POLICY ON THE USE OF OZONE IN SHELLFISH PLANTS
NOTES FOR SLIDE 86 IN MODULE 3

Ozone and Molluscan Shellfish:

21 CFR 173.368
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=173.368 covers conditions of use of ozone on "food" which would include fisheries products. The FDA regulation for ozone (gaseous and aqueous) under 21 CFR 173.368 permits its use as an antimicrobial agent on food, including meat, fish and poultry. The regulation permits use of ozone (gaseous and aqueous phases) in processing shellfish. In addition, 21 CFR 184.1563 allows for the use of ozone in bottled water as an antimicrobial.

The use of ozone as a sanitizer for food contact surfaces is not covered under 21 CFR 173.368, as food contact surface sanitizers are not under FDA regulatory authority. Substances that have their antimicrobial effect on the surfaces of food contact articles and equipment (except food packaging) are under EPA's authority. Ozone must be used in accordance with EPA requirements. The Seafood HACCP Alliance (SHA) Sanitation Control Procedures provides supplemental information for the use of ozone as a food contact surface sanitizer in Chapter 2 (Condition and Cleanliness of Food Contact Surfaces). It cautions:

"Ozone is an unstable oxidizing gas that must be generated on-site, contributing to its relative high cost. It is a more aggressive sanitizer than chlorine but requires careful monitoring to prevent the release of excessive levels of the toxic gas. Ozone, like chlorine, is dissipated when in contact with organic soils. It can be injected into water systems as an alternative to chlorine gas, to make it safe for processing."

The requirements for drinking water (potable water) also fall under EPA. If the processor is using ozonation to assure the safety of their processing water, they must meet EPA's requirements and monitor the water/treatment system daily to verify the function of the equipment and treatment system as part of their sanitation monitoring program. For daily verification of ozone equipment/treatment system function, an oxidation/reduction potential (ORP)/Redox analysis using a sensor or meter, or a simple water quality DPD colorimetric test (i.e. Hach Method 8311 with spectrophotometer) would suffice. The firm should measure values before and after ozonation of the water and document/retain records as part of their daily sanitation records. The measurement of ozone levels does not preclude the firm from the requirements stipulated in NSSP Guide for the Control of Molluscan Shellfish, 2019 Revision, Chapter VII .04 C. (3) (a), (b), (c), and (d), as indicated in Chapter VI .05 D. (1).

Ozone may be used in a shellfish processing facility for water treatment, equipment sanitizing, and as an antimicrobial on shucked meats. However, it must be used in accordance with GMPs, which includes following instructions for use, and meeting FDA's or EPA's requirements, as applicable. In addition, if it is used as an antimicrobial on shucked meats, that treatment cannot replace sanitary practices that prevent adulteration or cross contamination.

Additional Research:

Goncalves, A. and G. Gagnon. 2011. Ozone application in recirculating aquaculture system: an overview. Ozone: Science & Engineering. 33:345-367. doi:10.1080/01919512.2011.604595.

"Ozone oxidation can kill microorganisms, but disinfecting the water requires maintaining a certain dissolved ozone concentration for a given contact time. Thus, disinfecting efficiency depends on the product of the ozone residual concentration multiplied by its contact time. An ozone contact vessel should provide the time necessary for the ozone residual to react with and

inactivate the target microorganism(s). Disinfecting water can require maintaining a residual ozone concentration of 0.1–2.0 mg L−1 in a plug-flow type contact vessel for periods of 1–30 min, depending upon the target microorganism (Summerfelt, 2003). Ozone at a concentration not exceeding 0.5 mg L−1 (to minimize bromate production) can be used to treat seawater in batches for periods up to 10 minutes (Lee et al., 2008). If disinfection is the primary goal of ozonation, the amount of ozone necessary is largely dependent on the background organic loading of the water to be treated (Summerfelt, 2003). In pure water, residual concentrations of 0.01–0.1 mg L−1 ozone for periods as short as 15 sec can be effective in reducing bacterial loads. However, in water with organic loadings the residual ozone concentration and/or contact time of ozone must be increased to produce significant disinfection. Natural waters (seawater, brackish and freshwaters) generally require residual concentrations of between 0.1–0.2 mg L−1 ozone and contact times of 1–5 min for disinfection. Aquaculture effluent generally requires between 0.2–0.4 mg L−1 residual ozone for 1–5 min for significant disinfection to occur after oxidation of organics (Read, 2008)."

References:

Lee, R., A. Lovatelli, and L. Ababouch. "Water Treatment Methods" (Chap. 6, p.33–40). In: Lee, R., A. Lovatelli, and L. Ababouch (eds.), Bivalve Depuration: Fundamental and Practical Aspects. Rome: Food and Agriculture Organization of the United Nations. FAO Fisheries Technical Paper 511, 140 p. (2008).

Read, P., "Ozone in Recirculating Aquaculture", New South Wales Department of Primary Industries – Fishing and Aquaculture. New South Wales, Australia, 2008. Available at: <http://www.dpi.nsw.gov.au/fisheries/aquaculture/publications> Access on October 07 (2008)

Summerfelt, S.T. (2003) Ozonation and UV Irradiation—An Introduction and Examples of Current Applications. Aquacult. Eng. 28(1–2): 21–36.