PFMA
Pennsylvania Food Merchants Association

Original: 2255

pennsylvania convenience store council

March 25, 2002

Chris Markham
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

Dear Chris:

Thank you for your phone call the other week advising us of the publication of PA's proposed Food Code in Volume 32 of the *PA Bulletin* (32 PA.B. 1046).

For your information, I am forwarding comments that the PA Food Merchants Association has submitted to the Department of Agriculture in response to their proposed Food Code.

We appreciate the opportunity to comment on these regulations and look forward to working with the Department on these suggested changes.

Please feel free to contact me at 717.760.5911 if you have any questions.

Sincerely,

Jennifer Walker
Director of Government Relations

Enclosures

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PFMA
Pennsylvania Food Merchants Association

pennsylvania convenience store council

March 25, 2002

Sheri Dove
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408

Dear Sheri:

Listed below are comments that the Pennsylvania Food Merchants Association has compiled in response to proposed changes to the PA Food Code as published in the *PA Bulletin*, Volume 32 (32 PA.B. 1046).

We appreciate the Department's forthrightness while working on revisions to the Code over the past two years. Since our last discussion about changes to the Code, the Federal Food and Drug Administration published their revised model code and various events have occurred on the local levels. The following comments have been prompted as a result of these recent activities:

1. **Critical Items** is not currently defined within code. Process or guidance should be provided to clearly define Critical Items.

2. Proposed definition of **Foodborne Disease Outbreak** is inconsistent with FDA's definition. We suggest the following: "means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food".

3. Definition of **Potentially Hazardous Food** is inconsistent with FDA's definition: Suggest revising proposed definition as stated in FDA's 2001 Food Code.

4. **Section 46.422 Labeling, Part (c) (page 60)**: Section states "... Bulk food that is available for consumer self dispensing or unpackaged foods portioned to consumer specifications shall be prominently labeled with one of the following in plain view of the consumer ..."
   Suggest clarifying alternative options in addition to those already listed to complying with this section's requirements as it pertains to unpackaged foods portioned to consumer specifications.

5. **Section 46.521 Materials in multiuse utensils and food contact surfaces, Part (I) Wood (page 67)** : Suggest adding Pizza Peel to examples provided.

6. **Section 46.591 Warewashing Machines, Part (d) (page 75)**: Request clarification of Department's intentions of requiring Sanitizer Level Indicator to simply provide an audio or visual alarm alerting operator that in-use chemical container is empty.

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7. **Section 46.633 Temperature measuring devices for manual warewashing (page 78):** Section states the requirement to provide thermometers to measure washing and sanitizing temperatures at manual warewashing locations. It is our understanding this section within the FDA Food Code is intended for Mechanical warewashing machines.

8. **Section 46.712 Frequency of cleaning equipment food contact surfaces and utensils, Part (2 – II) (page 85):** Request clarification of Department's intentions of requiring documentation of ambient temperature within refrigerated room. Suggest (ii) to be rewritten as follows: The cleaning frequency based on the ambient temperature of the refrigerated room or area is *monitored by* the food facility.

9. **Section 46.1121 Facility and operating Plans, Part (b) (page 123):** Request the reference to ...(relating to HACCP plans)... in part b is removed. This section suggests or implies HACCP plans would be required for all facility plan reviews which we understand is not the intent of this section or Department of Agriculture.

10. **Section 46.1122 HACCP plans, Part (a) (1) (ii) (page 124):** Section states " a variance is required ... 46.345 (d)(3) ..." Part 46.345 (d)(3) is not included within proposed code.

11. **Section 46.1144 Conditions or retention: responsibilities of the food service operator, Part (9) (page 127):** Request clarification from the State that the referenced term "variance" in this section is not intended to mean a HACCP plan would be required.

12. **Section 46.261 Preventing contamination from food employee's hands (page 43):** Recently, the Conference for Food Protection helped facilitate a meeting for all stake holders impacted by prohibiting bare hand contact with ready-to-eat foods as defined in the 1999 and 2001 FDA Food Code. The intent of this recommendation is to fully comply with the food code. A general statement excluding bare hand contact is not realistic. A consensus was achieved by this committee and an issue submitted for final approval to the 2002 Conference for Food Protection and consideration to the next published FDA Food Code. We propose Section 46.261 as written in the proposed PA Food Code be replaced with the following.

    (A) Food employees shall wash their hands as specified under § 46.131.

    (B) *Except when washing fruits and vegetables as specified under § 46.285 or,* as specified under ¶ D of this section, food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.

(C) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.[s]

(D) Food employees may contact exposed, ready-to-eat food with their bare hands if:
(1) The food establishment demonstrates to the regulatory authority conformance to a written plan that documents the following:
(a) Why the person-in-charge of the food establishment is unable to comply
(b) The public health hazard(s) associated with bare-hand contact specific to the food establishment operation is identified and understood;
(c) Documentation and verification of the prerequisite programs as specified under ¶ 46.102 (4)§ 46.111, 46.112,, 46.113, 46.114, and 46.115.
(d) Exposed, ready-to-eat foods that will be contacted with bare hands are identified and procedures and practices are in place so that:
(i) Food employees wash their hands before returning to their work station;
(ii) Cross-contamination from touching raw animal foods and then touching ready-to-eat food is precluded; and
(e) A training program, which emphasizes not working when ill with any of the symptoms of foodborne illness, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures, is implemented for food employees. The training program includes a documented training plan, training program content, and the frequency of administration of the training, including periodic refresher sessions.
(2) Documentation of the plan describing the practices, procedures, corrective actions and training program as specified in Subparagraph D(1) of this section shall be maintained in the FOOD ESTABISHMENT and readily available to the REGULATORY AUTHORITY upon request.
(3) A food establishment that elects to comply with ¶ D(1) of this section may implement one or more of the following:
(a) Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;
(b) *Double handwashing;*
(c) Use of nail brushes; or
(d) Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Article.

13. **Section 46.241 Receiving temperature of food, (b) (page 39) and Section 46.385 Potentially Hazardous Food: hot and cold holding, (a)(1), (page 57):** Request the sections described above and their reference to maintaining hot

PHF's at a minimum product temperature of 60°C (140°F) be changed to 54°C (130°F). **Detailed comments are attached to justify this request.**

14. **Wild Mushroon Expert** – consider adding a statement of qualification and training, specifically related to mushroom identification. Recognition and credibility of an approved mushroom identification expert has been debated and challenged by numerous state public health agencies and the food industry. The FDA Food codes does not provide pre-requisites for an approved mushroom identification expert.

Thank you for your time and consideration of these comments. If you have any questions or need some clarification, please do not hesitate to contact me at 717.760.5911.

Sincerely,

Jennifer Walker
Director of Government Relations

Enclosures

Bacillus cereus Fact Sheet

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Bacillus cereus was reported as the cause of 14 outbreaks and 691 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in 11 outbreaks (*9*). Since *B. cereus* usually causes mild to moderate symptoms, the true incidence of foodborne infections is probably much higher than the reported incidence and is estimated at 27,360 cases yearly in the USA (*30*). *Bacillus cereus* has been identified as the cause of 42% of foodborne disease outbreaks in canteens serving the German military (*21*).

Bacillus cereus spores occur in soil, air, and dust. The spores are commonly detected in spices and herbs, suggesting their presence in foods containing these ingredients. *Bacillus cereus* is also a problem in the dairy industry and is infamous for multiplying in cooked rice left at room temperature (*3*). A survey of ready-to-serve moist foods from a cafeteria in Washington D.C. revealed that *B. cereus* spores were present in 88–100% of noodles, mashed potatoes and rice, in 50–83% of cooked vegetables, and in 25–75% of gravies sampled (*18*). Lower levels of contamination were reported from a similar survey in Italy (*2*).

Bacillus cereus grows in the presence and absence of oxygen (aerobically and anaerobically) at temperatures of 39–122°F, with optimal growth at 82.4–95°F. Growth rates at particular temperatures depend on acidity and concentrations of sodium chloride, sodium nitrite, and other inhibitors and nutrients in food or growth medium (*5, 6, 7*). Some other species of *Bacillus* grow at temperatures exceeding 140°F (*14*).

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *B. cereus* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of foods. There is a wide range of natural heat resistance of *B. cereus* spores (*13*). Heat resistance of spores is decreased by acidity (*8, 11, 17, 24, 26*). Heat resistance is increased by low water activity (e.g., high salt concentrations) (*27*) and by gradual heating, which allows some adaptation to heat (*10, 15, 27*). *Bacillus cereus* spores are also more heat resistant in phosphate buffer than in soybean oil (*31*).

Spores may be activated by heat and can germinate and grow if the food is maintained at a permissive temperature. Studies have demonstrated that some warmers do not always keep all parts of food hot enough to prevent growth and toxin production by activated spores (*7*).

To prevent the growth of undesirable microorganisms of public health significance in foods that can support their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

Exposure to heat during cooking may activate spores but can also injure them, and germination will only occur if the damage is repaired. Heat activation is not required for all *B. cereus* strains. The optimal temperature for germination appears to be 86°F although germination has been reported to occur at a wide range of temperatures (*12*).

Acidity (pH <6.7) and a low water activity (<0.98) inhibit germination and growth of *B. cereus* after heating (*10, 11*).

Initial stages of germination have been reported to occur in laboratory media at temperatures as high as 138°F (*22*).

Spore Germination and Growth in Foods

In cooked rice, *B. cereus* spores germinated and grew at temperatures as high as 122°F. However, percent germination decreased and generation time increased as temperatures increased above 40°F (*20*). No germination or growth was observed in cooked rice maintained at 140°F (*28*).

Sodium chloride, at concentrations of 2 and 4%, inhibited growth of *B. cereus* in mashed potatoes, but this effect was stronger at lower temperatures (*25*). Some organic acids, such as lactates, can prevent growth of *B. cereus* in beef goulash at 50–68°F (*4*). Powdered lacticin 3147 (a bacteriocin produced by *Lactococcus lactis*) reduced by 80% the number of *B. cereus* in soup (*32*).

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Heat resistance of *B. cereus* spores as affected by pH (*11, 17*)
- Heat resistance and germination of *B. cereus* spores as affected by isothermal and nonisothermal heating (*15, 16*)
- Growth from *B. cereus* spores in boiled rice (*29*)
- Growth of *B. cereus* as affected by eight organic acids at pH 5.25 (*19*)
- Recovery and lag time to growth of *B. cereus* as a function of duration and temperature of heating (*23*)

Data from these papers and others on the growth of *B. cereus* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet. Several parameters, including temperature, pH, sodium chloride and sodium nitrite concentrations, can be varied and growth curves generated (*33*).

Summary

Viable, activated spores may be present in cooked foods and may start growing if temperature decreases to 122°F. Generation times of some *B. cereus* strains are as short as 11 minutes. Therefore, it is important to maintain the holding temperature of all parts of a food above the maximum temperature that allows growth. If these foods are to be kept for another day, they must be cooled rapidly through the permissible temperature range for growth (41–122°F) to prevent multiplication and toxin production. There are some strains of *B. cereus* which can grow at refrigeration temperatures, but lag times are as long as 9–10 days (*6, 13*).

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Clostridium perfringens Ú¿½Í ¸»»¬

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Clostridium perfringens was reported as the cause of 57 outbreaks and 2,772 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in 46 outbreaks (*10*). Since *C. perfringens* usually causes mild to moderate symptoms, the true number of cases of foodborne infections is probably much higher than the reported incidence and is estimated at 248,520 cases yearly in the USA (*19*).

Although *C. perfringens* is widespread in the environment, most of the strains involved in foodborne illness are more heat resistant than strains isolated from the general environment. *Clostridium perfringens* grows in the absence of oxygen (anaerobic) at temperatures ranging from 53.6 to 125°F. Growth is rapid, even at high temperatures, with a reported generation time of 6.6 min at 109.4°F in beef cubes. Growth rates depend on the acidity and the concentrations of sodium chloride, sodium nitrite, and other inhibitors and nutrients in a food. Usually, meat is the vehicle for *C. perfringens* food poisoning because this bacterium requires the presence of 13 amino acids that it cannot synthesize (*2, 6, 7, 17*). However, an outbreak of *C. perfringens* poisoning associated with tofu (soy bean curd) was reported from Japan (*20*).

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *C. perfringens* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of food. Spores can survive several hours of boiling and are activated by heat, so that they can germinate and grow if food is maintained at a permissive temperature. This may present a problem for hot-held cooked foods: if the holding temperature is not hot enough, activated spores can grow and produce toxins.

To prevent the growth of undesirable microorganisms of public health significance in foods that can support growth their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

A temperature of 221°F injures spores, but, if the medium contains enough nutrients, repair can occur as the temperature decreases (*4*).

Cell growth has been reported at temperatures up to 125°F. When *C. perfringens* is heated to temperatures just above 122°F, it may appear to die off. But if incubation is continued for several hours longer, viable cells reappear. This has been dubbed the "Phoenix phenomenon." During the stage when no viable cells can be cultured, the heat-injured cells are repairing themselves and then they grow and increase in number (*24*).

If cells grow at higher temperatures (113 vs 98.6°F), they are more likely to survive short cooking at modest temperatures (*23*). Curing salts, in concentrations used commercially, prevent growth of *C. perfringens* at pH ≤6.2 (*12, 22*).

Spore Germination and Growth in Foods

Effects of various factors, including holding temperature, pH, Eh, water activity, curing salts, other additives, protein supplements, and presence of other bacteria, on growth of *C. perfringens* in foods have

Although spores germinate at higher temperatures, there appears to be no appreciable growth until temperatures have fallen below 119°F (proteolytic strains) or 113°F (non-proteolytic strains). Proteolytic *C. botulinum* strains grow in laboratory media at 118.4°F but not at 122°F (*13*). Lower pH and higher sodium chloride concentrations inhibited growth of non-proteolytic *C. botulinum* at lower growth temperatures (<59°F) (*6*). Other factors also inhibiting growth and toxin production include sodium lactate (*10*), sodium nitrite, sorbates, and some other preservatives (*9*). Some of these compounds are commonly used in preserved meats, and it may or may not be feasible to use them to limit growth of *C. botulinum* in some cooked foods.

Heat may injure spores and then germination occurs only if the damage is repaired during growth in a nutrient-rich medium. It is important to note that there is some variability in tolerance to environmental conditions in a population of spores and that certain conditions, such pH 5.5, may retard germination but do not significantly affect growth of vegetative cells (*2*). Therefore, the cells arising from the few spores that germinate at this pH will, in time, grow and produce toxin.

Spore Germination and Growth in Foods

Foods are complex systems which encompass important variables that may not be tested in carefully controlled laboratory experiments. Therefore, it is important to study pathogen survival in foods under realistic cooking and hot-holding conditions. However, there is little relevant data available on potential for germination and outgrowth of *C. botulinum* in foods at hot holding temperatures.

Addition of some inhibitory substances to a food may provide a hurdle to bacterial growth if temperature control is inadequate. Bacteriocin-producing lactic acid bacteria can inhibit growth of *C. botulinum* in gravy at 59°F, but experiments have shown that they may not be effective at higher temperatures (77–95°F) (*5*).

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Germination kinetics of proteolytic *C. botulinum* spores as a function of incubation temperature, pH, and sodium chloride concentration (*4*).
- Growth of proteolytic *C. botulinum* at 53.6–118.4°F in laboratory media (*13*).
- Growth from spores of non-proteolytic *C. botulinum* as a function of temperature, pH, and sodium chloride concentration (*7*).

Data from these papers and others on the growth of *C. botulinum* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet (*24, 25*). Various combinations of preservatives, salts and acid may effectively inhibit growth of *C. botulinum* (*23*).

Summary

Vegetative cells of *C. botulinum* are killed by cooking temperatures but spores survive and can germinate, grow, and produce toxin if environmental conditions are suitable. Since the maximum temperature for growth in laboratory media has been measured as 118°F, hot holding at the recommended temperature of 140°F should prevent outgrowth of cells from spores. However, experimental data indicate that spores can start germinating at temperatures at or below 150–170°F. If the temperature of a part of hot-held food declines to about 118°F, then the germinated spores could start outgrowth. It is important to note that heat resistance of *C. botulinum* is often greater in foods than in laboratory media and is greater in foods that are less acidic, have higher concentrations of fat or lower levels of salts. As yet there are not published studies which report the potential for growth of *C. botulinum* in cooked foods maintained for several hours at temperatures above 118°F and below 140°F.

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Clostridium botulinum Ú¿½Í ¸»»¬

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Clostridium botulinum was reported as the cause of 13 outbreaks and 56 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in nearly half of these outbreaks (*3*). When these bacteria grow in foods they produce a neurotoxin, and this toxin frequently causes death or severe symptoms requiring long periods of hospitalization before recovery. The true incidence of foodborne botulism poisonings has been estimated at 58 cases yearly in the USA (*17*). Although the number of cases is small, effects on health and economic costs of outbreaks are substantial.

Clostridium botulinum is commonly present in the environment and grows in the absence of oxygen (anaerobic). Proteolytic strains (Types A, B, and F) produce more heat-resistant spores than non-proteolytic strains (Types B, E, and some F); only non-proteolytic strains grow and produce toxin at refrigerator temperatures. The generally accepted maximal growth temperatures for proteolytic and non-proteolytic strains are, respectively, 118.5 and 113°F. However, these numbers vary somewhat depending on the acidity and composition of the food or growth medium.

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *C. botulinum* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of foods. Thermal destruction of *C. botulinum* spores does not follow first-order kinetics, indicating that some spores are more heat resistant than others (*15, 20*). Heat resistance of spores is greater at higher pH values (*14, 16*) and fat content (*18*) and lower water activity values (*19*) and sodium chloride (*11, 14*) and sodium pyrophosphate concentrations (*14*). Generally, spores are more resistant to heat in foods than in test solutions used in the laboratory (*12*).

Spores are activated by heat and will germinate and grow if cooked food is maintained at a permissive temperature. In laboratory experiments, exposure of *C. botulinum* spores to 176°F for 10 min activates them. If the hot-holding temperature of cooked foods is not hot enough to prevent germination and growth, then activated spores may grow and produce toxin in foods.

To prevent the growth of undesirable microorganisms of public health significance in foods that can support their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

Following heat activation, spores go through a process of germination and then start outgrowth and produce toxin if environmental conditions are suitable. Experiments have demonstrated that germination of some non-proteolytic strains of *C. botulinum* proceeds rapidly at 122°F (*8*) and germination of some proteolytic strains can occur at temperatures up to 158°F (*21*). Germination kinetics of proteolytic strains of *C. botulinum* spores have been studied as a function of temperature (59–86°F), pH (5.0–6.5), and sodium chloride (0.5–4.0%). Increasing sodium chloride concentrations inhibited germination, especially at low temperatures and/or pH values. Germination was also very slow or undetectable at pH 5.5 (*22*).

been reviewed. Growth generally does not occur in meat at temperatures ≤59°F or >122°F (*11*). Generation times in ground beef can be very rapid, with one report of 6.6 min at 109.4°F (*17*).

Surface layers of cooked meat are of particular concern when foods are being held hot prior to serving customers. When meat loaf slices were kept uncovered in an incubator at 140°F, *C. perfringens* was able to grow slowly on the surface because evaporative cooling reduced the temperature on the surface (*18*). Surfaces of gyros (beef or lamb broiled on a spit) were heated sufficiently during cooking to kill vegetative bacteria, but after cooking and cooling high concentrations of *C. perfringens* were recovered from samples taken just underneath the surface of the meat (*9*). This points out the necessity for rapid cooling if meat is to be kept overnight for serving the next day.

Clostridium perfringens grew on beef cubes at 124°F but not at 128°F (*7*). Heating of beef cubes (8×8×8 cm) for 24 hours (as a tenderizing method) at 131°F did not allow growth of *C. perfringens*. But some growth did occur if beef cubes were larger (*16*).

Germination and growth of heat-activated *C. perfringens* occurred in chili within 2 hours of incubation at 118.4°F (*5*).

Heat resistance of vegetative cells can be increased up to three-fold by a short sublethal heat shock. If such temperature abuse has occurred then foods may need to be cooked longer or at higher temperatures to destroy vegetative *C. perfringens* (*13, 15, 21*).

Some organic acids, such as lactates, can prevent growth of *C. perfringens* in beef goulash at 59–77°F (*3*).

Hazard analysis of roast beef preparation in foodservice establishments was investigated, and it was found that vegetative organisms could have survived in the center of some roasts. In about 25% of cases, roasts were held in hot storage devices with inadequate temperature control, which would have allowed spore germination and significant bacterial growth (*8*).

A review of several studies on hot holding of meats and other cooked foods concluded that careful maintenance of temperatures greater than 140°F would assure safe foods (*25*). Even though *C. perfringens* apparently does not grow on meat at temperatures above 124°F, there is some variability in heat resistance of different strains grown under different conditions and some variability in the efficiency of hot-holding devices.

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Growth rate as a function of temperature (*26*)
- Interactive effects of temperature, pH, sodium chloride, and sodium phosphate on growth rate (*14*)

Data from these papers and others on the growth of *C. perfringens* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet. Several parameters, including temperature, pH, sodium chloride and sodium nitrite concentrations, can be varied and growth curves generated (*27, 28*).

Summary

Clostridium perfringens may pose the greatest threat of bacterial foodborne illness from foods which are kept hot for several hours before serving. Not only do its spores survive cooking, but vegetative cells grow rapidly at relatively high temperatures (up to about 123°F). However, *C. perfringens* requires 13 amino acids for growth and therefore is most likely to be a problem in protein-rich foods, particularly those containing meat or soy proteins. Cooking can activate spores, which may germinate and grow if the holding temperature of any part of a food decreases enough to permit growth. The activated spores can also grow if food is to be saved for the next day and is cooled slowly during refrigeration.

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PENNSYLVANIA FOOD MERCHANTS ASSOCIATION
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NO. OF PAGES (INCLUDING THIS PAGE): 14

TODAY'S DATE: 3/25/02

TIME: 4:05 pm

TO: Chris Markham
CO.: IRRC
FAX:
RE:

FROM: Jennifer Walker
CO.:

OPERATOR:

MESSAGE:

Hi Chris:

Per my voicemail earlier today, I am faxing a copy of the comments we submitted to the Department of Agriculture. I will follow this with a hard copy via mail.

Thank you,
Jennifer

ORIGINAL: 2255

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VIA FACSIMILE and HAND DELIVERY

March 25, 2002

Department of Agriculture
Bureau of Food Safety and
Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408
Attn: Sheri Dove

Re: Proposed Rulemaking -- Food Code Regulations
32 Pa. Bulletin No. 8, February 23, 2002

Dear Ms. Dove:

We represent the Pennsylvania Catholic Conference, an association comprised of the eight Latin Rite Roman Catholic Dioceses of Pennsylvania and the two Byzantine Rite Catholic Dioceses whose territories include the Commonwealth of Pennsylvania. The Catholic Conference has authorized us to submit the following comments regarding the proposed Food Code Regulations published by the Department of Agriculture ("the Department"). The proposed regulations are extensive and have the potential to impact all Catholic schools, social service agencies, and diocesan and parish entities that might prepare and serve food.

Although we respect the Department's intentions of reducing foodborne illnesses, we believe that the Department has unnecessarily overstepped its legal authority in drafting the proposed regulations, as follows:

1. The Department appears to be exceeding its authority under the Public Eating and Drinking Place Law ("the Law")(35 P.S. §§ 655.1-655.13) by promulgating overly broad definitions of "food facility" and "food facility premises." See 32 Pa. B. No. 8 at 1051 (Prop. Reg. § 46.3). These definitions contain examples of food facilities that would be subject to regulation, licensing and inspections such as an "organized camp or campground," a "school" or a "recreation camp." No distinctions are made between public and private facilities in the regulations.

2. In contrast, the Pennsylvania Superior Court in Com. v. Loyal Order of the Moose Lodge No. 148, 188 Pa. Super. Ct. 531, 149 A.2d 565 (1959), significantly limited the reach of the Public Eating and Drinking Place Law. In Loyal Order of the Moose, the Superior Court held that a private lodge -- a nonprofit corporation that served food and refreshments and maintained a kitchen -- was not a public eating and drinking place because the lodge only admitted its members and their guests in accordance with its constitution and bylaws. If a lodge is exempt from regulation as a public eating and drinking establishment, a religious school or any other private entity, which limits enrollment based on its charter and rules, should also be exempt. It is our understanding that Loyal Order of the Moose has not been overturned or superseded by statute. Thus, the Department should provide an exception that incorporates the holding of the Superior Court pertaining to private entities.

3. Further, the proposed regulations provide no exemptions for non-profit entities. However, the General Assembly established exemptions for non-profit organizations in the Food Employee Certification Act. See 3 Pa.C.S.A. § 6510(d). These exemptions make clear that the General Assembly intended to limit the regulatory reach of the Department to commercial or for-profit food establishments. The Department should amend its proposed regulations to respect this legislative intent.

4. The regulations do not adequately explain the distinctions among permits, licenses or registrations, but simply indicate that the Department will supply the appropriate application form based on the type of food facility involved. See 32 Pa. B. No. 8, p. 1094 (Prop. Reg. § 46.1142). Without any additional objective standards, the Department could subject food facilities to arbitrary or inconsistent treatment.

5. Under the Public Eating and Drinking Place Law, the Department's authority to license public eating and drinking places appears constrained. See 35 P.S. §§ 655.1 and 655.2. The power to act as a "Licensor" -- the entity authorized to issue a license to a public eating and drinking place -- is primarily vested in county or local health authorities. The Department's authority to issue a license seems limited to the occasions when townships of the second class, which are not under the jurisdiction of a county health department or joint county health department, elect not to issue licenses. 35 P.S. § 655.2. However, the regulations would give the Department sole authority to issue permits, licenses and registrations, but make no mention of county or local health authorities. See 32 Pa. B. No. 8, p. 1094 (Prop. Reg. §§ 46.1141 and 46.1142). This would appear to circumvent the legislative intent of delegating primary licensing authority to county or local health authorities.

We request that the proposed regulations be revised to correct these deficiencies. In the alternative, please provide the legal basis upon which the Department relies in support of its position. We look forward to working with the Department to ensure that the rights of private, non-profit entities are not disregarded by well-intentioned, but unnecessary regulatory intrusion.

Very truly yours,

Thomas A. Capper

cc: Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
(via First Class Mail)
Dr. Robert J. O'Hara, Jr., Executive Director
Pennsylvania Catholic Conference

Original: 2255

PENNSYLVANIA
SCHOOL BOARDS
ASSOCIATION, INC.

774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

March 22, 2002

John H. Jewett
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. ~~Jewett~~ John:

Enclosed are the comments of the Pennsylvania School Boards Association to the Department of Agriculture concerning its proposal published in the February 23, 2002 issue of the *Pennsylvania Bulletin* to adopt 7 Pa. Code, Chapter 46 (food code) and delete various existing chapters of regulations concerning food safety issues. Our comments focus on the proposal as it would relate to the operations of cafeterias in public school entities.

Currently, the department provides training for cafeteria employees and also conducts regular inspections of school cafeterias. These activities are done through an agreement between the departments of Agriculture and Environmental Protection and are not established in regulation and would not be affected by provisions under the proposed Chapter 46. However, under 25 Pa. Code, Chapter 171, school cafeterias are required to comply with provisions under 7 Pa. Code, Chapter 78, regarding the operation of these facilities. With the proposed deletion of Chapter 78, Chapter 171 should be amended to reflect the new Chapter 46. Although this is not within the purview of the Department of Agriculture, PSBA notes that an inconsistency will exist and suggests that Department of Environmental Protection be notified of the issue. Without a change, §171.6 would reference a chapter of regulations that no longer exists.

We also note that currently, school cafeterias are not required to be licensed, or have any type of permit or registration in order to operate. While we understand that it is not the intention of the Department of Agriculture to make a change, Chapter 46 as written inadvertently appears to create a new mandate. As drafted, there is no specific definition of school cafeterias and therefore schools would fall within the definition of "food facilities;" Chapter 46 states that food facilities would not be able to operate without a valid permit, license or registration issued by the department. PSBA requests that clarifying language be added to exempt cafeterias of public school entities.

We hope that these comments are considered by you as well, as the proposal moves through the regulatory review process. Please contact me if you have any questions or need further clarification on the issues addressed in this letter. Thank you for reviewing our comments.

Sincerely,

Timothy M. Allwein
Assistant Executive Director
Governmental and Member Relations

Original: 2255

PENNSYLVANIA
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774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

March 22, 2002

Ms. Sheri Dove, Food Program Manager
Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408

Dear Ms. Dove:

The Pennsylvania School Boards Association would like to provide comments concerning the Department of Agriculture's proposal published in the February 23, 2002 issue of the *Pennsylvania Bulletin* to adopt 7 Pa. Code, Chapter 46 (food code) and delete various existing chapters of regulations concerning food safety issues. This comprehensive code would include many of the procedures and food safety standards that were under the chapters to be deleted. Our comments will focus on the proposal as it would relate to the operations of cafeterias in public school entities.

Currently, certain provisions regarding school facilities are incorporated under 25 Pa. Code (Environmental Protection), Chapter 171 (schools). Specifically relating to cafeterias, §171.6 states that "whenever food service is provided, the food service facilities and operations shall comply with 7 Pa. Code, Chapter 78 (food establishments)." With the department's proposed deletion of Chapter 78, this section of regulations will need to be amended to reflect the new Chapter 46. Although this is not within your purview and will be the responsibility of the Department of Environmental Protection, PSBA notes that an inconsistency will exist and suggests that DEP be notified of the issue.

With the deletion of Chapter 78, then, it would be assumed that school cafeterias would be required to comply with the comprehensive regulations under Chapter 46. While school cafeterias are not individually referenced or defined, it appears that they may fall under the definition of "food facility" since the definition of "food facility premises" does specifically include schools.

As we look at Chapter 46, it also appears that many of the same requirements that currently affect the operations of school cafeterias would continue without significant change. There is, however, one section that PSBA believes must be clarified. Under §46.1141, "a person may not operate a food facility without a valid permit, license or registration issued by the department." While cafeterias operated by public school entities are subject to inspection and employee training provided by the department, they have never been required to have

any type of permit, license or registration. Because public school entities do not provide food service to the general public, PSBA believes it is not the intention of the department to establish a new mandate at this time, and therefore requests that clarifying language be added. The association suggests that §46.1141 be amended to include a provision such as the following: "Food facilities operated by school entities as defined under the Public School Code, including school districts, intermediate units and area vocational-technical schools, are exempt from this requirement."

PSBA has no objection to the establishment of a comprehensive food code; however, much of its provisions appropriately will apply to what are now known as "food establishments" and "public eating and drinking places" that provide service to the general public. Cafeterias operated by school entities, as you know, do not. The association supports provisions for cafeterias to abide by food safety regulations, but also recommends that Chapter 46 clearly exempt schools from requirements that the department did not intend to impose.

We appreciate the opportunity to review and comment on these proposed regulations. Please contact me if you wish to discuss the issues addressed in this letter.

Sincerely,

Timothy M. Allwein
Assistant Executive Director
Governmental and Member Relations

Original: 2255

THE COUNTY OF CHESTER

Received 3/21

COMMISSIONERS:
Karen L. Martynick, Chairman
Colin A. Hanna
Andrew E. Dinniman

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Certified Food Manager 610-344-5938
Engineering/Public Water 610-344-6237

Solid Waste Mgt./Recycling 610-344-5937
Weights & Measures/Consumer Affairs 610-344-6150
Laboratory 610-344-6249

March 19, 2002

Sheri Dove
Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408

Re: Proposed PA Food Code

Dear Ms. Dove:

The PA Food Code as published in the PA Bulletin on February 23, 2002 is an impressive document. The formal and comprehensive provisions proposed are particularly needed at this time in the Nation's history when a special concern is now attached to the safety of our food supply.

The Chester County Health Department for some time has been providing its food inspectors with up-dated versions of the FDA Model Food Code as they are published. The current FDA Model Codes are used as an interpretive guide to the County Health Department's Rules and Regulations, which are admittedly outdated. Therefore, the wish of the Chester County Health Department is to do precisely what is proposed here by the PA Department of Agriculture. There are several changes that are recommended by the Chester County Health Department as listed below.

The currently proposed regulations as published in the PA Bulletin, February 23, 2002 are quite different from those Agriculture was considering and circulating in 1998. It is understood that the 1998 version was based on the 1977 Model Food Code while the current proposal is based on the 1999 Model Code. The proposed PA Food Code as published in the PA Bulletin is also quite different in format to a circulating version obtained from Agriculture in November, 2001.

Comments on the 1998 circulating version of the proposed PA Food Code were submitted in a letter to Mr. Rabinovitch dated October 9, 1998. All of our concerns then have been corrected by the new proposed regulation except the concern with the defined term "Private water system" (see below).

The following are comments on the proposed PA Food Code regulations published in the PA Bulletin:

- **Subsection 46.3 Definitions.**

"Bed and breakfast homestead or inn" appears correctly defined here but the term is not used either in another definition or in the Requirements of Operations Section as an exempted operation. It seems as though the term should show up in one place or the other as an exempted operation.

- **Subsection 46.3 Definitions.**

"Department" should be qualified similarly to the definition of "Secretary" which includes the qualifying phrase, "or any authorized representative, employee or agent of the Department". This because "Department" is very narrowly defined as the PA Department of Agriculture. Therefore, according to the regulations as written, only Agriculture can "Approve", assign shellfish numbers, issue shellfish Permits, approve variances as listed throughout the regulations, review and approve plans, conduct preoperational inspections, issue licenses, and receive reports of ill employees.

There are differing opinions regarding the meaning of Section 13. "Rules and Regulations", and Section 17. "Acts not affected", of Act 70 of 1994 when it comes to the jurisdiction of other agencies at "food facilities". If all County and Local jurisdictions will be required to utilize the Agriculture Food Code, then the term "Department" needs to be modified to meet the intent and directives of the Act. If the Act will not allow the modification of the definition of "Department" then the term "Secretary" should replace the term "Department" in most places throughout the proposed regulation.

- **Subsection 46.3 Definitions.**

"Private water system" cannot be found in the provisions. What appears is "Nonpublic water supply". Change one or the other.

- **Subsection 46.112 Disease or medical conditions that must be reported.**

The proposed regulations as published in the PA Bulletin were reviewed beside the FDA Model Food Code 2001. Most changes in the 2001 over the 1999 Code involve clarification of existing provisions. The one change in the 2001 Code that should be considered here is the use of the term "Shiga toxinproducing *E. coli*" to replace the term "Escherichia coli O157:H7". Rapid nonculture assays are available for Shiga toxinproducing *E. coli* that includes other disease-producing subtypes of E coli. It is recommended the term Escherichia coli O157:H7 be replaced

by Shiga toxinproducing *E. coli.* Changing the term allows for the use of rapid nonculture assays avoiding lengthy delays in waiting for results of time-consuming culture-based subtyping procedures. The suggested term also recognizes other subtypes that are pathogenic.

- **Subsection 46.132 Duty of food employees to wash.**

The 2001 Model Code includes the need to wash hands before donning gloves. This is important because glove juices that build up in gloves can leak out at the cuff. Washing hands prior to donning can reduce the bacteria of glove juices.

- **Subsection 46.246 Receiving shucked shellfish: packaging and identification.**

Here the term "detention": is used referencing the Act. Detention provisions should be listed in the regulations not only for shellfish but also generally for all other food items.

- **Subsection 46.2261 Preventing contamination from food employees' hands.**

The no-hand-contact provision has been weakened additionally by the inclusion of the phrase, "unless hands have been washed as specified in §46.131(b)" and at the end by, "whenever possible". It is felt these phrases should be removed as the existing phrase, "or whenever approved" is sufficient to exempt the need for gloves in those very rare occasions. Hands continue to be a large concern in food facilities with the fecal-oral route transmission of Hepatitis A and especially of Norwalk-Like viruses. Recent studies have shown that foodhandlers and others can be shedding Norwalk-Like viruses asymptomatically and otherwise for extended periods following a symptomatic illness.

- **Patron Handwashing.**

This comes under the heading of, "Everything I Need to Know in Life I Learned in Kindergarten". Wash your hands before you eat. In the last year this has been re-emphasized with the outbreaks of Shiga toxinproducing *e coli. (cf.* CDC, MMWR, April 20, 2001, "Outbreaks of *Escherichia coli* O157:H7 Infections Among Children Associated With Farm Visits --- Pennsylvania and Washington, 2000").
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5015a5.htm

Although the proposed regulations require toilet rooms and handwashing for employees, the proposed regulations are silent on any need for patron toilet or handwashing facilities.

Handwashing and dining should be as inseparable as seatbelts and driving. There is nothing more reasonable in the realm of Public Health than to require food facilities allowing eating on the premises to provide toilet facilities for patrons with the necessary handwashing facilities.

It is questioned whether or not County Health Departments or Local Jurisdictions can adopt a separate requirement requiring toilet rooms for patrons in those public facilities serving food on their premises, since this might be considered contrary to the purpose of Act 70 and contrary to the provision of Subsection 13 (b) "Local inspections".

It is felt that Subsection 15.(2) of Act 70 allows PA Agriculture to consider Patron Toilet Rooms as such would, "protect an important public interest that would otherwise be unprotected".

Thank you for allowing the Chester County Health Department to comment on this very important subject.

Sincerely yours,

Andrew Worth, R.S.
Environmental Health Supervisor

cc: Dvid A. Jackson, R.S.
Joseph Arvay

Original: 2255

5/23/02

March 25, 2002

Ms Sheri Dove
Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron street
Harrisburg, PA 17110-9408

Dear Ms Dove

In response to the publication of the proposed Food Code in the Pennsylvania Bulletin I am submitting the following comments for consideration in the proposed regulations:

1) Definitions: a) Potentially hazardous foods – typo section (i)

b) Under the definition of Public Eating and Drinking Place Section (ii), (dining cars and bed and breakfast homestead or inn) is included as part of this definition. Does this mean that the Commonwealth and any other agencies responsible for the inspection and regulation of public eating and drinking establishments will have inspection responsibility for these establishments?

2) Section 46.133 Required washing locations.

This section does not specify anything prescriptive concerning the location of hand washing facilities. This section prohibits hand washing using specific plumbing fixtures. The title would be clearer as "Approved hand washing locations." The prohibition against the use of a utility sink is not appropriate in all instances. Food establishments with small available square footage for their operation may only need and use a small container of cleaning solution to clean environmental surfaces on a limited basis. The provision of a single stainless steel one compartment sink that is installed to meet general utility purposes but is equipped to be used predominantly for hand washing purposes need not prelude other occasional utility uses. No definition of utility sink is in the body of regulations to clarify what is meant by this term of utility sink. By inference it may be assumed that a "janitorial sink" comes to mind for this sections meaning but this is not clear.

3) Section 153. Animals and Section 46.982 Limitations on animals.

The exception provision (B)(1) permits patrons of food facilities to bring their pets into these locations under the stipulation that food, clean equipment, utensils, linens and unwrapped single service and single-use articles can not be contaminated. Every pet owner that hand carries or leashes their pet will argue that their pet will not be a contamination risk to the food establishment environment. It is recommended that the first line of this section be revised to read:

(1) "Only" live animals may be allowed "that meet" any of the ..... .

4) Section 46.241 Receiving temperature of food. Part D Visible evidence of improper food temperature.

Recommend additional language providing example(s) of visible evidence.

5) Section 46.241 Protection from approved additives.

Sulfiting agents may be appropriately used as an additive for a number of foods that may be offered to the consumer. When such foods are offered for self service (bulk retail sales or for immediate consumption) food ingredient labeling in addition to another form of direct notice to the consumer that the food has been treated with a sulfiting agent is recommended and can be added as part "c" of this section.

6) Section 46.303 Linens and napkins: use limitation.

This section does not include use of clean linens for use in retail display of dry non-potentially hazardous foods (rolls in a bakery). It is recommended that the term "approved retail display" be added to use condition and linen replacement upon refilling of the retail display unit.

7) Section 46.385 Potentially hazardous food: hot and cold holding.

This equivalent section in the FDA Model Food Code Section 3-501.16 includes stipulation as to the time food should be held and maintained at specific food temperatures. No more than 7 days when food is held at 41° F or less and for a limit of 4 days when food is held at or below 45° F.

The proposed "food code" has no provisions related to date marking, tracking or using foods within a time frame. This provides no public health protection measures from Listeria monocytogenes growth in foods that are prepared in the establishment and refrigerated for future use or foods that are commercially packaged and opened for use in the operation of a food facility.

It is highly recommended that this position be re-evaluated. This position is directly counter to the recent media and public concerns about the safety, quality and control of foods being offered to the general public. This position nullifies years of food safety training providing support for monitoring food inventory and actively controlling food product inventory to ensure the service or sale of safe, quality foods.

8) Section 46.676 Manual warewashing equipment.

Part (b) permits use of a warewashing sink for food washing and food thawing activities, and washing soiled wiping cloths. Separate equipment is needed for food preparation activities to limit cross contamination exposure of food that will be prepared in a ready-to eat form from chemical contaminants and environmental contaminates associated with cross use of the utility/ware washing sink. Wiping cloths may readily be used for cleaning spills on floors thus becoming similar to disposal of mop water waste or mop cleaning. It is not practical to routinely fill and drain a three-compartment sink every time such activity may occur within the food facility operation as stipulated.
Separate sinks for food preparation, utensil/equipment cleaning and utility cleaning purposes are needed and need to be required. A variance or departmental approval clause would more appropriately handle particular operation circumstances when combined sink uses would make more sense under specific limited circumstances.

Thank you for the opportunity to review the proposed regulations and make recommendations for refinement.

Respectfully submitted,

George Zameska, Chief
Office of Food Protection

Original: 2255

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VIA FACSIMILE and HAND DELIVERY
March 25, 2002

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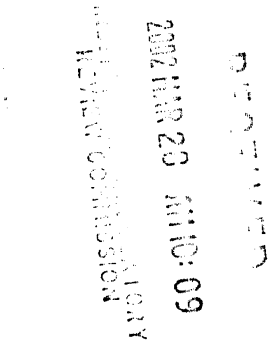

Re: Proposed Rulemaking -- Food Code Regulations
32 Pa. Bulletin No. 8, February 23, 2002

Dear Ms. Dove:

We represent the Pennsylvania Catholic Conference, an association comprised of the eight Latin Rite Roman Catholic Dioceses of Pennsylvania and the two Byzantine Rite Catholic Dioceses whose territories include the Commonwealth of Pennsylvania. The Catholic Conference has authorized us to submit the following comments regarding the proposed Food Code Regulations published by the Department of Agriculture ("the Department"). The proposed regulations are extensive and have the potential to impact all Catholic schools, social service agencies, and diocesan and parish entities that might prepare and serve food.

Although we respect the Department's intentions of reducing foodborne illnesses, we believe that the Department has unnecessarily overstepped its legal authority in drafting the proposed regulations, as follows:

1. The Department appears to be exceeding its authority under the Public Eating and Drinking Place Law ("the Law")(35 P.S. §§ 655.1-655.13) by promulgating overly broad definitions of "food facility" and "food facility premises." See 32 Pa. B. No. 8 at 1051 (Prop. Reg. § 46.3). These definitions contain examples of food facilities that would be subject to regulation, licensing and inspections such as an "organized camp or campground," a "school" or a "recreation camp." No distinctions are made between public and private facilities in the regulations.

2. In contrast, the Pennsylvania Superior Court in Com. v. Loyal Order of the Moose Lodge No. 148, 188 Pa. Super. Ct. 531, 149 A.2d 565 (1959), significantly limited the reach of the Public Eating and Drinking Place Law. In Loyal Order of the Moose, the Superior Court held that a private lodge -- a nonprofit corporation that served food and refreshments and maintained a kitchen -- was not a public eating and drinking place because the lodge only admitted its members and their guests in accordance with its constitution and bylaws. If a lodge is exempt from regulation as a public eating and drinking establishment, a religious school or any other private entity, which limits enrollment based on its charter and rules, should also be exempt. It is our understanding that Loyal Order of the Moose has not been overturned or superseded by statute. Thus, the Department should provide an exception that incorporates the holding of the Superior Court pertaining to private entities.

3. Further, the proposed regulations provide no exemptions for non-profit entities. However, the General Assembly established exemptions for non-profit organizations in the Food Employee Certification Act. See 3 Pa.C.S.A. § 6510(d). These exemptions make clear that the General Assembly intended to limit the regulatory reach of the Department to commercial or for-profit food establishments. The Department should amend its proposed regulations to respect this legislative intent.

4. The regulations do not adequately explain the distinctions among permits, licenses or registrations, but simply indicate that the Department will supply the appropriate application form based on the type of food facility involved. See 32 Pa. B. No. 8, p. 1094 (Prop. Reg. § 46.1142). Without any additional objective standards, the Department could subject food facilities to arbitrary or inconsistent treatment.

5. Under the Public Eating and Drinking Place Law, the Department's authority to license public eating and drinking places appears constrained. See 35 P.S. §§ 655.1 and 655.2. The power to act as a "Licensor" -- the entity authorized to issue a license to a public eating and drinking place -- is primarily vested in county or local health authorities. The Department's authority to issue a license seems limited to the occasions when townships of the second class, which are not under the jurisdiction of a county health department or joint county health department, elect not to issue licenses. 35 P.S. § 655.2. However, the regulations would give the Department sole authority to issue permits, licenses and registrations, but make no mention of county or local health authorities. See 32 Pa. B. No. 8, p. 1094 (Prop. Reg. §§ 46.1141 and 46.1142). This would appear to circumvent the legislative intent of delegating primary licensing authority to county or local health authorities.

We request that the proposed regulations be revised to correct these deficiencies. In the alternative, please provide the legal basis upon which the Department relies in support of its position. We look forward to working with the Department to ensure that the rights of private, non-profit entities are not disregarded by well-intentioned, but unnecessary regulatory intrusion.

Very truly yours,

Thomas A. Capper

cc: Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
(via First Class Mail)
Dr. Robert J. O'Hara, Jr., Executive Director
Pennsylvania Catholic Conference