

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF INTENTION
TO AMEND ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE

NOTICE OF PUBLIC HEARING

In compliance with §1043(b) of the New York City Charter (the “Charter”) and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice is hereby given of the proposed amendment of Article 81 of the New York City Health Code (the “Health Code”).

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE (the “DEPARTMENT”) WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON TUESDAY, NOVEMBER 27, 2007 FROM 10:00 A.M. TO 12:00 P.M. IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY 5:00 P.M., ON MONDAY, NOVEMBER 26, 2007. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL WORKING HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 ON OR BEFORE 5:00 P.M., ON NOVEMBER 16, 2007.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 12:00 P.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ONLINE (WITHOUT ATTACHMENTS) AT <http://www.nyc.gov/html/doh/html/notice/notice.shtml> ON OR BEFORE 5:00 P.M. ON NOVEMBER 27, 2007. ATTACHMENTS TO COMMENTS MUST BE MAILED OR FAXED.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A TRANSCRIPT OF THE PUBLIC HEARING WILL BE AVAILABLE FOR PUBLIC INSPECTION WITHIN A REASONABLE TIME AFTER RECEIPT, BETWEEN THE HOURS OF 9:00 A.M. AND 5:00 P.M. AT THE OFFICE OF THE SECRETARY. THE DEPARTMENT’S GENERAL POLICY IS TO MAKE WRITTEN COMMENTS AVAILABLE FOR PUBLIC VIEWING ON THE INTERNET. ALL COMMENTS RECEIVED, INCLUDING ANY PERSONAL INFORMATION PROVIDED, WILL BE POSTED WITHOUT CHANGE TO <http://www.nyc.gov/html/doh/html/comment/comment.shtml>.

STATUTORY AUTHORITY

These amendments to the Health Code are promulgated pursuant to §§558 and 1043 of the Charter. Section 558(b) and (c) of the Charter empowers the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 grants the Department rule-making authority.

STATEMENT OF BASIS AND PURPOSE

The Department enforces provisions of the Health Code and other applicable laws intended to protect the safety of food served directly to the consumer throughout the City, including food that is commercially prepared and sold, or distributed for free, by food service establishments (FSEs), a broad category that includes restaurants, caterers (non-retail food processing establishments), mobile food vending units, and cafeterias.

The Department proposes that the Board of Health amend Article 81 of the Health Code to establish requirements enabling FSEs to use reduced atmosphere packaging (ROP) food processing techniques that are not specifically addressed within either Article 81 or the State Sanitary Code. These processing techniques include reduced oxygen packaging (ROP) for storage and preservation of food, cook chill and *sous vide* processing. These new provisions codify minimal standards for such processes.

When Article 81 was last repealed and reenacted in 1996, the food processing techniques that this amendment seeks to regulate were not commonly used in New York City FSEs. Increasingly, operators of FSEs are experimenting with food technology, including *sous vide* and cook chill processing that are not currently covered by specific provisions of Article 81 or the New York State Sanitary Code. Used properly, these techniques can extend the shelf life of a product and may improve the taste and quality of foods. However, these processing techniques, which extract air, can create a significantly anaerobic environment that inhibits the growth of aerobic spoilage organisms, but may support pathogens that are either facultative (organisms capable of living under varying conditions, with or without oxygen) or anaerobic (able to live without oxygen), such as *Bacillus cereus*, *Staphylococci*, *Listeria monocytogenes*, *Clostridium perfringens*, and *Clostridium botulinum*, and it is therefore important to establish minimum food safety requirements for ROP processing

Amend §81.03 Definitions

The following terms and definitions used in regulating these processes will be added to this section: fish, Hazard Analysis and Critical Control Point (HACCP) plan, critical control point, critical limit, cook chilled foods, cook chill processing, reduced oxygen packaging, packaging, *sous vide* water activity (a_w), and the "pH" symbol for the negative logarithm of the hydrogen ion concentration.

Amend §81.06 Prevention of imminent health hazards

This section is amended, by adding a new subdivision (b), prohibiting processing and preparation of certain foods without Department approval, and a new subdivision (c) that describes the content of a HACCP plan whenever such plans are required by the Department or the Health Code to prevent the occurrences of imminent health hazards, relettering the current provision as subdivision (a). The proposed HACCP plan requirements are modeled on those in the FDA 2005 Food Code §§8-201.12 and

8-201.14. All HACCP plans will be submitted to DOHMH for approval, then maintained at an FSE and be made available to DOHMH inspectors for review upon request. This provision will explicitly authorize the Department, as applicable, to require that an FSE submit additional information so that it may determine that food safety is not compromised by the proposal, and enable the Department to maintain the confidentiality of trade secrets that may be contained in HACCP plans when requested by an FSE.

The proposed provisions codify minimal standards for developing and implementing a HACCP plan. The HACCP plan outlines the FSE's formal procedures for use of the specific technique and when properly applied by the FSE enables safe use of the technique. HACCP plans were developed by the U.S. FDA's National Advisory Committee on Microbiological Criteria for Foods. Their use is widely recommended in the FDA's Food Code in a variety of potentially hazardous food preparation processing techniques that the FDA considers high risk, where combinations of time and temperatures differ from those specified in the Food Code, State Sanitary Code and Health Code, to promote food safety.

HACCP plan preparation requires consideration of each of the following:

- 1) Hazard analysis and risk assessment: the potential hazards associated with food processes at all stages are identified and the likelihood of occurrence is assessed.
- 2) Identification of critical control points (CCPs) in a process. CCPs are any points, procedures or operational steps that can be controlled during the process to eliminate a hazard or minimize its likelihood for occurrence.
- 3) Establishing critical limits for each CCP; determining target levels and tolerances to ensure each CCP is under control.
- 4) Establishing a monitoring schedule for each CCPs. The system should ensure control of each CCP by scheduled testing, i.e., measuring temperature.
- 5) Establishing corrective action to be taken when a deviation occurs at a CCP, i.e., when monitoring indicates a CCP is out of control.
- 6) Establishing a record keeping-system to document each HACCP step.
- 7) Establishing a verification procedure enabling an FSE's food protection certificate holder, chef, and the Department to determine if the food processing operation conforms to the requirements of the HACCP plan.

Adding a new §81.12 Reduced oxygen packaging; cook chill and *sous vide* processing.

Reduced Oxygen Packaging

These new amendments to the Health Code will better inform FSE permittees of correct and safe procedures when utilizing reduced oxygen packaging (ROP) techniques, and will promote safer food processing by FSEs. The following 2005 FDA Food Code definitions of ROP processes have been incorporated in the new Health Code definitions in §81.03 and will be regulated by the new §81.12:

(1) Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package.

(2) Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of packaging material or the respiration of the food. Such packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

(3) Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers¹ or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(4) Cook chill packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens.

(5) *Sous vide* packaging, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens.²

These processing techniques, which extract air, can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms. These aerobic organisms are responsible for the off-odors, slime, and texture changes that are also warning signs of spoilage. The benefits of ROP include its ability to prevent degradation or oxidative processes in food products; retard the amount of oxidative rancidity in fats and oils; prevent color deterioration in raw meats caused by oxygen; and shrinkage of the food by preventing water loss.

Sous Vide

Sous vide, a specialized ROP cooking process, simply means “under vacuum.” *Sous vide* cooking is favored by some food scientists and operators of FSEs who claim it provides the best possible heat transfer coefficient between the heat source and packaged foods during cooking, enables consistency of taste and texture, and makes it possible to store cooked products under proper (i.e., under 38° F [3.3°C]) holding temperature for longer periods of time. There has been an increase in the demand for the *sous vide* which contains little or no chemical preservations, and are given a mild heat treatment in order to achieve a fresh cooked taste. *Sous vide* products rely on a combination of minimal processing and storage under controlled chill conditions to prevent growth of pathogenic organisms and achieve microbiological safety, unlike conventional thermally processed products which rely on thermal destruction of any pathogens presents.³ The *sous vide* cooking process is a pasteurization step that reduces bacterial load but is not sufficient to sterilized a product; thus making the food shelf-stable without temperature controls.⁴ Psychotrophic *C. botulinum* types E and B are the organisms of most concern to minimally processed chilled foods with an extended shelf life as they may be able to grow during storage and produce a powerful neurotoxin which, if ingested, would cause botulism. Additionally, these organisms are able to survive the mild heat treatment and continue to live and grow in an oxygen free environment.

In *sous vide* processing, vacuum packaged cooked, partially cooked, raw ingredients or combinations of ingredients require immediate refrigeration or frozen storage until the package is thoroughly cooled. The process may involve some or all of the following steps:

¹ Oxygen scavengers are small sachets or self adhesive labels that are placed inside modified atmosphere packs to help extend the shelf life of the product and improve product appearance. They work by absorbing any oxygen left in pack by oxidation of the iron powder contained in sachet/label.

² FDA, 2005 Food Code §1-201. Psychotrophic pathogens grow at temperatures below 41°F (5°C) and include, but are not limited to, *L. monocytogenes*, *Bacillus cereus*, and *C. botulinum* type E.

³ *Sous Vide and Cook-chill processing for the Food Industry*, Edited by S. Ghazala, pg 131.

⁴ Microorganisms in foods, Characteristics of Microbial Pathogens, The International Commission on Microbiological Specifications of Foods of the International Union of Biological Societies, 1998.

- (1) Preparing raw materials (this step may include cooking, or partial cooking of some or all ingredients);
- (2) Packaging the product, application of vacuum, and sealing of the package;
- (3) Cooking the product for a specified and monitored time/temperature;
- (4) Rapid and monitored cooling of the product to 34° F or below;
- (5) Storage of the cooked product at or below 34° F for 30 days, or 72 hours at 38° F; and
- (6) Reheating of the *sous vide* packaged items to at least 140° F temperatures before opening and service.

Holding Temperatures for ROP Products

The new regulation requires that cold holding temperatures for all ROP products, regardless of processing methods, be lower than the cold holding temperatures currently provided for potentially hazardous foods in the Health Code. Most food borne pathogens are either anaerobes (able to multiply without oxygen) or facultative (able to multiply either with or without oxygen), requiring special care to control their growth. Refrigerated storage temperatures of 41°F (5°C) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but *C. botulinum* and *Listeria monocytogenes* are better controlled at temperatures at or below 38°F(3.3°C). Controlling these pathogens will control the growth of other food borne pathogens as well.

Packaging of Fish Using an ROP Method

The FDA *Food Code* currently recommends against ROP processing of any fish product at the retail level except frozen fish. Accordingly, this proposed amendment will prohibit FSEs from processing fresh, unfrozen fish by ROP methods.

The Department supports stringent requirements for preparation and storage of fish processed by *sous vide* because research has shown that seafood products are subject to outgrowths of *C. botulinum* type E when improperly heated.⁵ *C. botulinum* type E is naturally occurring in marine organisms, and will grow at refrigeration temperatures as low as 37.2°F (2.9°C.). Fish that may contain this microorganism include, but are not limited to salmon, trout, herring, whitefish, cod, plaice, eel, pollack, flounder and flatfish. The localization of contaminating spores of *C. botulinum* type E differs among fish species. Some fish species are contaminated in the intestines and viscera, some in the gills and the peritoneum, while others are contaminated on the outer surfaces (skin and fins). In some cases, strains have been isolated from internal organs and surface area of the same fish.

The presence of spores in the internal organs and skin of fish is a reflection of the general contamination of the environment, feed and water of the harvest area. However, the germination of spores, growth of vegetative cells and production of toxins in fishery products is due to a number of factors: the exposure of fish to temperature danger zones between time of harvest and delivery to food service or processing establishments; further exposure to temperatures in the danger zone during

⁵Principles of Modified-Atmosphere and Sous Vide Product Packaging, edited by Jeffrey Farber, Ph.D and Karen L. Dodds, Ph.D. Bureau of Microbial Hazards Health Canada. Chapter 7: Fish and Shellfish Products in Sous vide and Modified Atmosphere Packs: .

preparation or processing in the establishments; subjection to mild heat treatments or insufficient cooking temperatures; untrained or careless food workers' introduction of spores into the tissues and carcasses of the fish during preparation; and subsequent subjection of the finished (fishery) products to refrigerated storage temperatures warmer than 38°F (3.3°C).

Factors that may control *C. botulinum* type E growth and toxin production include efficient heat treatment (194° F for 10 minutes), restricted shelf life, pH below 4.6, and holding temperatures at or below 37.4°F (3°C). In order for a food borne type E botulism outbreak to occur, a combination of the following four prerequisites must be present: the fish is already contaminated by type E spores from the environment; processing of the food is inadequate to inactivate type E spores; and there are inadequate holding temperatures, or the product is recontaminated after processing; or food is consumed without cooking or after insufficient heating. Thus, relative to other proteinaceous foods, there is concern that fish and fish products may be undercooked and that pathogens could survive in apparently cooked products. To require that fish be frozen during all stages of processing eliminates these hazards.

Sous Vide Cooking Temperatures

Cooking temperatures are one of the prime factors that control the growth of pathogens in food. For cooking temperatures to be effective in reducing pathogens, the following factors are to be considered: the pathogenic bacteria count prior to cooking; the initial holding temperature of the raw product; and the product mass and characteristics that affect the time the product takes to reach its intended internal cooking temperature. To eliminate microorganisms and pathogens through cooking, the product must be held at a sufficient temperature for a specified kill time. Cooking temperatures in the Health Code are based, in part, on the biology and chemistry of specific pathogens that are associated with certain protein-based foods, and are also required to be consistent with the New York State Sanitary Code.⁶ To assure that heat treatment of a *sous vide* product is safe, the Department will require that FSEs cook food to temperatures required by §81.09 of the Health Code.

Requiring a Hazard Analysis Critical Control Point Plan (HACCP) for ROP

The use of the Hazard Analysis Critical Control Point or HACCP approach is probably the single most important strategy for controlling the safety of a food product. It has been demonstrated scientifically that the application of a combination of different multiple inhibitory factors like water activity (A_w) of 0.91 or less, pH of 4.6 or less, and high levels of competing microorganisms can impede the growth of these virulent facultative anaerobic organisms in vacuum packaged foods. However, *sous vide* and cook chill processes lack these barriers, and therefore depend on monitoring of critical limits, such as time and temperature for safety⁷. A HACCP plan is the recognized standard for monitoring critical limits in food processes and assuring food safety. The lack of inhibitory factors (e.g., aerobic bacteria) makes *sous vide* and other ROP processes high risk for transmission of food borne illness.

⁶ These temperatures are prescribed in both the Health Code and the State Sanitary Code, and the Department does not have the legal authority to allow lower cooking temperatures at FSEs engaging in ROP. See, e.g., Charter §558 (b) (“The board of health from time to time may add to and alter ... any part of the health code, and may therein publish additional provisions for security of life and health in the city and confer additional powers on the department not inconsistent with the constitution, laws of this state or this charter...”) “Not inconsistent” generally means that a Health Code provision must be as or more stringent than the State Sanitary Code.

⁷ FDA 2005 Food Code §3-502.12 – Public Health Reasons & Administrative Guidelines

The importance of a HACCP plan for ROP methods of food processing like *sous vide* in FSEs begins with an understanding that the raw food received from the wholesale supply system is normally contaminated with either or both vegetative cells and/or spores of pathogenic microscopic organisms, some naturally occurring in their environment (e.g. seafood)⁸, and that the majority of the most virulent are either anaerobes or facultative anaerobes⁹, with a competitive advantage enabling them to survive and grow better in reduced oxygen environments¹⁰, such as vacuum sealed food bags, than in the presence of aerobic spoilage organisms. In addition, several studies have shown that further contamination of food, growth of pathogens, and production of toxins more often than not occur in the FSE due to the exposure of food to unsanitary environmental factors, and production processes, such as preparation and preservation of food by untrained and inexperienced food workers. Since scientific evidence has shown that the inactivation of some of these pathogens, especially their spores, and destruction of toxins require temperatures far higher than the minimal heat processing usually employed for the production of most vacuum packaged foods, like *sous vide*, documented application of safety procedures must therefore be guaranteed¹¹, and the only tested, proven and up-to-date procedure that guarantees drastic reduction of hazards to a safe level is use of a HACCP plan.

The new §81.12 of the Health Code will allow FSEs to package and process food using cook chill or *sous vide* methods, provided they submit and obtain approval from the Department for a HACCP plan conforming with the new §81.06(b) of the Health Code for each food item to be processed using one of these techniques.

STATEMENT PURSUANT TO SECTION 1042 – REGULATORY AGENDA

The proposed amendment was not included in the Department’s Regulatory Agenda because it resulted from a recent analysis by the Department that determined ROP procedures have become increasingly common in NYC restaurants and pose a potential threat to health.

The proposal is as follows:

Note-matter in brackets [] to be deleted

Matter underlined is new

RESOLVED, that §81.03 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as amended by resolution adopted on the first of July, one thousand ninety-eight, be and the same hereby is amended, to be printed together with explanatory notes, as follows:

§81.03 Definitions.

When used in this Title and Code:

(a) A_w means water activity which is the measure of the free moisture in a food, and is indicated by the symbol A_w . Its numeric value is the quotient of the water vapor pressure of the food substance divided by the vapor pressure of pure water at the same temperature.

⁸ FDA, Critical Steps towards safer seafood (1997)

⁹ FDA, 2005 Food Code §3-502.12 – Public Health Reasons & Administrative Guidelines

¹⁰ FDA, 2005 Food Code §3-502.12 – Public Health Reasons & Administrative Guidelines

¹¹ PubMed Publication, Mar. 1995, Safety Aspects of *Sous vide*

[(a)] (b) Comminuted means reduced in size by methods including chopping, flaking, grinding, mincing; or a mixture of fish or meat products that have been reduced in size and restructured and reformulated.

[(b)] (c) Contaminated means adulterated or spoiled food, or food and equipment which is exposed to filth, toxic substances, rodent or insect contact or infestation, or potentially hazardous foods held at temperatures between 41 degrees Fahrenheit (5 degrees Celsius) and 140 degrees Fahrenheit (60 degrees Celsius) for a period of time exceeding that reasonably required for preparation, including potentially hazardous foods which are not heated or cooked to the temperatures specified in §81.09, or food in or subject to any condition which could permit the introduction of pathogenic microorganisms or foreign matter, including manual contact during service or preparation if such foods will not be subsequently cooked or heated to the temperatures specified in §81.09.

[(c)] (d) A controlled-location vending machine means a food vending machine which dispenses only food that is not potentially hazardous, can be serviced in a sanitary manner by an untrained person at the location and is located where it is protected from environmental contamination, abuse and vandalism.

(e) Critical control point means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

(f) Critical limit means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(g) Cook chill foods mean perishable foods which have undergone a heat or pasteurization process and which, to extend the time during which they remain wholesome, are intended to be kept in the temperature range of 32-38 degrees Fahrenheit (0-3.3 degrees Celsius).

(h) Cook chill processing means a type of reduced oxygen packaging process in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.

[(d)] (i) Easily cleanable means readily accessible and of such material and finish that residues may be completely removed by normal cleaning methods.

[(e)] (j) Easily movable equipment means equipment that is mounted on wheels or casters with flexible, extensible, or quick disconnecting utility connections, if any, so that the equipment may be easily moved for cleaning.

[(f)] (k) Equipment means all stoves, ranges, microwave ovens, hoods, meatblocks, tables, counters, refrigerators, sinks, dishwashing machines, steamtables and similar items, other than utensils, used in the operation of a food service establishment or non-retail food processing establishment.

(l) Fish means fresh or saltwater finfish, crustaceans and other forms of aquatic life other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

[(g)] (m) Food-contact surfaces mean the surfaces of equipment, utensils, tableware and kitchenware, such as ladles, colanders, serving spoons, spatulas, pots and pans, which normally come into contact with food or from which liquids and residues may drain back into food or onto other food-contact surfaces.

[(h)] (n) Food-grade means intended to be used with food products, utensils or equipment without reacting with such food products, and without imparting odor, color or taste to such food products, or approved by the National Sanitation Foundation or its equivalent.

[(i)] (o) Foodworker means foodhandler or any [employee] other person who works in a food service establishment or non-retail food processing establishment, including but not limited to any person described in §11.01(f) of this Code.

[(j)] (p) Food service establishment means a place where food is provided for individual portion service directly to the consumer whether such food is provided free of charge or sold, whether consumption occurs on or off the premises or is provided from a pushcart, stand or vehicle.

[(k)] (q) A food vending machine means a self-service device which when activated, dispenses unit servings of food or beverage without requiring replenishing between each vending operation.

[(l)] (r) A food vending machine commissary means a place where food, containers or supplies are processed or packaged and prepared for use in food vending machines.

[(m)] (s) A food vending machine operation means the place where food vending machines are located and includes the food vending machines, machine servicing equipment, utensils, personnel, single-service articles, tables, chairs, that part of the premises used in connection with the food vending machine operation and all other appurtenances required and used to operate and maintain the food vending machines.

(t) Hazard Analysis and Critical Control Point (HACCP) plan means a written document that delineates the formal procedures for following the hazard analysis and critical control point principles developed by the FDA National Advisory Committee on Microbiological Criteria For Foods.

[(n)] (u) Imminent health hazard means any violation, condition, combination or violations or conditions making it probable that food served to the public by the establishment or its continued operation will be injurious or dangerous to the health of any person consuming such foods.

[(o)] (v) Indirect drain means a waste line which does not connect directly with the drainage system, but conveys and discharges liquid wastes through an air break into an approved plumbing fixture or receptacle that is directly connected to the drainage system.

[(p)] (w) Non-retail food processing establishment means a place where food is processed, prepared, stored or packed for consumption off the premises and not given or sold directly to the consumer. This shall include but not be limited to mobile food vending commissaries, food vending machine commissaries and places where fish or shellfish is kept, sold or offered for sale which are not otherwise regulated or permitted by the Department of Agriculture and Markets or other appropriate regulatory agency.

(x) Packaged means bottled, canned, cartoned, securely bagged, or securely wrapped, and does not include a wrapper, carry out box, or other non durable container used to containerize food for the purpose of facilitating food protection during service and receipt of the food by the consumer.

(y) pH means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

[q] (z) Potentially hazardous food means any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, crustacea, cooked potato, cooked rice, or ingredients in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms, or growth of *C. botulinum*. The term does not include food with a water activity (A_w) value of 0.85 or less, or a hydrogen ion concentration (pH) level of 4.6 or below.

[(r)] (aa) Processed fish means fish that has been cured, salted, marinated, dried, pickled, fermented or smoked for human consumption.

(bb) Reduced oxygen packaging means the reduction of the amount of oxygen in a food packaged 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) and where the food being packaged requires control of *Clostridium botulinum* or *Listeria monocytogenes* in the final packaged form. Reduced oxygen packaging includes, but is not limited to, vacuum packaging, cook chill packaging, and *sous vide* processing.

[(s)] (cc) Sanitization means effective bactericidal treatment by heat or chemical means which destroys pathogens on surfaces treated. Acceptable sanitization methods are:

(1) immersion for at least one-half minute in clean hot water at a temperature of not less than 170 degrees Fahrenheit (76.7 degrees Celsius);

(2) immersion for at least one minute in a clean solution containing at least 50 parts per million of available chlorine at a temperature of at least 75 degrees Fahrenheit (23.9 degrees Celsius);

(3) immersion for at least one minute in a clean solution containing at least 12.5 parts per million of available iodine and having pH not higher than 5.0 and at a temperature of at least 75 degrees Fahrenheit (23.9 degrees Celsius);

(4) immersion in a clean solution containing any other food grade chemical sanitizing agent that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as hypochlorite which has been held at a temperature of at least 75 degrees Fahrenheit (23.9 degrees Celsius) for one minute;

(5) treatment with culinary-quality steam in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(6) swabbing fixed equipment with a solution of at least twice the strength required for that sanitizing solution when used for immersion.

[(t)] (dd) Single service articles means cups, containers, lids, or closures, plates, knives, spoons, stoppers, paddles, straws, place mats, napkins, doilies, wrapping materials, toothpicks and all similar articles which are intended by the manufacturer for single eating and drinking usage and generally recognized by the public as items to be discarded after one usage.

(ee) Sous vide processing is a type of reduced oxygen packaging in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, and either served or rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.

[(u)] (ff) Stand means a movable, portable or collapsible structure, framework, device, container, or other contrivance, other than a vehicle or pushcart, used for displaying, keeping or storing any food.

[(v)] (gg) Temporary food service establishment means any food service establishment which operates at a fixed location for a temporary period of time, not to exceed 14 consecutive days, in connection with a single event or celebration such as a fair, carnival, circus, public exhibition, advertising campaign or business promotion, religious or fraternal organization function or transitory gathering. In addition to the provisions of this Article, a temporary food service establishment shall be operated at all times in compliance with the provisions of Article 88 and all applicable provisions of this Code.

[(w)] (hh) Utensil means any tableware, such as knives, forks, spoons, glasses, cups and the like, and kitchenware, implements or containers used for storage, preparation, transfer, conveyance or service of food.

[(x)] (ii) Wholesale food establishment means any establishment which sells food or which manufactures food for other than retail sale directly to the consumer.

Notes: Section 81.03 was amended by resolution on XXX, adding definitions for various terms incorporated into new provisions of this Article, including reduced oxygen packaging processes, and HACCP plans, based on the definitions of these terms in §1-201.10 of the FDA 2005 Food Code, and relettering existing subdivisions.

Notes: This section was further amended by resolution on XXX to add definitions related to cook chill and *sous vide* processing and preparation of a Hazard Analysis Critical Control Point plan, and existing definitions were relettered.

RESOLVED, that §81.06 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as adopted by resolution on the seventh of June, two thousand five, be and the same hereby is amended by relettering the current provision as subdivision (a), and by adding new subdivisions (b) and (c), to be printed together with explanatory notes, as follows:

§81.06 Prevention of imminent health hazards.

(a) Additional requirements. Whenever necessary to prevent the occurrence or recurrence of imminent health hazards the Department may, in specific instances, impose additional requirements on an establishment. The Department shall describe in writing the terms and conditions of operation that have been imposed, the reasons therefore, shall provide such document to the permit holder, and shall maintain such document with the records of the Department.

(b) Hazard Analysis and Critical Control Point (“HACCP”) plans.

(1) To prevent the occurrence of an imminent health hazard, a HACCP plan shall be prepared by a food service establishment or non-retail processing establishment whenever such establishment prepares, processes, cooks, holds and stores foods in a manner other than as specified in this Code or other applicable law.

(2) Whenever a HACCP plan is required, such plan shall be submitted to and approved by the Department prior to its implementation, and shall thereafter be maintained at the establishment and be made available to Department inspectors for review upon request.

(3) A HACCP plan shall include the following:

(i) Types and categories of foods to be addressed by the plan.

(ii) Food flow diagram or plan identifying critical control points, specifying ingredients, materials and equipment used in processing, and addressing the food safety concerns identified at each such point.

(iii) Standard operating procedures for implementing the plan, including clearly identifying each critical control point; method and frequency of monitoring and controlling each critical control point by a foodworker designated by the person in charge of food operations; and the method and frequency whereby the person in charge of food operations routinely verifies that the foodworker is following standard operating procedures and the action to be taken by the responsible foodworker if the critical limits for each critical control point are not met.

(iv) The critical limits for each critical control point, and the method and frequency for monitoring and controlling critical limits at each critical control point by the designated foodworker.

(v) Records/logs shall be maintained by the permittee to demonstrate that the HACCP plan has been properly implemented.

(c) Prior approval required for certain foods and processing. The following food items shall not be processed in a food service establishment without prior approval of the establishment's HACCP plan by the Department: reduced oxygen packaging and preservation of any food items and cured and smoked products produced on the premises.

Notes: Section 81.06 was amended by resolution adopted on xxx relettering the existing provision as subdivision (a), adding a new subdivision (b) to incorporate requirements for developing and implementing hazard analysis critical control point ("HACCP") plans when such plans are required to prevent the occurrence of imminent health hazards, and a new subdivision (c) specifying certain foods and processes that always require HACCP plans. These requirements are substantially the same as those in the FDA 2005 Food Code.

RESOLVED, that Article 81 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as amended by resolution adopted on the fifth of December, two thousand and six, be, and the same hereby is further amended, to add a new section 81.12, to be printed with explanatory notes, as follows:

§81.12 Reduced oxygen packaging; cook chill and sous vide processing.

(a) Scope and applicability. A food service establishment may package and process food using reduced oxygen packaging ("ROP"), as defined in §81.03 of this Code, in accordance with this section, provided that the food being processed shall have at least two controls in place, including but not limited to time, temperature, Aw or pH, to prevent the growth and formation of *C. botulinum* or *Listeria monocytogenes*.

(b) Approved Hazard Analysis and Critical Control Point (HACCP) plan required. A food service establishment shall not utilize ROP processes without obtaining prior Department approval of a Hazard Analysis and Critical Control Point (HACCP) plan. The establishment shall submit to the Department its HACCP plan that conforms to §81.06(c) of this Article for each food item or food category it intends to prepare using a ROP processing technique.

(c) Food safety. Foods processed by ROP shall be prepared and consumed on the premises of the food service establishment, or off premises if the preparation site is properly permitted and wholly owned and

operated by the same business entity as the food service establishment, and no ROP food products shall be sold or distributed to any other business entities or consumers.

(d) Specific requirements. Foods shall be:

(1) Prepared within two hours of removing the item from refrigeration at which the internal temperature of the food item is at or below 41 degrees Fahrenheit (5 degrees Celsius).

(2) Placed in a ROP package or ROP bag with before cooking, or placed in a package or bag immediately after cooking and before reaching an internal temperature below 140 degrees Fahrenheit (60 degrees Celsius).

(3) Cooked to required minimum internal temperatures specified in §81.09 of this Article within 12 hours of packaging. However, if such food has an A_w of 0.91 or less; has a pH of 4.6 or less; is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, or successor regulation, and is received in an intact package; or is a food with high level of competing organisms such as raw meat or raw poultry, it may be held without being cooked for no more than 14 calendar days, and shall be discarded thereafter.

(4) Protected from contamination after cooking as specified in §81.07 of this Article.

(5) Properly cooled to an internal temperature of 38 degrees Fahrenheit (3.3 degrees Celsius) or below in the ROP package within two hours of cooking; further cooled to an internal temperature of 34 degrees Fahrenheit (1.1 degrees Celsius) or less within six hours of reaching 38 degrees Fahrenheit (3.3 degrees Celsius); held at an internal temperature of 34 degrees Fahrenheit (1.1 degrees Celsius) and consumed or discarded within 30 days after the date of preparation. However, if removed from a storage unit that maintains an internal food temperature of 34 degrees Fahrenheit (1.1 degrees Celsius), the food must be held at internal temperature of 38 degrees Fahrenheit (3.3 degrees Celsius) or less for no more than 72 hours before consumption.

(6) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily.

(7) Labeled with the product name, date packed, and dates to be discarded, and stored in accordance with a “First-in” “First out” storage rotation procedure.

(e) Fish. Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using an ROP method.

(f) Cheese. A food service establishment may package cheese using an ROP method provided that it limits the cheeses packaged to those commercially manufactured in a food processing plant with no ingredients added by the food establishment, and provided the cheese meets the USFDA standards of identity specified in 21 CFR §133.150 (“Hard cheeses”); 21 CFR §133.169 (“Pasteurized process cheese”); and 21 CFR §133.187 (“Semisoft cheeses”), or successor regulations. The “use by” date of

cheese shall not exceed 30 days, or the original manufacturer's "sell by" or "use by" date, whichever occurs first

(g) Equipment. All equipment used in ROP processing shall be approved by the Department, shall comply with all specifications for equipment in this Article, and the following additional criteria:

(1) Thermometers used in cook chill or *sous vide* cooking methods shall be food grade thermocouple type, equipped with probe, with a temperature range of -40 degrees Fahrenheit (-40 degrees Celsius) to 212 degrees Fahrenheit (100 degrees Celsius), and shall not contain glass or any parts that can easily fall into food. Thermometers shall be calibrated before each batch process, and at other times in accordance with manufacturers' instructions and whenever calibration could have been compromised by extreme temperatures or after being accidentally dropped.

(2) ROP products that are transported off site to a satellite location of the same business entity shall be kept in containers equipped with verifiable monitoring devices enabling monitoring of time and temperature and kept at temperatures no higher than 38 degrees Fahrenheit (3.3 Celsius) during transportation. Such products or containers shall be labeled with the product name, date packaged, and discard date.

(3) *Sous vide* processed foods shall be cooked in an approved water immersion unit or combination oven (an oven combining convection and added moisture) that can be equipped with an electronic system that continuously monitors time and temperature, and is visually examined for proper operation twice daily. At least one item of each type of food of similar size cooked in a water immersion or combination oven shall have its internal temperature monitored to determine if the food is being cooked to the temperatures required by §81.09 of this Article.

(4) *Sous vide* cooking equipment shall include a thermal bath and immersion circulator or a combination oven. The thermal bath and immersion circulator shall be a commercial type able to heat water to precise temperatures. The immersion circulator or combination oven shall be equipped with a temperature controller, temperature sensor, heater, and circulating element, and continuous temperature recorder and display accurate to one tenth of a degrees, capable of recording temperatures between 32 degrees Fahrenheit (0 degrees Celsius) and 212 degrees Fahrenheit (100 degrees Celsius), and large enough to enable complete immersion of the largest piece of food.

(5) ROP processors shall utilize a chamber type vacuum packaging machine with a pump able to achieve a flow rate of 10m³ per hour and capable of heat sealing the food storage bag to maintain the vacuum.

(6) Cook chill processors shall utilize an ice bath or a NSF approved blast or tumble chiller that can lower temperatures of food from 185 degrees Fahrenheit (85 degrees Celsius) to 32-38 degrees Fahrenheit (0-3.3 degrees Celsius) within two hours, and is equipped with a factory installed temperature monitoring

device and alarm system. If a tumble chiller is used, the associated ice builder must meet the sanitary requirements of this Article.

(7) Cook chill processors shall utilize a commercial type stainless steel NSF approved cook tank or steam kettle with an agitation mechanism, and factory installed temperature monitoring devices.

(8) All cook chill bags (casings) shall be made of food grade plastic, able to withstand temperatures of 212 degrees Fahrenheit (100 degrees Celsius) to -20 degrees Fahrenheit (-28.8 degrees Celsius) and rapid temperature change from 185 degrees Fahrenheit degrees to 34 degrees Fahrenheit or below (1 degrees Celsius).

Notes: Section 81.12 was added by resolution adopted on XXX to establish procedures for food processing using reduced oxygen packaging, cook chill and *sous vide* methods.

RESOLVED, that the list of Section Headings in Article 81 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as amended by resolution adopted on the fifth of December, two thousand six, be, and the same hereby is, amended, to be printed together with explanatory notes, as follows:

ARTICLE 81

FOOD PREPARATION AND FOOD ESTABLISHMENTS

* * *

§81.11 Food; disposition if unfit for human consumption; re-service of food prohibited.

§81.12 Reduced oxygen packaging; cook chill and *sous vide* processing.

§81.13 Foodworkers; health; clothing

* * *

Notes: Section 81.12 was added by resolution adopted on XXX to establish procedures for preparing foods by reduced oxygen packaging methods, including cook chill and *sous vide* processing.