Phytosantiary Measures (SPS Committee) of the proposed produce rule and related "docket" instructions. Those who wish to submit comments should pay particular attention to the comment period for the proposed rule (120 days) and must submit any comments by the due date.

FDA will consider the comments received during the comment period for each of the proposed rules and will then consider revising the rules, based upon its review of the comments, before issuing final rules. FDA will address all significant comments that were received during the comment period in the preamble to the final rule.

More information on the Rulemaking Process and How to Submit Comments can be found at: http://www.fda.gov/Food/FoodSafety/FSMA/ucm277706.htm

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Outreach and Industry Assistance

In developing each of the proposed rules, FDA has engaged in extensive outreach to stakeholders in the United States and foreign countries. For example, since January 5, 2011, FDA has made presentations at, or participated in nearly 350 meetings with global regulatory partners and domestic and international stakeholders; hosted an Embassy Briefing for the Washington, D.C. diplomatic community; translated key FSMA documents into 11 languages; led delegations to China, Mexico, Canada and the European Community to discuss how FSMA will affect foreign countries; maintained close communications with other federal and international partners including the United States Department of Agriculture, the Foreign Agricultural Service, the World Trade Organization, and the United States Trade Representative; and developed and maintained a comprehensive, interactive, FSMA website to inform and educate stakeholders and subscribers of important FSMA updates.

In the coming months, FDA will continue its outreach efforts and is committed to:

- Developing practical guidance documents that explain, in plain language, the requirements of each of the proposed rules.
- Establishing public-private alliances to develop training and outreach materials.
- Creating a uniform training program for industry through a cooperative agreement with the Institute for Food Safety and Health that will serve as a standardized curriculum.
- Leveraging federal, state and local partners to ensure that appropriate technical assistance is available to small and very small businesses.
- Utilizing our Foreign Posts around the globe to ensure our foreign regulatory counterparts and the international community are equipped with the information and knowledge they need to comply with the new requirements when shipping food to the United States.
- Informing the international community of our activities, including making any notifications of proposed and final measures to the World Trade Organization (WTO).
- Holding regional public meetings, during the comment period, to explain the proposed rules and to provide additional opportunity for input.
- Maintaining and updating the FSMA website with comprehensive, current information at: http://www.fda.gov/Food/FoodSafety/FSMA/default.htm

Clearly, we will face many challenges as we proceed with fully implementing the letter and spirit of FSMA. The FDA will be working especially hard to address these challenges, and we look forward to working side by side with you in our implementation efforts. To stay current with the most updated information regarding FDA's FSMA implementation efforts, please visit FDA's website at: www.fda.gov/fsma. Please do not hesitate to submit any questions or comments regarding FDA's FSMA implementation efforts to: FSMA@fda.hhs.gov

This is truly an exciting era in global public health protection. On behalf of FDA, please accept my sincere gratitude for your ongoing support and for your commitment to enhancing the safety of our global food supply.

Sincerely,

Bruce Ross, MA, MPH
Director-FDA India Office