



General Assembly  
State of Colorado  
Denver

October 8, 2013

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

Docket No. FDA-2011-N-0921  
Regulatory Information Number: RIN 0910-AG35

The Water Resources Review Committee is an interim committee of the Colorado General Assembly that is authorized to review water issues and proposed legislation related to conservation, use, development, and financing of Colorado's water resources. We the undersigned members of the committee are writing to express our opposition to the Food and Drug Administration (FDA) proposed rules for "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" as it relates to standards for irrigation water quality, section 112.45. The committee supports any efforts that reinforce the ability of farmers of raw agricultural commodities (RAC) to provide a safe food supply but feels that more scientific research is needed to identify the specific risks between different RACs and farming practices before a blanket standard for water quality is applied to products that have not been associated with any human health contamination problems.

Colorado's fresh fruit and vegetable industry is a vital source of economic activity for the state and plays a critical role in providing its citizens with a variety of healthy choices of RAC. Meeting these nutritional needs is an important effort to fight the issue of obesity that this nation faces. The blanket application of the proposed rule to all RAC without consideration of the different levels of risk associated with the different products will severely impact Colorado fruit and vegetable production with little to no food safety improvements. Not only will the proposed rule likely reduce vegetable production but it will also hamper efforts to increase irrigation efficiency in a state that is struggling to meet water quantity demands.

First, we would encourage the FDA prior to establishing water quality standards for irrigation water to fund on-the-ground research to identify the specific risks, the specific pathways for possible contamination, and the effectiveness of control measures for each specific RAC under the variety of growing conditions that occur. The current approach of the FDA to apply a one-size-fits all restrictive standard and then allow the use of "alternatives" is like assigning guilt first and then asking farmers to prove their innocence when the alternative threshold will be unachievable for most to attain. For crops like dry bulb onions, which as a part of the growing process are not irrigated for at least a month prior to harvest in order to field cure the crop and have never been associated with any non-processed food borne issues, research could help identify valuable information from the specific conditions/nature of this crop that could help reduce risks in other crops without the additional expense and unintended consequences of this proposed rule as it stands now.

Since the World Health Organization (WHO) has set standards that are far less restrictive, the FDA should, at a minimum, develop scientific evidence to justify its current position, especially in light of the fact that the standard that the proposed rule has chosen to apply is based not on irrigation use but recreational use. Risks associated with water and recreational use include direct contact with the water and potential direct ingestion. Risks associated with irrigation water have many more variables associated with them including the length of time between application of the water and final ingestion of the RAC. Conditions like those found in Colorado's semi-arid desert may significantly reduce the potential of food-borne pathogens to survive. Altitude and the intensity of natural UV radiation may also play a role in reducing risk. Also, as identified by the WHO, the simple act of washing RAC with clean water reduces the risk. There are many factors that should be taken into consideration before establishing a water quality irrigation standard.

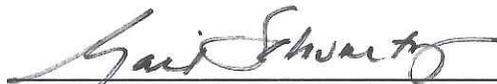
The current rule acknowledges that there are no chemicals with EPA-labeled registration for use as a sanitizing treatment for irrigation water, and the committee hopes that this void can be filled within the delayed effective date that has been incorporated into the rule. The committee has concerns that not only is FDA proposing a standard not based on sound science but a standard that has no way of being economically achieved. Farmers of RAC will have to make many capital improvements in order to comply with other requirements of this rule. Because these investments will be costly and will only be applicable to the production of RAC, the uncertainty of how to meet the water quality requirement would be a stumbling block where farmers will chose simply to divest totally from RAC production.

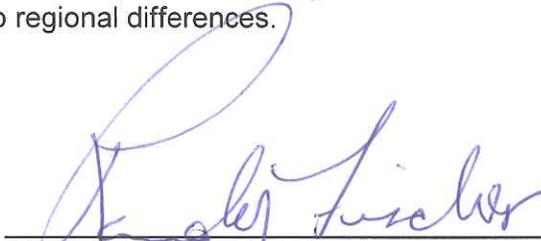
Of particular concern to this committee are the unintended consequences of this proposed rule. Water quality is of key importance and issues like disinfection by-products should be addressed if farmers are expected to meet the proposed standard. The use of hypochlorite as a water disinfectant has been shown to combine with organic matter to form trihalomethanes which have the potential to be carcinogenic. The risks associated with different levels of water quality need to be compared to the overall risks associated with treatment alternatives.

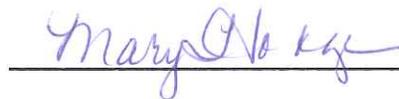
This proposed rule may lead to unintended consequences for efforts to promote agricultural irrigation efficiencies. The conversion from furrow to overhead sprinkler irrigation is the most economically viable option for gaining irrigation efficiency. This proposed rule will hinder this effort as the proposed water quality standard will be applicable to most RAC grown under overhead irrigation systems and not furrow irrigation systems. Crop rotation is an important best management practice and investments in costly systems like subsurface drips will reduce the application of this practice versus the more economical approach of overhead sprinklers, another unintended consequence. The Doctrine of Prior Appropriation is how water rights are administered in the state of Colorado, and now that efforts are being made to conserve water in closed basin aquifers, many of the ground water wells are restricted in their use or not able to pump at all, eliminating the option for many farmers to use these sources of water to meet the proposed standard.

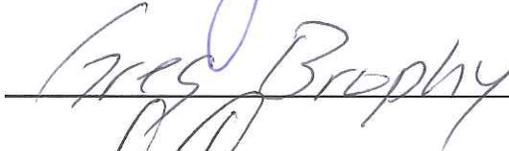
We urge the Food and Drug Administration to reconsider its current approach to meet the requirements of the Food Safety Modernization Act and instead develop a set of regulations based on sound science that address the risks associated with each type of RAC rather than the blanket approach now being use. Because of the unintended environmental consequences, at a minimum, the irrigation water quality standards should be removed from the rule. We would recommend that FDA convene a scientific advisory committee (SAC) to establish what research FDA could fund to establish a scientifically based standard rather than adoption of a recreational-use standard that was established to protect recreational uses based on the treatment capabilities of wastewater utilities and not farming. We would also recommend that participation on this SAC not only be representatives from the USDA but also individual state departments of agriculture in order to provide important local perspectives and insight into regional differences.

Sincerely,

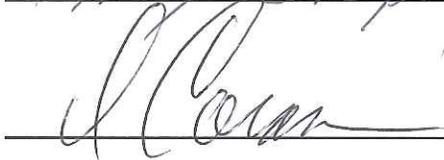
  
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Senator Gail Schwartz, Chair

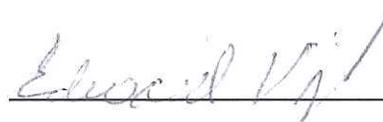
  
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Representative Randy Fischer, Vice-Chair

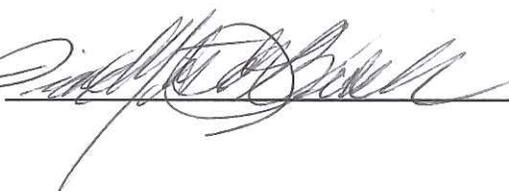
  
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cc: Senator Michael Bennett  
Senator Mark Udall  
Representative Mike Coffman  
Representative Diana DeGette  
Representative Cory Gardner  
Representative Doug Lamborn  
Representative Ed Perlmutter  
Representative Jared Polis  
Representative Scott Tipton  
John Salazar, Commissioner of Agriculture