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To the ISSC Executive Board:

Over the past 10 to 15 years the popularity of rainfall conditional classifications has vastly limited the number of growing areas classified restricted for depuration. Making matters more difficult is the fact that depuration is regulated on 1970's science, in particular, the notion that viruses do not depurate. However, in 2012, we now know that viruses do indeed depurate, albeit at a much slower rate which is strongly dependent upon season and water temperature. Likewise, the FDA's policy of using 1000:1 dilution as the basis for sizing the prohibited zones around point sources of treated sewage is seriously flawed. Although the viral contamination potential is a function of dilution (distance) from a point source, it is more strongly influenced by seasonality. Viruses persist much longer in environmental waters and in shellfish meats in the winter months than in the summer months by a factor of 2-3 logs. Conversely, the area between the 100:1 dilution and 1000:1 dilution lines, which can be very significant, is only a single log. Epidemiological studies conducted in the US and especially in the EC clearly show effect of seasonality on viral illness, especially Norovirus.

Currently depuration is a very prescriptive process for removal of lower level bacterial contaminants over a 44-hour depuration cycle using fecal coliform for process verification. The future of depuration, if there is to be a future, is to mitigate viral as well as bacteriological contaminants in growing areas where rainfall conditional management strategies will not do the job. Depuration for 2012 and beyond needs urgent regulatory modernization, beyond what can be accomplished within the ISSC proposal process alone. ISSC Committees getting together every two years will not get the job done in time to save this important component of the NSSP. Some of the fundamental changes that will be required include:

- 1) Mindset and regulatory modification to realize that viral mitigation strategies may be seasonally limited and process water temperature dependent to allow for depuration of viruses when the initial viral levels are low and the viral depuration rate is high,
- 2) Under proper conditions, a single log reduction of MSC and NV can be realized in a 2 day cycle. To achieve the 2 and 3 log reductions, mindset, regulations, and practices may need to use 4 and 6 day cycle times, respectively,
- 3) Using FC to process validate viral pathogens is inappropriate. MSC more accurately models viral depuration kinetics,
- 4) Upper FC limits of water quality in the restricted for depuration classification are a major, needless, impediment to business from a number of aspects. The upper limits are responsible for closing areas

needlessly during rainfall closures, prevent interstate depuration (regional instead of a single state limited depuration operator), and cost state control agencies precious resources to assess bacterial water quality when the public health concern is both bacterial and viral.

Modern viral depuration fits more appropriately into the container relay regulations of the MO. Future depuration operators will need to conduct pathogen reduction studies using both FC and MSC to customize a process and process verification controls for a variety of situations. Times less than 14 days, assessed through pathogen reduction studies and interim cycle and end-point sampling, are adequate and appropriate. The current mind-set around depuration just does not allow innovation.

Innovation is a key ingredient into the vitality of modern business. If depuration cannot innovate, it cannot survive in this program. Your urgent attention is needed to address this regulatory inertia and salvage an important segment of the NSSP and one that may become more important in the future as coastal population grows and growing areas become less numerous and smaller.

Thank you,

Thomas L. Howell