

## **Vac Attack:**

# **The Legal and Regulatory Environment of Sous Vide for New York City Restaurants**

## **Introduction**

The nascent practice of sous vide within restaurants is relatively misunderstood, and even faced a temporary ban in March of 2006 by the New York City Department of Health and Mental Hygiene.

While it is true that any food handling introduces possible pathogenic vectors, they may be largely reduced or eliminated with the introduction of a Hazards Analysis Critical Control Point (HACCP) program. Indeed, any restaurant which introduces HACCP protocols will become a safer environment in all areas.

This paper interprets the Federal 2005 FDA Food Code as it might apply to restaurants using Reduced Oxygen Packaging (ROP) for sous vide. Some sections of the 2005 FDA Food Code are listed verbatim, others are cross-referenced from sections within the Food Code, and still others are clarified with examples relevant to a commercial kitchen environment.

## New York City Bans Sous Vide

The New York City ban on sous vide is specifically targeted at restaurants who preserve food in a plastic vacuum bag, ‘cryovac’, or Reduced Oxygen Packaging (ROP), without proper hygienic controls. The primary issue is that such packaging creates an anaerobic environment where deadly bacteria such as *Clostridium botulinum* or *Listeria monocytogenes* may thrive. Restaurants do not typically maintain HACCP programs to ensure a proper food handling chain, and most do not train kitchen staff with proper sous vide technique and safety procedures.

The NYC health department recently instructed restaurants to discard all vacuum-preserved food, and to stop using vacuum sealing equipment until a HACCP program is filed with the department. Fines of up to \$300 per offense are threatened for unsanctioned uses of vacuum equipment.

Associate Commissioner Elliott Marcus, who was present at a recent sous vide training class given by Georges Pralus, the inventor of sous vide, indicated that because Reduced Oxygen Packaging was not covered by the New York City food handler’s license, the agency is concerned about improper packaging which may lead to *botulism* outbreaks. Deputy Executive Director Michelle Robinson has been working to provide guidelines for safe sous vide cooking. The Health department has prioritized the release of rules to govern the use of vacuum equipment, and will allow chefs who file HACCP plans to use vacuum equipment.

## 2005 FDA Food Code provisions for sous vide

2005 FDA Food Code concentrates on industrial sous vide processes, where a product is prepared, packaged, pasteurized, then frozen for later use, in a continuous process. In a typical restaurant, products may be prepared and packaged, then held in a raw chilled state for an undetermined period of time before pasteurization and immediate service. During this chilled holding period, raw foods are most susceptible to pathogenic reproduction of anaerobic bacteria such as *Clostridium botulinum*, *Listeria monocytogenes*, *Clostridium perfringens*, or *Bacillus cereus*.

FDA Food Code compliance is not mandatory, and subject to optional adoption by local authorities and regulatory agencies. As of May 1<sup>st</sup>, 2006 New York City local health codes have not fully adopted the guidelines set forth by the 2005 FDA Food Code, and do not include specific provisions for ROP in restaurant settings. The Department of Health and Mental Hygiene is expected to release ROP and sous vide guidelines in summer, 2006, and will likely model but not necessarily follow the 2005 FDA Food Code specifications outlined below.

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Interpretation and integration of the 2005 FDA Food Code from a commercial restaurant perspective, for sections related to sous vide, reduced oxygen packaging, cooking, chilling, and HACCP plans yield the following conclusions:

Section 3-502.11 of the 2005 FDA Food Code instructs that food establishments must obtain a variance, which is an extremely complicated undertaking, from the regulatory authority before packaging food using Reduced Oxygen Packaging (ROP), *except* if the establishment complies with specifications in 3-502.12, where refrigeration and at least one other barrier to bacterial growth exists.

Section 3-502.12 specifies criteria for *Clostridium botulinum* and *Listeria monocytogenes* Controls and Reduced Oxygen Packaging (ROP).

- A) Paragraph A stipulates that with the exception of establishments that have obtained a variance, and with the exception of fish [3-502.12(C)] and cheese [3-502.12(E)], and as specified for sous vide [3-503.12(D)], food establishments must set up at least two barriers, such as temperature, low active water content or acid, to control the growth and toxin formation of pathogens.
- B) Food establishments which use reduced oxygen packaging methods must establish HACCP plans which contains the information specified under 8-201.14(D) and that:
  - 1) Identifies the food to be packaged

- 2) Except for Fish [3-502.12(C)] and Cheese [3-502.12(E)] and as specified for sous vide [3-502.12(D)], all packaged food must be maintained below 5C (41F) and meet at least one of the following barriers:
  - a) Has an active water content ( $A_w$ ) of 0.91 or less
  - b) Has an acidic pH of 4.6 or less
  - c) Is a meat or poultry product cured at a USDA food processing plant using substances specified in 9 CFR 424.21, and is received in an intact package
  - d) Is a food with a high level of competing organisms such as raw meat or poultry.
- 3) Must be prominently and conspicuously labeled with instructions to:
  - a) Maintain the food at 5C (41F) or below
  - b) Consume or discard within 14 days of packaging
- 4) Limits refrigerated shelf life to no more than 14 calendar days from packaging to consumption or disposal.
- 5) 3-502.12(B)(5) Operational procedures must:
  - a) Prohibit food contact with bare hands
  - b) Identify and designate a work area and method by which
    - (i) Physical barriers or methods of separation of raw foods and ready to eat foods minimize cross contamination
    - (ii) Access to processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and
  - c) Delineate cleaning and sanitization procedures for food contact surfaces.

6) 3-502.12(B)(6) Training procedures specify that the training program ensures that the individual responsible for operation of the reduced oxygen packaging equipment understands the:

- a) Concepts required for safe operation
- b) Equipment and facilities, and
- c) Operational procedures described by 3-502.12(B)(5) and 8-201.14(D), related to HACCP critical control points.

C) Fish may not be ROP processed, except if the fish is frozen before, during, and after packaging.

An exception is given for food establishments to package food using a sous vide process without obtaining a variance under 3-502.11(D), provided the following conditions are met:

D) With the exception of fish [3-502.12(C)], the food establishment may use ROP technology without a variance if:

- 1) A HACCP plan which contains information as specified under 8-201.14(D) is implemented, and

The food is:

- a) Prepared and consumed within the same business entity, that is not packaged for resale or sold as a bagged product,
- b) Heat treated to a temperature and time compliant with specifications listed under 3-401.11. Temperatures and times listed in 3-401.11 are higher than those typically used for sous vide cooking (63C/145F – 74C/165F, depending on the product), however there is a provision under 401.11(B)(2) which allows *whole meat roasts* to be cooked at lower temperatures, provided the minimum cooking time corresponding to the target temperature throughout the entire product is met:

Temperature °C (°F)	Time <sub>1</sub> in <i>Minutes</i>	Temperature °C (°F)	Time <sub>1</sub> in <i>Seconds</i>
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		

<sub>1</sub>Holding time may include postoven heat rise.

- c) Protected from contamination
- d) Sealed in a bag prior to cooking or immediately after cooking and before dropping below 57C (135F)
- e) Cooled within two hours from 57C (135F) to 21C (70F), then cooled within a total of 6 hours to less than 5C (41F) as specified under 3-501.14. Foods

designated as cooked via sous vide techniques must then be further chilled to 1C (34F) or less within 48 hours of reaching 5C (41F) and:

- (i) Held at 1C (34F) and consumed or discarded within 14 days after preparation. (Although 3-502.12(D)(2)(e)(i) provides for a holding interval of 30 days at 1C (34F), 3-502.12(B)(3)(b) *Clostridium botulinum* and *Listeria monocytogenes* Controls advises discarding food within 14 calendar days of packaging.)
  - (ii) Held at 5C (41F) or less for no more than 72 hours before consumption
  - f) Held in a refrigeration unit that is equipped with an electronic monitoring system, and visually examined for proper operation twice daily
  - g) If transported off site within the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and
  - h) Labeled with the product name and date of packaging, and
- 2) Proper records must be kept to confirm that cooling and cold holding time/temperature parameters are required as part of the HACCP plan. They must be regularly maintained, and:
- a) Made available to the local regulatory authority upon request, and
  - b) Held for 6 months
- 3) Establish written operational procedures as specified under 3-502.12(B)(5) and actively maintain training programs as specified under 3-502.12(B)(6), as referenced above.

Section 8-201.14 outlines the contents of a HACCP plan, and indicates that plans and specifications should minimally provide:

- A) A categorization of the types of potentially hazardous foods specified in the menu, such as soups, sauces, salads, bulk, or solid foods such as meats or other potentially hazardous foods.
- B) A food handling flow diagram within the establishment, categorized by specific food type. The following information should be presented:
  - 1) Ingredients, materials, and equipment used in the preparation of food
  - 2) Formulations or recipes which provide methods and controls to address risks associated with each food type
- C) An employee and supervisory training plan which addresses food safety concerns
- D) Standard operating procedures which clearly identify:
  - 1) Each Critical Control Point, such as temperature barriers
  - 2) Critical Limits for each Critical Control Point, such as exposure to temperatures greater than 5C (41F) for an extended period of time
  - 3) The method and frequency for monitoring and controlling each Critical Control Point by the food employee designated by the person in charge
  - 4) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures
  - 5) Actions to be taken by the person in charge if the Critical Limits for each Critical Control Point are not met, such as discarding or reprocessing product which has exceeded 5C (41F) for an extended period of time

- 6) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed
- E) Additional scientific data or other information to support the determination that food safety is not compromised by the proposal.

## HACCP planning for restaurants

What does all this mean for restaurants in New York City wanting to use ROP for sous vide? Until official guidelines are released, restaurants must submit a HACCP plan to the Department of Health and Mental Hygiene. According to the FDA, HACCP is based on the following seven principles<sup>1</sup>:

- **Analyze hazards.** Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe; chemical, such as a toxin; or physical, such as ground glass or metal fragments.
- **Identify critical control points.** These are points in a food's production--from its raw state through processing and shipping to consumption by the consumer--at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.
- **Establish preventive measures with critical limits for each control point.** For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.
- **Establish procedures to monitor the critical control points.** Such procedures might include determining how and by whom cooking time and temperature should be monitored.

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<sup>1</sup> <http://www.cfsan.fda.gov/~lrd/bghaccp.html>

- **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met**--for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
- **Establish procedures to verify that the system is working properly**--for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly.
- **Establish effective recordkeeping to document the HACCP system.** This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by sound scientific knowledge: for example, published microbiological studies on time and temperature factors for controlling food-borne pathogens.

Beyond following and documenting HACCP procedures for the production of sous vide processed foods, restaurants should always follow these simple steps to minimize food-borne illness risk<sup>2</sup>:

- Always ensure that product temperature remains below 5C (41F) or above 60C (140F)
- Ensure that ROP product is packed in a drained bin with alternating layers of ice to support temperature stability below 3C (37F)

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<sup>2</sup> “Des techniques de caisson sous vide,” sous vide training class instructed by Georges Pralus

- Never store raw ROP inventory for more than 2 calendar days
- Never store sous vide pasteurized ROP inventory for more than 8 calendar days from date of packaging to minimize risk of bacterial growth and spoilage.
- Clearly label sous vide and ROP packages with:
  - The food item description
  - The date and time of packaging, preferably in conjunction with a color coding system
  - The date and time of pasteurization
  - The expiration limit date no more than 8 calendar days from the date of packaging
- Regularly use an invasive temperature probe connected to a digital thermometer to monitor core temperature of a sample product
- Ensure that the product's core temperature reaches at least 60C (140F) during pasteurization
- Discard or reprocess any inventory which exceeds or violates established Critical Control Points
- Train employees who work with sous vide equipment on proper handling and operational procedures.
- Monitor compliance with established operational procedures on a regular basis
- Document the entire production process and retain records for 6 months.

## Conclusion

Sous vide technology, though used in Europe for decades, is a relatively new cooking technology in North America. Because of the hazards associated with anaerobic bacterial growth, it should only be used in a professional setting with a registered HACCP program to control, monitor, and document the production environment. New York City's Department of Health and Mental Hygiene temporarily banned the use of ROP machines without a HACCP plan until a comprehensive set of guidelines is released.

Until the new guidelines are released, analysis of the 2005 FDA food code gives an indication of the policies governing sous vide, which will likely be issued by the end of summer, 2006.

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