

Pursuant to the authority vested in the Public Health and Health Planning Council and Commissioner of Health by Sections 225(4) and 201(1) of the Public Health Law, Subparts 14-1, 14-2, 14-4 and 14-5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

New sections 14-1.89 is added to read as follows:

14-1.89 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.
- (d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

Section 14-2.3 is amended to include a new subdivision (g) to read as follows:

- (g) For the purposes of this subdivision, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food

additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (1) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (2) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (3) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.
- (4) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

New section 14-4.96 is added to read as follows:

14-4.96 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.
- (d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

New sections 14-5.46 is added to read as follows:

14-5.46 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (b) Liquid Nitrogen, used in the preparation of food, is to be drained or allowed to evaporate completely prior to vending.
- (c) Dry Ice, used in the preparation of food, shall be sublimated completely or removed prior to vending.
- (d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The New York State Public Health and Health Planning Council is authorized by New York State Public Health Law (PHL) Section 225(4) to establish, amend and repeal sanitary regulations known as the Sanitary Code of the State of New York (Sanitary Code), subject to approval by the Commissioner. PHL Section 201(1)(m) authorizes the New York State Department of Health (Department) to supervise and regulate the sanitary aspects of public eating and drinking establishments.

Legislative Objectives:

This rulemaking is in accordance with the legislative objective of PHL Sections 225(4) and 201(1)(m) authorizing the PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety through the regulation of the sanitary aspects of Food Service Establishments. In accordance with this objective, the proposed amendments prohibit Food Service Establishment operators from using liquid Nitrogen or Dry Ice at the point of sale to protect the health and safety of New Yorkers patronizing Food Service Establishments.

Needs and Benefits:

The Department is aware of new trends in food service that utilize liquid Nitrogen and Dry Ice at the point of sale. Using liquid Nitrogen and Dry Ice at the point of sale of

food products may cause serious injury if the consumer touches or consumes the residual liquid Nitrogen or Dry Ice.

One of these food trends is commonly referred to as “Dragon’s Breath.” Dragon’s Breath is made by pouring liquid Nitrogen over cereal puffs, popcorn or other similar foods, immediately before serving. The liquid Nitrogen (boiling point: -320°F) super cools the food which is then served in a cup with a skewer to be used to remove the puffs from the cup. When chewed the cold food condenses the moisture in the consumer’s breath creating the appearance of breathing smoke. The Department identified reports of injuries associated with Dragon’s Breath, including a 14-year old girl in Florida who suffered frost bite after touching liquid nitrogen in the cup, and a boy in Korea who suffered severe gastrointestinal injuries after drinking residual liquid Nitrogen. More recently, an incident was reported where a boy in Florida suffered an asthma attack which may have been triggered by consuming Dragon’s Breath. In September 2018, the Department received its first complaint of injury from liquid Nitrogen from a food product served in a New York State food service establishment. An 11-year old boy in Victor, NY reportedly experienced oral bleeding and burning sensation shortly after consuming Dragon’s Breath from a mall food service.

Currently, at least three local health departments in New York State have enacted local laws prohibiting the use of liquid Nitrogen at food service establishments and others are exploring similar actions. The US Food and Drug Administration (FDA), on August 30, 2018, issued a Consumer Advisory, advising consumers to avoid eating, drinking or handling foods prepared with liquid Nitrogen at the point of sale, citing the potential for injuries such as those described above. Consequently, the Department is proposing to

amend Part 14 to prevent consumers of Food Service Establishments from coming into contact with liquid Nitrogen or Dry Ice added at the point of sale of the food product.

Liquid Nitrogen is an FDA approved food additive and has various uses in the food service industry. Not all these uses of liquid Nitrogen have the potential for accidental service of liquid Nitrogen to the customer. Therefore, the proposed regulation amendment only pertains to the use of liquid Nitrogen just prior to service of the food product to the customer, to prevent accidental service of residual liquid Nitrogen.

The proposed amendment also restricts the use of Dry Ice (solid carbon dioxide) in foods at the point of service. Like liquid Nitrogen, Dry Ice is an approved food additive that is widely available and can be used to create a fog effect in foods. Dry Ice has a sublimation temperature of -109°F and, if touched or consumed in solid form, presents a risk of thermal injury like that of liquid Nitrogen. If the use of liquid Nitrogen is restricted without similar restrictions for Dry Ice, operators may use Dry Ice as a substitute ingredient.

Costs:

Cost to Regulated Parties:

The proposed amendments will impose minimal if any additional costs to regulated parties. Menu boards and signs may need to be updated to remove products that require the use of liquid Nitrogen or Dry Ice at point of sale. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

Cost to State and Local Governments:

There are no direct costs to State or Local Governments associated with the proposed amendments as the State and Local Governments are currently inspecting Food Service Establishments.

Local Government Mandates:

The proposed amendments do not impose any new mandates, duties or responsibilities on any county, city, town, village, school district, fire district or special district. City and County health departments already enforce Part 14 therefore health department staff will incorporate the proposed amendment as part of their existing program responsibilities.

Paperwork:

Adoption of this regulation does not impose any new paperwork requirements for regulated parties or State or local health departments.

Duplication:

The proposed amendments do not duplicate existing State or Federal requirements.

Alternatives:

The Department considered two alternatives to the proposed amendments. The first was to propose no regulatory change but recognize that local health departments may

adopt more stringent requirements through local laws or regulations. The second alternative included amending Part 14 of the State Sanitary Code to incorporate the requirements of the Department's previously issued guidance that require operators to maintain a written safety plan for the use of liquid Nitrogen, approved by the permit-issuing-official, with an additional requirement of providing a written consumer advisory be conspicuously posted at the point(s) of sale and service.

Both alternatives are inconsistent with FDA guidance to avoid consuming products with liquid Nitrogen added at the point of service. They also create a paperwork burden for operators and local health departments staff.

Federal Standards:

Nitrogen is an approved food additive and there are no Federal regulations restricting the use of liquid Nitrogen in food service establishments. The FDA does not have any direct regulatory authority over retail food operations. However, the FDA's consumer advisory warning to not eat foods with liquid Nitrogen added at the point of service establishes a clear federal position that the practice is considered unsafe.

Compliance Schedule:

The proposed amendments will become effective upon publication of a Notice of Adoption in the State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENT

Effect on Small Business and Local Government:

While many of New York State's food service establishments are considered small businesses, none of the amendments are directed solely at small businesses. The rule will apply to all 100,000 regulated food service establishments operating in New York State, although the vast majority of establishments do not use liquid Nitrogen or Dry Ice in the preparation of food. These establishments are already required to comply with the food safety provisions of Part 14. The proposed amendments will not result in significant costs to comply for regulated parties and none of the proposed amendments will apply solely to small businesses. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

Local Health Departments are already responsible for overseeing the food service operations of New York State, so there will not be a significant effect on local governments.

Compliance Requirements:

Small businesses must comply with the proposed regulation by not utilizing liquid Nitrogen or Dry Ice in food products at the point of sale. The proposed amendments do not create any new reporting or record keeping requirements.

Professional Services:

The proposed amendments do not create a need for regulated parties to seek any professional services.

Compliance Costs:

The proposed amendments will impose minimal, if any additional, costs to regulated parties. Menu boards and signs may need to be updated to remove products that require the use of liquid Nitrogen or Dry Ice at point of sale. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

Cost to State and Local Governments:

There are no direct costs to Local Governments associated with the proposed amendments as Local Governments are currently inspecting Food Service Establishments.

Economic and Technological Feasibility:

The proposed amendments do not require any new technology and have a negligible economic impact.

Minimizing Adverse Economic Impact:

The regulations currently allow for a waiver to be granted at the discretion of the permit-issuing official, provided that alternative arrangements are made to protect the health and safety of the public.

Small Business and Local Government Participation:

The proposed amendments implement a recommendation received from the New York State Association of County Health Officials. When considering regulatory alternatives, the Department also sought input from the New York State Restaurant Association.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

No rural area flexibility analysis is required pursuant to Section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

JOB IMPACT STATEMENT

Nature of the Impact:

The addition of Liquid Nitrogen and Dry Ice to food products at the point of service is a new novelty trend at food service operations. The proposed regulation's prohibition on the use of liquid Nitrogen and Dry Ice at the point of sale is expected to have no job impact on the majority of Food Service Establishments where such food products are not the focus of the business, as these food products make up only a small percentage of their sales. Businesses that specialize in or solely sell this type of product may be required to cease operating or modify their business to include other food items. We do not have an accurate estimate of the number of Food Service Establishments affected since there is no registration requirement for the use of liquid Nitrogen or Dry Ice, however the number is expected to be small.

Categories and Numbers Affected:

The main category affected by this regulation is the Food Service Establishment that focuses its primary business on the sale of novelty foods that have liquid Nitrogen or Dry Ice added to them at the point of sale. Because of the lack of data about the number of food establishments that sell these types of food products, it is not possible to accurately estimate the number of jobs affected, however the number is expected to be small.

Regions of Adverse Impact:

The Department anticipates any jobs or employment impacts will occur equally throughout the regions of the state.

Minimizing Adverse Impact:

The Department will consider different types/levels of enforcement while retailers adapt to the new regulation.

ASSESSMENT OF PUBLIC COMMENT

In response to the November 21, 2018 notice in the New York State Register for amendments to Subparts 14-1, 14-2, 14-4 and 14-5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, one written comment was received during the comment period.

The New York State Association of County Health Officials (NYSACHO) submitted a letter of support for the proposed amendments which restrict the use of liquid Nitrogen and Dry Ice added to foods at the point of service in food service establishments. Within its letter, NYSACHO referenced the potential dangers associated with consuming liquid Nitrogen and cited the US Food and Drug Administration's August 2018 Consumer Advisory, warning consumers to avoid such products, as confirmation of the need for public health protection measures. NYSACHO's letter concluded the following: *"NYSACHO strongly believes that the proposed amendments to restrict the use of liquid nitrogen and dry ice at the point of service are necessary to protect the public's health from the risk of serious injury and death, and fully endorses the adoption of the proposed amendments put forth by the New York State Department of Health."*

These comments in support are noted by the Department. No change was made to the regulation in response to these comments.