Reduced Oxygen Packaging
Sous Vide

Benefits of ROP:
1. Flavor enhancement;
2. Fresher food, reduced freezer burn;
3. Extended shelf-life;
4. Cost benefit: portion control, bulk purchasing, same package used during storage and reheating.

Safety Concerns:
1. Temperature abuse allowing for increased microbial growth;
2. Extended shelf-life increases risk of microbial growth;
3. Sanitation concerns

Things to Know:
1. Sous vide is a ROP process. With the exceptions identified below, sous vide processing requires a HACCP plan and may also require a variance.
2. ROP is NOT defined as packaging food items in a zipper/press and seal storage bag.
3. HACCP plans and variances are NOT required for non-time/temperature control for safety foods.
4. HACCP plans and variances are NOT required if sealing a product in a bag using ROP methods and held for less than 48 hours (after 48 hours product must be removed from package or unsealed) in accordance with §3-502.12 (F).
5. While conducting sous vide packaging of time/temperature control for safety foods, the only barrier to pathogenic growth is the time/temperature relationship. Therefore, it is important to monitor critical limits for cooking, cooling, and cold holding food.
6. When sous vide processes are conducted in accordance with §3-502.12 (D), only a HACCP plan will be required. If processes deviate from §3-502.12 (D), a variance will also be required.
7. Sous vide packaging of fish is not allowed without a variance, in accordance with §3-502.12 (C).

Be advised of additional limitations for not requiring a variance:
(refer to §3-502.12 for full details)

1. ROP food, packaged at the establishment, cannot be donated or sold directly to customers (refer §3-502.12 (D)(2)(a)).
2. All product shall be cooked fully in accordance with §3-401.11 (A), (B), and (C).

Definitions:
Reduced Oxygen Packaging (ROP) means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level).

Sous vide packaging refers to when raw or partially cooked food is vacuum packaged in an impermeable bag and cooked in the bag. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic (capable of surviving/thriving in cold environment) pathogens, which include Clostridium botulinum and Listeria monocytogenes.

2013 FDA Code References:
3-502.11 (D) Variance Requirement
3-502.12 (C), (D), (F) Reduced Oxygen Packaging Without a Variance, Criteria.
3-401.11 (A), (B), and (C) Raw Animal Foods

***Any deviation for conducting ROP from §3-502.12 would require a variance.***
Establishments seeking approval for a HACCP plan or variance for sous vide shall submit the following to the Department for review:

2. Application Fees
3. Detailed food preparation process
4. Complete Hazard Analysis and Critical Control Point (HACCP) Plan
   
   For guidance please refer to:
   
   https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm
5. Standard operating procedures for the following: labeling, date marking, tracking product from preparation to consumption, employee health, staff training, calibration of thermometers, and cleaning and sanitizing
6. Sample log sheets (e.g. cooking, thermometer calibration, staff training, etc.)
7. Equipment needed for process
8. Provide details on how person in charge will oversee process
9. Provide statements for the following: completed logs will be kept for 180 days and that the product will only be used in-house
10. If operating in a shared kitchen, provide details on how food process will be protected

Please note that if any of the above are not provided or if not complete, then the review process will be delayed.