

JANUARY 10

TENTATIVE AGENDA
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
Sunday, January 10, 1999
2 - 4 p.m.
Senate Finance Committee Room M-451

1. **Approval of Minutes** - Meetings of December 13, 15 and 16, 1998
2. **Review of Legislative Rules:**
 - a. **Division of Health**
Reportable Diseases, Events and Conditions, 64CSR7
 - b. **Division of Health**
Medication Administration by Unlicensed Personnel, 64CSR60
 - c. **Tax Commissioner**
Valuation of Public Utility Property for Ad Valore Tax Purposes, 110CSR1M
 - d. **Department of Tax and Revenue**
Registration of Telemarketers, 119CSR301
 - e. **Air Quality, Office of**
Ambient Air Quality Standards for Sulfur Oxides and Particulate Matter, 45CSR8
 - f. **Mining & Reclamation, Office of**
WV Surface Mining and Reclamation Rule, 38CSR2
 - g. **Water Resources, Office of**
Pollution Prevention and Compliance Assistance Rule, 47CSR3
 - h. **Family Protection Services Board**
Licensing Standards for Domestic Violence, 191CSR1
 - i. **Family Protection Services Board**
Licensure of Domestic Violence Perpetrator Intervention Programs, 191CSR2
3. **Other Business .**

January 10, 1999

2:00 p.m. - 4:00 p.m.

Legislative Rule-Making Review Committee
(Code §29A-3-10)

Earl Ray Tomblin
ex officio nonvoting member

Robert "Bob" Kiss
ex officio nonvoting member

Senate

Ross, Chairman
Anderson, Vice Chairman
Boley
Bowman (Absent)
Buckalew (Absent)
Macnaughtan (Absent)

House

Hunt, Chairman
Linch, Vice Chairman
Compton (Absent)
Faircloth
Jenkins
Riggs

The meeting was called to order by Mr. Hunt, Co-Chairman.

The minutes of the December 13, 15 and 16, 1998, meetings were approved.

Debra Graham, Committee Counsel, explained that the rule proposed by the *Department of Tax and Revenue-Registration of Telemarketers, 119CSR301*, had been laid over from the previous meeting. Sam Cipoletti, Government Relations from Bell Atlantic, and Dale Steager, Counsel with the Department, addressed the Committee and responded to questions.

Mr. Ross moved that the proposed rule be moved to the foot of the agenda. The motion was adopted.

Ms. Graham explained that the rule proposed by the *Division of Health-Reportable Diseases, Events and Conditions, 64CSR7*, had been laid over from the previous meeting. Randy Cox, representing the West Virginia Health Maintenance Organization Association, Dr. Henry Taylor, Director of the Bureau of Public Health, and Larry Arnold, Counsel with the Division, addressed the Committee. Loretta Haddy, Director of Surveillance and Disease Control for the Division, responded to questions from the Committee.

Mr. Jenkins moved that Section 9 of the proposed rule be modified to provide that copies of the rule are to be distributed by licensing boards or agencies. The motion was adopted.

Mr. Ross moved that the proposed rule be approved as modified. The motions was adopted.

Rita Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the *Division of Health-Medication Administration by Unlicensed Personnel, 64CSR60*, and stated that the Division has agreed to technical modifications. She responded to questions from the Committee.

Mr. Ross moved that the proposed rule be approved as modified. The motions was adopted.

Ms. Graham explained that the rule proposed by the *Tax Commissioner-Valuation of Public Utility Property for Ad Valorem Tax Purposes, 110CSR1M*, had been laid over from the previous meeting. Jerry Knight, Director of the Property Tax Division, addressed the Committee and responded to questions. Charlie Lorensen, representing public utilities, addressed the Committee.

Mr. Jenkins moved that the proposed rule be amended by removing all technical modifications not relating to motor carriers. The motion was adopted.

Mr. Ross moved that the proposed rule be approved as modified and amended. The motion was adopted.

Joseph Altizer, Associate Counsel, reviewed his abstract on the rule proposed by the *DEP, Office of Air Quality-Ambient Air Quality Standards for Sulfur Oxides and Particulate Matter*, and stated that the Division has agreed to technical modifications.

Mr. Ross moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Altizer explained the rule proposed by the *DEP, Office of Mining and Reclamation-West Virginia Surface Mining and Reclamation Rule, 38CSR2*, and stated that the Division has agreed to technical modifications.

Mr. Ross moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Altizer reviewed his abstract on the rule proposed by the *DEP, Office of Water Resources-Pollution Prevention and Compliance Assistance Rule, 47CSR3*, and stated that the Division has agreed to technical modifications.

Mr. Ross moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley explained the rule proposed by the *Family Protection Services Board-Licensure of Domestic Violence Perpetrator Intervention Programs, 191CSR2*, and stated that the Board has agreed to technical modifications.

Mr. Ross moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Linch moved that the Committee reconsider its action whereby it approved, as amended, the rule proposed by the *DEP, Office of Air Quality-To Prevent and Control Air Pollution from*

Hazardous Waste Treatment Storage or Disposal Facilities, 45CSR25. The motion was adopted. Karen Watson, Counsel for the Office of Air Quality, addressed the Committee and responded to questions.

Ms. Boley moved the proposed rule be moved to the foot of the agenda. The motion was adopted.

Mr. Faircloth moved that staff be directed to invite a representative of the Department of Agriculture to the Committee's next meeting to respond to questions and discuss the rule proposed by the Department, ***Marketing of Eggs Regulations, 61CSR7A.*** The motion was adopted.

The meeting was adjourned.

JANUARY INTERIM SCHEDULE
Legislative Interim Meetings
January 10, 11, and 12, 1998

Sunday, January 10, 1999

2:00 - 4:00 p.m.

Legislative Rule-Making Review Committee
(Code §29A-3-10)

Earl Ray Tomblin, ex
officio nonvoting member

Robert S. Kiss, ex
officio nonvoting member

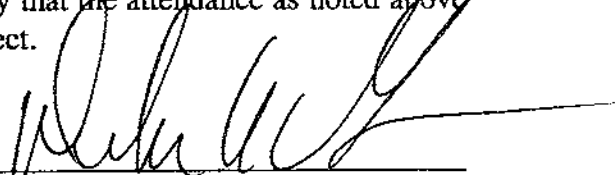
Senate

Ross, Chair ✓
Anderson, Vice Chair ✓
Bowman _____
Macnaughtan _____
Boley ✓
Buckalew _____

House

Hunt, Chair ✓
Linch, Vice Chair ✓
Compton _____
Jenkins ✓
Faircloth ✓
Riggs ✓

I certify that the attendance as noted above
is correct.



Staff Person

Debra



DIVISION OF ENVIRONMENTAL PROTECTION

CECIL H. UNDERWOOD
GOVERNOR

1558 Washington Street East
Charleston, WV 25311-2599

MICHAEL P. MIANO
DIRECTOR

January 9, 1999

Honorable Michael Ross, Co-Chair
Legislative Rule-Making Review Committee
Room MB49-State Capitol
Charleston, WV 25305

Honorable Mark Hunt, Co-Chair
Legislative Rule-Making Review Committee
Room MB49-State Capitol
Charleston, WV 25305

Re: 45CSR25--Office of Air Quality-- "To Prevent and Control Air Pollution from Hazardous Waste Treatment, Storage, or Disposal Facilities"

Dear Gentlemen:

I am writing to request that the Legislative Rule-Making Review Committee reconsider the action taken at its December 16, 1998 meeting, recommending that the above-referenced rule be amended to impose a one-year time frame on the agency to process a hazardous waste permit. The amendment further provided that if the agency fails to act within the one-year time frame, the permit would automatically issue.

The subject rule, 45CSR25, is the State's rule to regulate air emissions from hazardous waste treatment, storage, and disposal facilities. The federal counterpart to this rule is contained principally at 40 C.F.R. Parts 260 through 270, which is authorized by the federal Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§6901 et seq. (45CSR25 is also based on the authority of the State Air Pollution Control Act at W.Va. Code §§22-5-1 et seq. and the federal Clean Air Act, 42 U.S.C. §§7401 et seq.) In order for the State to have the primary authority to administer and enforce the hazardous waste program, it must receive authorization from the U.S. Environmental Protection Agency (EPA). The Division of Environmental Protection's Office of Air Quality (OAQ) and Office of Waste Management (OWM) (the lead State agency for the program) have been working closely with EPA to obtain full authorization of all portions of the federal RCRA program; however, to be authorized by EPA, the State's

Office of Air Quality

Phone: (304)558-4022 Fax: (304)558-3287

program must be equivalent to the federal program.

With regard to the amendment passed by the Committee, the insertion of the subject language in the rule potentially jeopardizes EPA's authorization of the hazardous waste program by imposing time constraints for processing permits which are inconsistent with the federal program and by including a "permit by default" provision if the agency fails to act on the permit.

The proposed language establishing a one-year limit would apply to the processing of all permit actions, including permits for new facilities and modifications of existing facilities. The federal counterpart regulations do not contain a time frame applicable to the agency in its processing of permits, new or modified, with one relatively minor exception, and that is for what is characterized as a Class 2 modification. This type of modification is subject to a 90-day time frame which may then be modified upon certain conditions. The OAQ's rule as proposed contains this 90-day time frame for Class 2 modifications and thus is equivalent to the federal program. The effect of the Committee's amendment is to create a conflict within the rule itself as it pertains to the processing time for a Class 2 modification.

Furthermore, as stated previously, for all hazardous waste permitting actions other than Class 2 modifications, the federal program does not require the agency to act within a prescribed period of time. It should be noted the processing of permits for new facilities and the more complex modifications for existing facilities, i.e., Class 3 modifications, can be time-consuming and resource intensive. A one-year time limit, even one which does not commence until the close of the public comment period, could be problematic for these types of permitting actions.

The nature of hazardous waste facilities and the environmental permitting process associated with those facilities is more complex and requires more extensive agency review than most other environmental permitting programs. Specifically, hazardous waste facilities requiring a permit under 45CSR25 must conduct at least one trial burn on their proposed emissions and a risk assessment to identify environmental risks posed by the proposed action. In addition, there are at least two public notice periods required in the process, and, in the case of new hazardous waste commercial facilities, there is an entirely separate approval process involving the Commercial Hazardous Waste Management Facility Siting Board under W.Va. Code §§22C-5-1 et seq. as well as the potential for additional public participation provided for by W.Va. Code §§22C-6-1 et seq. providing for a public referendum on commercial hazardous waste facilities. The one-year time frame in the Committee's amendment could be interpreted to "trigger" from one of the preliminary public notice periods, thus shortcutting the entire process, or, worse, could force a direct conflict with a public referendum decision provided for by statute.

Even if the amending language is interpreted to "trigger" from the last public comment period, there may well be times when, depending upon the significance of public comment and that of EPA's, one year would not be adequate to process a permit due to the necessity of requiring the facility to submit more information or conduct additional testing. The reason for this is, again, due to the complexity of the hazardous waste incineration process and the need to receive and interpret more information or conduct additional testing.

In addition to a permit being issued which does not fully comply with the statutory and regulatory requirements, a second unintended consequence of the Committee's amendment is the reviewing agency may determine the permit should be denied, since there is inadequate information to support the permit and the agency is required to act within a prescribed period of time. This result would not necessarily occur if the agency and facility had more time to generate and review the information deemed necessary.

One more important point is that in addition to creating an inconsistency between the federal program and the State program, the amendment creates a conflict in the respective rules of OWM and OAQ, since the OWM's rules as approved previously by the Committee do not contain a one-year time frame. Since both permits are necessary for a facility to begin construction or operation, a time frame imposed on one of the two offices will not necessarily authorize a facility to commence construction or operation of the proposed activity.

Lastly, we would note W.Va. Code § 22-1-3a requires the agency when it promulgates rules to be consistent and equivalent to any counterpart federal program, unless there are extenuating circumstances and the agency makes a specific written finding to that effect. The OAQ does not believe there are such circumstances in this case. To the best of our knowledge, the State's hazardous waste facilities have not had to wait inordinate periods of time to obtain permits from either the OWM or the OAQ.

For the above-stated reasons, we respectfully request the Committee to reconsider its action and to approve the rule with the technical modifications filed with the Secretary of State and the Committee on January 5, 1999. However, as an alternative to striking the entire amending language, we would suggest the amending language state as follows:

The final permit decision shall be issued within one year of closing of the final public comment period unless public comments or other information regarding the construction or operating parameters of the facility to be permitted indicate that additional testing or information is necessary before a final permit can be approved and that the review of the testing or information cannot be completed within the one-year period.

We appreciate the Committee's consideration in this matter. If you have any questions or need additional information, please contact me at (304) 558-4022 or Karen G. Watson, counsel to the OAQ, at (304) 558-4274.

Sincerely,

Edward L. Kropp
Chief

cc: Joe Altizer, Counsel



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1660 Arch Street
Philadelphia, Pennsylvania 19103-2029

JAN 08 1999

John H. Johnston, Chief
Office of Air Quality
WV Division of Environmental Protection
1558 Washington Street, East
Charleston, WV 25311-2599

Honorable Michael Ross, Co-Chair
Legislative Rule-Making Review Committee
Room MB49-State Capitol
Charleston, WV 25305

Honorable Mark Hunt, Co-Chair
Legislative Rule-Making Review Committee
Room MB49-State Capitol
Charleston, WV 25305

Re: Title 45 Legislative Rule,
Division of Environmental Protection
Office of Air Quality
Series 25

Dear Gentlemen:

During the past few years the Environmental Protection Agency, Region III has been working closely with the West Virginia Office of Waste Management (EPA's Lead State Agency for the Hazardous Waste Program), the Office of Air Quality, and other State Agencies to update the State's hazardous waste regulations and make them equivalent to the federal regulations. Some of these State agencies are in the midst of seeking Legislative approval of these regulatory revisions. EPA has been informed that the Legislative Rule-Making Review Committee is recommending that language be added to the proposed rule for the Office of Air Quality which would ensure that draft permits be processed within a year of the close of the public comment period, and if not issued as final permits within a year, such draft permits would automatically be considered approved and final.

Customer Service Hotline: 1-800-438-2474

EPA believes that such provisions would jeopardize EPA's ability to authorize West Virginia's Hazardous Waste regulations. Although EPA does not have any problem with the concept of establishing timeframes for agency action on permit decisions, the one-year time frame being proposed is inconsistent with the federal regulations in the following areas.

(1) With respect to new permits and Class 1 & 3 type permit modifications, there are no federal time limits for permit approval placed on the reviewing agency. EPA's concern is that there is a potential to issue a permit that is not fully responsive to public comments, because there could be times when the Division would need more than one year to adequately review comments received on a draft permit. In addition, the one-year time frame would not necessarily benefit the regulated community because if the Director believes a permit is not ready for issuance upon approaching the one-year deadline, his/her only recourse would be to deny the permit.

(2) The one-year time frame is inconsistent with a 90-day time frame set in EPA regulations for certain types of permit modifications (see 40 CFR 270.42(b)). At 40 CFR 42(b)(1)(I), the federal regulations require that the Director must approve or deny the request no later than 90 days after receipt of the notification request. EPA regulations (which West Virginia is proposing to adopt) go on to address other administrative options beyond the 90-day period. However, the proposed one-year time frame is less stringent than the Federal requirement for a 90-day Director's decision on Class 2 permit modifications.

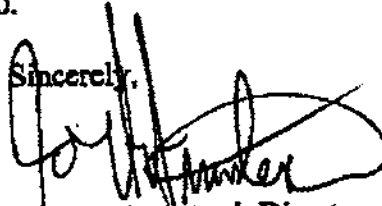
In addition, and as a general policy, EPA cannot authorize a program which includes an approval process by default. That would be inconsistent with our requirements for public participation at 40 CFR 271.14, 124.11, 124.17 (a) and (c) which provides that the public's comments be considered by the Director when issuing a final permit decision. It is our opinion that any permit which is "considered approved" due to inaction by the Director would not comply with these requirements.

Finally, EPA believes that the Office of Waste Management's permitting regulations, which pattern EPA procedures and have been approved by the Legislative Review Committee, would govern the permitting process. Those regulations do not have the one year time frame or "default approval" possibility. Consequently, EPA believes that even if the Air regulations are changed to include the additional language, there would be no real benefit since similar time frames are not reflected in the Waste regulations and a waste permit is essential to activate regulated waste activities at the facility.

3

I want to emphasize that much time and effort have been expended by the Office of Waste Management and the Office of Air Quality, as well as EPA, to develop WV regulatory revisions that would advance EPA authorization of WV's Hazardous Waste Program. I strongly suggest that the proposed changes to the Office of Air Quality regulations not be made. Thank you for your consideration in this matter. If you would like to discuss this further with me, please do not hesitate to contact me at 215-814-3110.

Sincerely,



John A. Armistead, Director
Waste and Chemicals Management Division

cc: Joe Altizer, Counsel to Legislative Rule-Making Review Committee
Karen G. Watson, Counsel to Office of Air Quality

TENTATIVE AGENDA
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
Sunday, January 10, 1999
2 - 4 p.m.
Senate Finance Committee Room M-451

1. **Approval of Minutes** - Meetings of December 13, 15 and 16, 1998
2. **Review of Legislative Rules:**

- Approved as modified* Division of Health
Reportable Diseases, Events and Conditions, 64CSR7
- Approved as modified* Division of Health
Medication Administration by Unlicensed Personnel, 64CSR60
- Approved as modified & amended* Tax Commissioner
Valuation of Public Utility Property for Ad Valore Tax Purposes, 110CSR1M
- Foot of the agenda* Department of Tax and Revenue
Registration of Telemarketers, 119CSR301
- Approved as modified* Air Quality, Office of
Ambient Air Quality Standards for Sulfur Oxides and Particulate Matter, 45CSR8
- Approved as modified* Mining & Reclamation, Office of
WV Surface Mining and Reclamation Rule, 38CSR2
- Approved as modified* Water Resources, Office of
Pollution Prevention and Compliance Assistance Rule, 47CSR3
- Approved as modified* Family Protection Services Board
Licensure of Domestic Violence Perpetrator Intervention Programs, 191CSR2

3. **Other Business.**

Reconsideration 45 CSR 25

Sunday, January 10, 1999

2:00 - 4:00 p.m.

Legislative Rule-Making Review Committee
(Code §29A-3-10)

Senate Finance Room

Earl Ray Tomblin, ex
officio nonvoting member

Robert S. Kiss, ex
officio nonvoting member

Senate
✓ Ross, Chair
✓ Anderson, Vice Chair
Bowman
Macnaughtan
✓ Boley
Buckalew

House
✓ Hunt, Chair
✓ Linch, Vice Chair
Compton
✓ Jenkins
✓ Faircloth
✓ Riggs

Minutes Dec 13, 15, 16 approved

Tax - Telemarketing

Sam Cipoletti, Bell Atlantic addressed the C

Dale Staeger, Tax addressed the C & responded

to q's
Approve rule v. as mod? adopted

Ross
adopted

Doss
adopted

Move rule to foot of the agenda

Health - Reportable Diseases

Approve as mod

Randy Cox, addressed the C

Loretta Haddy, DOT responded to q's

Larry Arnold, Counsel DOT addressed the C

Modify § 9 to provide that copies of rules
are to be distributed by licensing board or
agencies.

Ross
adopted

Jenkins
adopted

● Dott - Medication

Rita explained - responded to q's
Ross
Adopted Approve as mod

Ross Tax - Public Utility

Approve w/tech mod

Jerry Knight addressed the C
Charlie Lorenson ^{r rep public utilities} addressed the C

Jenkins Remove all technical mods

Call Jerry Knight
& have him sd
w/tech mod not
related to Motor
Caract.

● Air Quality - Ambient Air

Joe explained
Ross
Adopted Approve as mod

Ross Mining and Reclamation - Surface Mining

Joe explained
Approve as mod. Act

Ross Water Resources - Pollution

Joe explained
Approve as mod

● Family Protection - Licensure

Rita explained
Ross Approved as modified

45 CSR 25

Lynch
adopted
Boley
adopted

Reconsider its action whereby it amended rule
Karen Watson addressed the C & responded to q
Foot of Tues agenda

~~Agri~~

Faircloth

Agriculture - Eggs

Request Agri be here to respond to q & discuss
fed regs

REGISTRATION OF PUBLIC
AT
COMMITTEE MEETINGS
WEST VIRGINIA LEGISLATURE

Committee: Legislative Rule-Making Review Committee Date 1-10-99
Please print or write plainly.

NAME	ADDRESS	REPRESENTING	Please check (X) if you desire to make a statement.

JANUARY 12

TENTATIVE AGENDA
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
Tuesday, January 12, 1999
9 - 11 a.m.
Senate Finance Committee Room M-451

1. Review of Legislative Rules:

- a. **Department of Tax and Revenue**
Registration of Telemarketers, 119CSR301
- b. **Division of Health**
Emergency Medical Services, 64CSR48
- c. **Division of Health**
Behavioral Health Client Rights, 64CSR59
- d. **Division of Health**
Behavioral Health Consumer Rights, 64CSR74
- e. **West Virginia Board of Pharmacy**
Rules of the Board of Pharmacy, 15CSR1
- j. **Office of Air Quality**
To Prevent and Control Air Pollution from Hazardous Waste Treatment, Storage, or Disposal Facilities, 45CSR25
- f. **Division of Health**
Public Water Systems Capacity Development, 64CSR61
- g. **Division of Health**
Infectious Medical Waste, 64CSR56
- h. **Division of Health**
Benchmarking and Discount Contract Rule, 65CSR26
- i. **Accountancy, Board of**
Board Rules and Rules of Professional Conduct, 1CSR1

2. **Other Business**

- a. Direct the staff to prepare and submit the Committee's report and a bill of authorization for each rule contained in the report.
- b. Designate bill sponsors.
- c. **West Virginia Department of Agriculture**
Marketing of Eggs Regulations, 61CSR7A

January 12, 1999

9 a.m. - 11 a.m.

Legislative Rule-Making Review Committee
(Code §29A-3-10)

Earl Ray Tomblin
ex officio nonvoting member

Robert "Bob" Kiss
ex officio nonvoting member

Senate

Ross, Chairman
Anderson, Vice Chairman
Boley
Bowman
Buckalew (Absent)
Macnaughtan (Absent)

House

Hunt, Chairman (Absent)
Linch, Vice Chairman
Compton (Absent)
Faircloth
Jenkins
Riggs

The meeting was called to order by Mr. Ross, Co-Chairman.

Debra Graham, Committee Counsel, explained the rule proposed by the *West Virginia Board of Pharmacy-Rules of the Board of Pharmacy, 15CSRI*, and stated that the Board has agreed to technical modifications. Richard Stevens, West Virginia Pharmacists Association, and Doug Douglass, Executive Director of the Board, responded to questions from the Committee.

Debra Graham distributed a list of proposed modifications submitted by the Board to the Committee members.

Mr. Anderson moved that the Board's proposed modifications and technical modifications be approved. The motion was adopted.

Mr. Riggs moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Graham stated that the rule proposed by the *Department of Tax and Revenue-Registration of Telemarketers, 119CSRI*, had been placed at the foot of the agenda at the Committee's last meeting. She distributed a copy of the proposed modified rule submitted by the Department to the Committee.

Mr. Anderson moved that the proposed modifications be approved. The motion was adopted.

Mr. Anderson moved that the proposed rule be approved as modified. The motion was adopted.

Joseph Altizer, Associate Counsel, explained the rule proposed by the *Division of Health-Emergency Medical Services, 64CSR48*, and stated that the Division has agreed to technical modifications. Mark King, Director of Emergency Medical Services, and Kelly Blackwell, Chief of the Bridgeport Fire Department, addressed the Committee and responded to questions.

Mr. Linch moved that the proposed rule be moved to the foot of the agenda. The motion was adopted.

Rita Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the *Division of Health-Behavioral Health Consumer Rights, 64CSR74*, stated that the Division has agreed to technical modifications and responded to questions.

Mr. Anderson moved that the proposed rule be approved as modified. The motions was adopted.

Mr. Altizer reminded the Committee that the rule proposed by the *DEP, Office of Air Quality-To Prevent and Control Air Pollution From Hazardous Waste Treatment, Storage or Disposal Facilities, 45CSR25*, had been reconsidered and moved to the foot of the agenda at the January 10, 1999, meeting with technical modifications and an amendment pending. Karen Watson, counsel for the Office of Air Quality, responded to questions from the Committee.

Mr. Linch moved that the Committee reconsider its action whereby it adopted an amendment to paragraph 5.12.1.c of the proposed rule at the December 16, 1998, meeting. The motion was adopted.

Mr. Anderson moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Ross told the Committee that he had just been handed a letter withdrawing the rule proposed by the *Division of Health-Behavioral Client Rights, 64CSR59*.

Having voted on the prevailing side, Mr. Anderson moved that the Committee reconsider its action whereby it approved, as modified, the rule proposed by the *Division of Health-Behavioral Health Consumer Rights, 64CSR74*. The motion was adopted.

Mr. Anderson moved that the rule be moved to the foot of the agenda. The motion was adopted.

Ms. Graham explained the rule proposed by the *Division of Health-Public Water Systems Capacity Development, 64CSR61*, and stated that the Division has agreed to technical modifications.

Mr. Anderson moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley reviewed her abstract on the rule proposed by the *Division of Health-Infectious Medical Waste, 64CSR56*, and stated that the Division has agreed to technical modifications.

Mr. Anderson moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Ross stated that the rule proposed by the *Division of Health-Emergency Medical Services, 64CSR48*, would be next. Mr. Blackwell and Mr. King addressed the Committee and responded to questions.

Mr. Anderson moved that the Committee request that the Division withdraw the proposed rule be withdrawn by the agency. The motion was adopted.

Ms. Graham explained the rule proposed by the *Health Care Authority-Benchmarking and Discount Contract Rule, 65CSR26*, and stated that the Health Care Authority has agreed to technical modifications.

Mr. Bowman moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Graham reviewed her abstract on the rule proposed by the *Board of Accountancy-Board Rules and Rules of Professional Conduct, ICSRI*, and stated that she had not been contacted by the Board regarding the technical modifications. Barry Kerber, Assistant Attorney General representing the Board, stated that the Board agrees to the technical modifications.

Mr. Faircloth moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Linch moved that the Committee direct its staff to prepare the Committee's report and submit to the clerk of each House; ~~And that the staff~~ draft a bill of authorization for each rule contained in the report, and ~~that the staff~~ cause the bills to be introduced in each House with the members of the Committee as sponsors.

Mr. Faircloth told the Committee that he intends to continue working with the Department of Agriculture on the rule proposed by the Department, *Marketing of Eggs Regulations, 61CSR7A*.

Mr. Anderson told members of the Committee that any outstanding issues regarding the rule proposed by the *Division of Health-Behavioral Health Consumer Rights, 64CSR74* would be worked out in the Standing Committees.

Mr. Anderson moved that the proposed rule be approved as modified. The motion was adopted.

The meeting was adjourned.

JANUARY INTERIM SCHEDULE
Legislative Interim Meetings
January 10, 11, and 12, 1998

Tuesday, January 12, 1999

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Robert S. Kiss, ex
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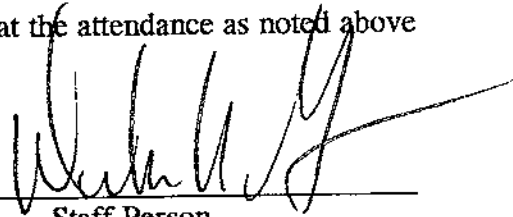
Senate

Ross, Chair ✓
Anderson, Vice Chair ✓
Bowman ✓
Macnaughtan ✓
Boley ✓
Buckalew _____

House

Hunt, Chair _____
Linch, Vice Chair ✓
Compton _____
Jenkins ✓
Faircloth ✓
Riggs ✓

I certify that the attendance as noted above
is correct.



Staff Person

Debra

TO: MIKE

FROM: DOUGLAS ISAAC

DATE: PAGES INCLUDING THIS PAGE

FAX #: 720-4034

FAX #:

PHONE #: 720-2506 13

TOPS 448

4 683

Rules and Regulations

James Campbell - Director Regulatory Div.

Federal Register

Vol. 83, No. 166

Thursday, August 27, 1998

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

7 CFR Part 58

[Docket No. 87-069F]

RIN 0583-AC04

Refrigeration and Labeling Requirements for Shell Eggs

AGENCY: Food Safety and Inspection Service.

ACTION: Final rule and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is revising its regulations governing the inspection of eggs and egg products to implement 1991 amendments to the Egg Products Inspection Act (EPIA). These amendments require that shell eggs packed for consumer use be stored and transported under refrigeration at an ambient temperature not to exceed 45°F (7.2°C). In addition, the amendments require that these packed shell eggs be labeled to state that refrigeration is required. Finally, the amendments require that any shell eggs imported into the United States packed for consumer use include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F (7.2°C).

DATES: *Effective Date:* The effective date of the final rule is August 27, 1999.

Comment Date: As noted below, the proposed rule concerning refrigeration and labeling requirements for shell eggs was published on October 27, 1992. Because the proposed rule was published approximately six years ago, FSIS is requesting comments on this final rule. FSIS requests comments on the economic impact analysis in these regulations and on options for monitoring compliance with the

refrigeration and labeling requirements. Comments must be received on or before October 26, 1998.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket #97-069F, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. Reference material cited in the document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia F. Stofa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205-0699.

SUPPLEMENTARY INFORMATION:

Background

In 1991, as part of the Food, Agriculture, Conservation and Trade Act Amendments of 1991 (Pub.L. 102-237) (hereafter referred to as "the 1991 EPIA amendments"), Congress amended the EPIA to require that egg handlers store and transport shell eggs destined for the ultimate consumer under refrigeration at an ambient temperature of no greater than 45°F (7.2°C) (21 U.S.C. 1034(e)(1)(A)). (See also 21 U.S.C. 1037(c)). The 1991 EPIA amendments specify that these refrigeration requirements apply to shell eggs after they have been packed into a container destined for the ultimate consumer. The 1991 EPIA amendments also require that egg handlers label the shell egg containers to indicate that refrigeration is required (21 U.S.C. 1034(e)(1)(B)). In addition, these amendments require that any eggs packed into a container destined for the ultimate consumer and imported into the United States include a certification that the eggs have, at all times after packaging, been stored and transported at an ambient temperature that is no greater than 45°F (7.2°C) (21 U.S.C. 1046(a)). The 1991 EPIA amendments specify that these requirements become effective 12 months after promulgation of final regulations implementing the EPIA amendments (21 U.S.C. 1034 note). The Agricultural Marketing Service (AMS) proposed a rule in 1992 to implement the 1991 EPIA amendments (57 FR 48559, October 27, 1992); however, AMS never published a final rule incorporating these amendments

into the regulations governing the inspection of eggs and egg products. Following enactment of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub.L. 103-354; 7 U.S.C. 2201e), food safety issues were consolidated in FSIS. Because these statutorily mandated requirements are intended to improve food safety, FSIS, rather than AMS, is promulgating this final rule to revise the regulations governing the inspection of eggs and egg products to implement the 1991 EPIA amendments. By January 1, 1999, FSIS and AMS will publish revisions to the regulations transferring the provisions concerning refrigeration and labeling of shell eggs from 7 CFR, Chapter I, to 9 CFR, Chapter III, so that these provisions will be in the same title as the Federal meat and poultry products inspection regulations.

The 1998 Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (1998 Appropriations) (Pub.L. 105-86) provides that \$5 million of FSIS' annual appropriation will be available for obligation only after the Agency promulgates a final rule to implement the refrigeration and labeling requirements included in the 1991 EPIA amendments. The Agency is thus revising its regulations to implement these requirements. FSIS is adopting the proposed regulations published in 1992 concerning refrigeration and labeling of shell eggs with some technical changes based on its review of the proposed rule and the comments on that proposal.

In addition to the refrigeration and labeling requirements, AMS's proposed rule included revisions to 7 CFR Part 58, Grading of Shell Eggs and U.S. Standards, Grades, and Weight Classes for shell eggs. FSIS is publishing this final rule on the refrigeration and labeling requirements but is not revising part 58.

Under the 1991 EPIA amendments, USDA is responsible for enforcing the refrigeration and labeling requirements at storage facilities and transport vehicles of shell egg packers (21 U.S.C. 1034(e)(1) and (2)). The Secretary of Health and Human Services is responsible for enforcing the labeling and refrigeration requirements at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs (21 U.S.C. 1034(e)(3)).

On May 19, 1998 (63 FR 27502), FSIS and the Food and Drug Administration (FDA) published an advance notice of proposed rulemaking (ANPR) concerning *Salmonella enteritidis* (SE) in eggs. Through this notice, the Agencies are seeking to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs. The ANPR may result in additional Agency actions concerning shell eggs. Although this final rule may bring about a small reduction in SE risk, it does not address many of the underlying food safety problems posed by eggs. These problems can only be dealt with in the context of a broader process that examines a variety of food safety issues in addition to ambient air temperatures. Through the ANPR, FSIS and FDA are looking at how best to address the food safety concerns of shell eggs as part of their mutual farm-to-table HACCP strategy. Any additional actions that may result from this process will be considered in light of identified public health risks and available alternatives.

On June 12, 1998, FSIS completed a risk assessment concerning SE in shell eggs and egg products in response to an increasing number of human illnesses associated with consumption of shell eggs (FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998). The objectives of this risk assessment are to: establish the unmitigated risk of foodborne illness from SE, identify and evaluate potential risk reduction strategies, identify data needs, and prioritize future data collection efforts. This risk assessment developed a model to assess risk throughout the egg and egg products continuum. The risk assessment model was used to estimate the possible benefits of this rule, as discussed below.

Comments

One hundred and fifty-nine comments were submitted in response to the proposed rule. Thirty-one commenters, including private citizens, State departments of agriculture, several trade associations, and several members of the egg industry, supported the proposal. The remainder of commenters opposed the proposed rule or suggested alternatives to it. Commenters opposed to the rule included private citizens, trade associations, and members of the egg industry. The majority of comments from the egg industry opposed the rule and suggested alternatives to it. Six comments were received after the close of the comment period. All of these comments were generally opposed to the proposed rule.

Size of Establishments Required to Comply With the Rule

Several small producers recommended exempting from the refrigeration and labeling requirements producers with flocks of 5,000, 10,000, or 50,000 hens, or exempting producers that marketed a specified number of cases of eggs or a specified number of eggs per week, such as 500 cases per week or 1,200 eggs per week. These producers wanted an exemption from the refrigeration requirements because, they stated, the high costs of complying with the refrigeration requirements would effectively force them out of business. In contrast to these comments from small producers, several other producers and several associations stated that all egg industry members should be treated equally, and that no producers should be exempt from the refrigeration and labeling requirements.

Several commenters stated that they had flocks of less than 3,000 layers but packed eggs from other producers. These commenters asked whether the refrigeration and labeling requirements would apply to them.

Consistent with current regulations that exempt from inspection egg handlers with flocks of 3,000 or fewer birds (see § 59.100), the 1991 EPIA amendments specify that any egg handler with a flock of 3,000 layers or less is not subject to inspection for purposes of verifying compliance with the refrigeration and labeling requirements (21 U.S.C. 1034(e)(4)). Given this consistency, FSIS is responding to Congress's clear intent and limiting the exemption from the refrigeration and labeling requirements in § 59.50 to egg handlers with flocks of 3,000 or fewer layers (§ 59.50(c)).

In response to the comments suggesting that the refrigeration and labeling requirements should apply to all producers, the Agency points out that the statute provides that the refrigeration and labeling requirements in the 1991 EPIA amendments are not applicable to any egg handler with a flock of 3,000 or fewer layers. FSIS concludes that, for clarity, it is appropriate to reflect this fact in its regulations with an exemption.

Egg packers who obtain eggs from other producers will not be exempt from the refrigeration and labeling requirements. The exemption will only apply to egg handlers with a flock of 3,000 or fewer layers who pack eggs from their own flock. This exemption is consistent with the exemption from registration requirements for producer-packers with an annual egg production

from a flock of 3,000 hens or less (see § 59.690).

Costs of the Rule

Approximately half the commenters stated that the rule would impose major costs on the industry. Many small businesses stated that the compliance costs associated with this rule could force them out of business.

Several commenters stated that they believed that the cost estimates in the 1992 proposed rule were too low and provided their own cost projections. For example, one small producer stated that it would cost its family-owned business approximately \$200,000 to comply with the requirements. One association that represents the poultry, egg, and allied industry received information from its members on the price of refrigerated trucks: One member estimated that a new 26 foot refrigerated tractor trailer would cost \$92,000, and another producer stated that a used refrigerated trailer portion costs \$25,000. The association stated that, on the basis of this information, the cost of replacing and modifying the industry's fleet might exceed the estimates made by the Department.

In addition, several commenters stated that costs would be particularly high because at the time the proposed rule was published, the Environmental Protection Agency (EPA) was revising laws concerning refrigerants. These commenters believed that, subsequent to purchasing new refrigeration equipment to comply with the 45° refrigeration requirements, they would again be required to replace refrigeration equipment once the new EPA law regarding refrigerants went into effect.

Five members of the industry stated that the proposed rule would be extremely costly to the entire shell egg industry. These commenters stated that the cost analysis included in the 1992 proposed rule ignored major costs such as new higher powered refrigeration units for both warehouses and vehicles, greater insulation requirements for warehouses and vehicles, ongoing depreciation expenses per year on the new refrigeration equipment, replacement costs of new equipment after its useful life, yearly maintenance costs, much higher ongoing yearly energy costs required for higher powered refrigeration units, and the effects of inflation. These commenters stated that compliance costs would outweigh any benefits of reducing cases of salmonellosis. In addition, these commenters stated that the increased compliance costs would force smaller producers and smaller distributors out of business, resulting in layoffs and

higher rates of unemployment. In addition, they stated that the higher cost of compliance would result in higher consumer prices for eggs.

The same five commenters discussed in the preceding paragraph stated that the requirements for imported eggs could also have a negative impact on international trade. These commenters stated that food products prepared with shell eggs abroad may not meet the U.S. refrigeration requirements for shell egg production. Thus, they maintained, the refrigeration requirements would lead to restrictions on imports of foreign food items prepared with shell eggs if refrigeration requirements in a particular country did not meet U.S. standards.

Finally, one association suggested costs to the industry might increase because of increased taxes on energy consumption.

Although the Agency agrees this rule is likely to result in an increase in costs to the industry, the 1991 EPIA amendments and the 1998 Appropriations require that FSIS promulgate this final rule. The Agency's current cost impact analysis is discussed below, under the heading, "Incremental Social Costs." The original analysis of the costs of the regulation was conducted in 1992. The current analysis updates the 1992 cost estimates for inflation and changes in the State regulatory environment. The comments submitted in response to the analysis in the proposed rule were based on 1992 costs. For these reasons, the Agency is providing opportunity for comment on the updated economic impact analysis.

In the discussion of the cost to the industry, the Agency notes that many States already have enacted laws that require ambient temperatures of 45°F for shell egg storage and transportation. As explained below, producers in these States may not incur any significant costs as a result of this rule. In the other States, there is likely to be some increase in costs to the industry.

In regard to EPA laws concerning refrigerants, FSIS notes that those laws are in effect. At this time, the industry will have met these EPA requirements. Therefore, these regulations will not affect industry compliance with EPA requirements.

In response to the comments on international trade, it should be noted that the requirements in these regulations apply to imported shell eggs that are not imported under disease restriction and are destined for the ultimate consumer. The requirements do not apply to other imported processed food products containing eggs.

Finally, with regard to costs that may be imposed due to taxes on energy consumed, no significant new taxes have been imposed based on energy consumed.

Transportation

Many comments from members of the egg industry concerned problems with complying with the proposed transportation requirements. Some commenters stated that the cost of complying with the transportation requirements would be extremely high for them. Others stated that maintaining 45°F during transportation would not be possible. For example, one company stated that its trucks average sixteen deliveries per load, and, in certain situations, the truck doors remain open for ten to fifteen minutes during delivery. Therefore, the company explained, on a warm day, it is impossible to maintain the 45°F temperature in the truck. Another commenter stated that producers servicing family-owned markets and restaurants use a truck with less than one ton capacity, and that a truck of this size is not made with a refrigeration unit with enough cooling capacity to maintain 45°F. One association explained that many of its members believed that the constant opening and closing of the truck's storage compartment during local deliveries would prevent the truck from reaching an ambient temperature of 45°F.

About 20 commenters offered a variety of alternative options for exempting small producers from the requirement that shell eggs remain refrigerated during transportation. These alternative options included exempting from refrigeration requirements eggs delivered within a certain radius of the packing facility, eggs delivered in a certain size truck, and eggs delivered within a certain specified delivery time.

The specific requirement of the 1991 EPIA amendments is that shell eggs be refrigerated at 45°F during transportation. Other than the exemption for egg handlers with 3,000 or fewer layers, the statute does not provide any exemptions from the requirement that shell eggs be refrigerated during transportation. Therefore, the Agency has no discretion concerning this requirement and is not making the changes in the regulations that were requested by the commenters.

Alternative Temperature Requirements

About 15 commenters suggested that eggs should be held at temperatures above 45°F, such as 50°F, 55°F, or 60°F. One commenter noted that the current voluntary grading program regulations

require that eggs be kept at 60°F, and that a change to 45°F would be a significant change. Several commenters stated that refrigerating eggs at 45°F would cause them to "sweat" when they are exposed to non-refrigerated conditions. These commenters stated that wet eggs can allow the passage of waterborne bacteria into the egg.

Several commenters offered suggestions for additional refrigeration requirements. One member of the industry suggested that the rule might be enhanced if it specified the time allowed for the shell eggs to reach an internal temperature of 45°F. Several other commenters recommended establishing refrigeration requirements that would apply to eggs prior to packing. For example, one State department of agriculture suggested that shell eggs should be refrigerated at 55°F or lower, within 24 hours of being laid, until the egg is washed and packed.

The statute specifically requires that eggs packed for consumer use be stored and transported at 45°F. Therefore, the Agency has no discretion concerning the required temperature.

In response to the suggestions concerning additional refrigeration requirements, the 1991 EPIA amendments do not specify requirements concerning the internal temperature of eggs or an ambient temperature requirement for eggs that are not yet packed. However, these actions may be considered as part of the review that flows from the joint FSIS/FDA ANPR. FSIS or FDA may take further action in response to these comments at a later time.

Benefits of the Regulation

Approximately 50 commenters questioned whether this regulation would result in any health benefits. Commenters stated that safety problems related to eggs are caused by inadequate food preparation in restaurants and hotels, and that refrigeration by the producer will not remedy this problem. Similarly, several commenters noted that problems often arise because of mishandling by the consumer. Other commenters stated that the Agency should focus efforts on specific egg production establishments or particular regions where *Salmonella* has been detected.

Five comments from members of the shell egg industry stated that there was inadequate scientific evidence to justify the proposal, and that available studies show that relatively few salmonellosis cases can be attributed directly to shell eggs. Therefore, these commenters asserted, there is a need for more complete epidemiological studies and

documentation of actual salmonellosis cases that are directly linked to inadequate refrigeration of shell eggs held by producers and distributors. These commenters noted that studies show no growth of SE in eggs with an internal temperature of 45 °F; however, the commenters explained that the internal temperature of eggs will not reach 45 °F as soon as they are stored under refrigeration. They also argued that packed eggs may never reach this temperature throughout the distribution process. Similarly, another commenter stated that commercial processing plants will be unable to bring eggs to 45 °F before they are transported, especially when they are packed in cartons, cased, and stacked on pallets. This commenter also questioned whether the ambient temperature refrigeration requirements would improve the safety of shell eggs.

In contrast, several commenters stated that they believed that these regulations would improve the safety of shell eggs. For example, one medical association stated that existing scientific evidence provides a sufficient basis for requiring that shell eggs be stored and transported in refrigerated trucks at an ambient temperature of 45 °F, and that this refrigeration requirement would control the replication of SE. This commenter stated that, once the rule is effective, reported cases of SE in humans will be markedly reduced. An epidemiologist employed by a Federal agency stated that most human outbreaks of SE in which shell eggs were the probable source could have been prevented if time and temperature abuse had not taken place.

Although there is no consensus concerning the level of health benefits these regulations may achieve, the 1991 EPIA amendments and the 1998 Appropriations require that FSIS promulgate this final rule.

In response to concerns regarding food safety problems because of mishandling of eggs at retail establishments, FDA may propose a rule addressing refrigeration of eggs at retail, as discussed in the ANPR.

With regard to public education efforts, the Food Safety Education and Communications Staff within FSIS provides information to the public concerning numerous food safety issues, including egg-related food safety issues. This office provides food safety education information through USDA's Toll-Free Meat and Poultry Hotline (1-800-535-4555), through public service announcements, printed materials, and a variety of communication channels. In addition, FSIS makes this information

available over the Internet (URL: <http://www.fsis.usda.gov/>)

Finally, as noted under the heading, "Incremental Social Benefits," the Agency has estimated that these regulations would result in a mean reduction of 1.54 percent in salmonellosis cases related to SE in shell eggs. To estimate the reduction of the number of salmonellosis cases that would result from the implementation of these regulations, FSIS's risk-assessment model, discussed below, was adjusted so that all eggs were exposed to ambient temperatures of 45 °F or lower after packing. The risk assessment predicts that additional measures would result in greater benefits than would result from the ambient temperature requirements in this rule. For example, the risk assessment predicts that maintaining ambient temperatures of 45 °F throughout processing and distribution (that is, from processing through retail) will result in an eight percent average reduction in human SE illnesses. In addition, the risk assessment model predicts that maintaining internal temperatures of eggs at 45 °F would result in a twelve percent decrease in human SE illnesses (FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998: 26-27). The Agency recognizes that requiring an internal shell egg temperature of 45 °F (7.2 °C) would result in greater benefits than an ambient temperature requirement; however, the statute provides for an ambient temperature requirement only, and any such additional requirement will have to be considered in response to the ANPR.

Labeling Requirements

Approximately 30 commenters were opposed to the labeling requirements. Some of the commenters mistakenly believed "warning labels" would be required. Others stated that the labeling provisions were unnecessary because they believed consumers know that eggs should be refrigerated. Finally, many of these commenters believed the labeling requirements would be costly for producers, and that increased costs would be incurred by consumers.

Several commenters who supported the labeling requirements suggested requiring additional information on egg containers, such as a "pull date" or expiration date; a statement identifying the flock that produced the eggs in the container; the phrase, "keep refrigerated at 45°F or below"; and the packing date and the packing plant number.

Three comments were from companies promoting time/temperature indicators. The companies explained

that these indicators are labels that act as temperature recording devices and change color to indicate the temperature at which the carton is held and the length of time the carton is held at particular temperature. These commenters suggested that time/temperature indicators should be affixed to egg cartons.

Establishments can meet the labeling requirements adopted in this rule (see §§ 59.50(b), 59.410(a), 59.950(a)(4) and 59.955(a)(6)) simply by including the phrase, "Keep Refrigerated," or words of similar meaning, on the egg containers. Therefore, the labeling provisions do not require a warning statement. The Agency has determined that adding this phrase to shell egg labeling will result in only minimal costs for producers that do not currently include this labeling on egg cartons. Furthermore, many producers are currently labeling egg cartons to indicate that the product should be kept refrigerated.

With regard to the recommendations for additional labeling requirements, the statute does not specify any additional labeling provisions, and the Agency is not including additional labeling requirements in these regulations.

Implementation Details

Several commenters questioned how the rule would be implemented and provided suggestions concerning methods for measuring the temperature in transportation vehicles and storage facilities. For example, several commenters questioned the particular location an inspector would use inside a cooler or a truck to obtain the ambient temperature. One commenter recommended that the temperature should be checked at least 10 minutes after all doors are closed. One commenter asked what would happen during a mechanical breakdown, and whether producers should use recording thermometers both in cooler rooms and trucks. One association suggested that inspection of coolers be handled on a case-by-case basis because, the association explained, no two coolers are alike, and their configurations and holding capacities differ. The association also recommended that cooler doors be closed for at least five minutes before temperature readings are taken, and that readings be taken at least three locations. This same commenter recommended that truck inspections be limited to trucks of property not being loaded, and that inspection of trucks occur before loading, with the door closed for at least five minutes and refrigeration equipment operating. Finally, this same commenter stated that when plants are

found to be out of compliance with the temperature regulations, consideration should be given for re-inspection within the annual quarter before a citation is issued.

Several commenters questioned the intent of proposed § 59.134(b). They were concerned that the provision stating that "the perimeter of each cooler room * * * shall be made accessible" would require that they create a walking aisle around the cooler room, or that the entire perimeter would need to be accessible for inspection. The commenters explained that to make the entire perimeter accessible to an inspector would result in reduced storage capacity and increased costs.

In response to the concerns about accessibility of the perimeter of the cooler room, the Agency advises that it does not intend that producers would be required to reduce storage space or create a walking aisle. The Agency is specifying that the perimeter must be accessible because it may often be the warmest area in the cooler, and because the center of the cooler room is typically accessible. An establishment could comply with the requirement that the perimeter of the cooler room be made accessible to inspectors by locating thermometers along the perimeter or allowing inspectors to use extension devices with attached thermometers to obtain the temperature along the perimeter.

The rule will not be effective until a year after the publication date. The Agency is currently considering various policy options for monitoring industry compliance with the rule. In response to the question concerning whether producers should use recording devices in cooler rooms and trucks, producers may install thermometric equipment and temperature recording devices; however, these regulations do not require that producers do so. FSIS requests comments on implementation of this rule.

Longer Phase-In Period

Several commenters recommended that the Department implement the rule over a phase-in period (two commenters suggested a three-year phase-in period), explaining that a phase-in period would provide producers adequate time to bring their equipment into compliance. Similarly, a small producer that expressed general support for the rule argued that the effective date for the final rule should be extended beyond a year from publication to allow the industry more time to meet the refrigeration requirements.

The EPIA specifies that the refrigeration and labeling requirements

become effective 12 months after promulgation of final regulations implementing the amendments (21 U.S.C. 1034 note). Therefore, the Agency does not have the authority to provide for an extended phase-in period.

Technical Suggestions

A State department of agriculture commented that the proposed definition of "immediate container" is confusing and recommended changing the phrase "not consumer packaged," as used in the proposed definition, to "not packaged by the consumer."

In response to the comment concerning the definition of "immediate container," the Agency points out that the phrase, "not consumer packaged" refers to eggs packed for a buyer, such as a restaurant or hotel, that buys containers of eggs larger than those for household consumers. This definition simply provides that an immediate container could be a carton for household consumers or a larger container for a restaurant or other institution. To clarify the definition, FSIS has revised it to read, "immediate container means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers."

One commenter questioned the intent of the provision in proposed § 59.132, which stated that "access shall not be refused at any reasonable time to any representative of the Secretary to any plant, place of business, or transport vehicle subject to inspection." This commenter suggested wording that would provide that access be provided to any representative of the Secretary at any time business operations are being conducted.

In § 59.132, as well as in § 59.760, FSIS has removed the phrase "at any reasonable time," which the commenter questioned, for greater consistency with the EPIA, which does not limit Agency access to establishments (see 21 U.S.C. 1034). FSIS is also making these changes for greater consistency with the Federal meat and poultry inspection regulations (see 9 CFR 381.32 and 9 CFR 306.2), which do not restrict Agency access to establishments.

The Final Rule

When these regulations become effective, egg handlers with flocks of more than 3,000 layers will be required to comply with the new refrigeration and labeling provisions. Consistent with current regulations that exempt from inspection egg handlers with flocks of 3,000 or fewer birds (see § 59.100), the 1991 EPIA amendments specify that any

egg handler with a flock of 3,000 layers or less is not subject to inspection for purposes of verifying compliance with the refrigeration and labeling requirements (21 U.S.C. 1034(e)(4)).

To monitor temperatures in storage rooms and transport vehicles, egg handlers with flocks of more than 3,000 layers may choose to install thermometric equipment and temperature recording devices; however, these regulations do not prescribe the means by which egg handlers are to comply with these provisions or to monitor their compliance. These regulations allow establishments the flexibility to determine how to meet the statutory requirements and how to monitor and ensure their compliance. U.S. Department of Agriculture (USDA) inspectors will verify that storage facilities and transport vehicles are refrigerated at or below 45°F (7.2°C).

In § 59.5, FSIS is adding new definitions to the regulations to reflect the terminology in the 1991 EPIA amendments. AMS proposed adding all of these definitions in the 1992 proposed rule. FSIS has added the term "ambient temperature," as used in the 1991 amendments, to clarify that the 45°F (7.2°C) refrigeration requirement refers to the air temperature maintained in a shell egg storage facility or transport vehicle.

The regulations include a definition for "ultimate consumer" that reflects how this term is used in the 1991 amendments. The Agency has defined the "ultimate consumer" as any household consumer, restaurant, institution or any other party who has purchased or received shell eggs or egg products for consumption. In 1992, AMS proposed to define this term as a household consumer, retail store, restaurant, institution, food manufacturer or other interested party who has purchased or received shell eggs or egg products for use or resale. After review of the proposed language, FSIS determined that an ultimate consumer should be defined as a party that purchases shell eggs or egg products for consumption, rather than for use or resale. Therefore, FSIS determined that a retail store or food manufacturer would not be considered an ultimate consumer and has modified the definition accordingly. The term "ultimate consumer" is used in the existing regulations, and each time it is used, examples of "ultimate consumers" follow the term. As was proposed, FSIS has revised §§ 59.28(a)(1) and 59.80 to remove these examples, because the term will now be included in the definitions section.

The 1991 EPIA amendments specifically refer to eggs that have been packed into a "container" and establish refrigeration requirements for shell eggs after packing (21 U.S.C 1037(c)). To implement these amendments, this final rule adds new language to the definition of "container or package" to refer to shell eggs in containers destined for the ultimate consumer. The current definition for "container or package" does not provide specific examples of a container or package for shell eggs. Therefore, as was proposed, FSIS has revised the definition of "container or package" to distinguish between containers for egg products and containers for shell eggs. In the definition of "immediate container", FSIS has modified the language proposed in 1992 to clarify that an immediate container means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers. The labeling requirements would apply to all types of containers (that is, both immediate containers and shipping containers).

As was proposed, FSIS has revised the definition of the term "egg handler" to clarify that the ultimate consumer is not considered an egg handler.

As was proposed in 1992, FSIS is incorporating the refrigeration and labeling requirements prescribed by the 1991 EPIA amendments for domestic shell eggs into its regulations by adding §§ 59.50 and 59.410(a). In these sections, FSIS has made only minor revisions to the provisions proposed in 1992. Section 59.410(a) provides that all shell eggs packed into containers destined for the ultimate consumer be labeled to indicate that refrigeration is required and includes an example of labeling that would meet this requirement, "Keep Refrigerated." The provision also allows establishments to use other words of similar meaning.

To reflect the fact that the 1991 amendments specify that egg handlers with flocks of 3,000 or fewer layers are not subject to inspection for purposes of verifying compliance with refrigeration and labeling requirements, § 59.50(c) includes new language that clarifies that producers-packers with a flock of this size are exempt from these refrigeration and labeling requirements.

As was proposed in 1992, FSIS is amending §§ 59.132, 59.134, and 59.760 to clarify that inspectors must be granted access to transport vehicles and cooler rooms to verify that any shell eggs packed into containers for the ultimate consumer are stored and transported at an ambient temperature of no greater than 45°F (7.2°C).

Transport vehicles that would be subject to inspection would include containers holding eggs that are attached to railroad cars or semi-trailer chassis.

As discussed above, FSIS has revised the provisions proposed in 1992 under §§ 59.132 and 59.760 to remove the phrase "at any reasonable time" for greater consistency with the EPIA and for greater consistency with the Federal meat and poultry inspection regulations.

FSIS has also revised the provision proposed in 1992 under § 59.760 to refer to representatives of the "Secretary" rather than representatives of the "Administrator." In the near future, FSIS intends to revise the current definition of "Administrator" in this part, which refers to the Administrator of AMS, to refer to the Administrator of FSIS. Because AMS retains surveillance activities under § 59.760, FSIS has revised this section to refer to representatives of the "Secretary" rather than representatives of the "Administrator." This revision reflects a change in Agency organization made in response to the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994.

As was proposed in 1992, FSIS has revised § 59.915 to incorporate the statutory amendment that imported shell eggs packed into containers destined for the ultimate consumer include a certification stating that the eggs have, at all times after packing, been stored and transported under refrigeration at an ambient temperature of no greater than 45°F (7.2°C). In addition, §§ 59.950 and 59.955 require that imported shell egg containers and imported egg shipping containers be labeled to indicate that refrigeration is required. In each of these sections, FSIS has made only minor changes to the language AMS proposed in 1992.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule. Public Law 102-237 provides that with respect to the temperature requirements contained therein, no State or local jurisdiction may impose temperature requirements pertaining to eggs packaged for the ultimate consumer which are in addition to, or different from, Federal requirements.

Executive Order 12868

FSIS is required to publish these regulations to comply with the 1991 EPIA amendments and the 1998

Appropriations. This rule has been designated significant and was reviewed by the Office of Management and Budget under Executive Order 12868. Executive Order 12868 requires USDOA to identify and, to the extent possible, quantify and monetize benefits and costs associated with the rule. This section estimates these benefits and costs. As discussed below, because of changes in State laws concerning the refrigeration of shell eggs, FSIS has changed the baseline that was used for determining costs in the 1992 proposed rule. If the Agency had used the original baseline, the estimated costs would have been higher than the estimates in this rule. In addition, the benefits in this rule are based on the recently completed SE risk assessment and data that were not available in 1992. The estimated annual benefits of this rule are lower than those estimated in 1992 (see FR 48572).

Incremental Social Benefits

The incremental social benefits of the rule are the avoidance of illnesses and deaths associated with consumption of eggs contaminated with SE. SE is a serotype of the family of pathogenic *Salmonella*. When the disease affects humans, it causes salmonellosis, which usually appears 6 to 72 hours after eating contaminated eggs and egg products and lasts up to 7 days. Symptoms of this disease include diarrhea, abdominal cramps, fever, nausea, and vomiting (nausea and vomiting develop in less than 50 percent of cases). Children, the elderly, and people with compromised immune systems are particularly vulnerable to SE infection. Deaths from SE disease occur in these vulnerable groups. Statistics of outbreaks reported to the Centers for Disease Control and Prevention (CDC) on foodborne diseases reveal that an increasing number of salmonellosis cases are associated with SE; however, it should be noted that the CDC actively contacts each State to obtain information concerning SE but does not actively contact the State for information on the other *Salmonella* serotypes.

From 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was identified (CDC, "Outbreak of *Salmonella enteritidis* Associated with Homemade Ice Cream—Florida, 1993," *Morbidity and Mortality Weekly Report* 43(36) (September 16, 1994): 669-671). The proportion of cases of salmonellosis reported to CDC attributable to SE increased from 1 percent in 1976 to 26 percent in 1994 (CDC, "Outbreaks of *Salmonella*

Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs—United States 1994–1995,” *Morbidity and Mortality Weekly Report* 45(34) (August 30, 1996): 737–742. In 1995 and 1996, salmonellosis cases attributable to SE represented about 25 percent of salmonellosis cases reported to the CDC. Preliminary data from the Foodborne Diseases Active Surveillance Network (FoodNet) indicate that SE represented 17% of all cases of *Salmonella* in 1996 (FSIS, FSIS/CDC/ FDA Sentinel Site Study: *The Establishment and Implementation of an Active Surveillance System for Bacterial Foodborne Diseases in the United States*, February 1997).

In the discussion below, FSIS assumes that SE cases associated with the consumption of eggs represent 25 percent of all human salmonellosis cases. This assumption is based on the percentage of SE cases reported to the CDC in recent years. FSIS is using this percentage rather than the 17 percent

based on FoodNet data because the FoodNet database is still being implemented and covers only Minnesota, Oregon, and counties in Connecticut, Georgia, and California. In addition, only the first year of data is available from the Foodnet. The CDC surveillance system has been active for approximately 30 years, all States contribute to the CDC surveillance data, and States receive incentives for submissions to the CDC surveillance system.

In 1996, 39,027 confirmed cases of human salmonellosis were reported to the CDC by State, local, and Federal departments of health. From 1985 through 1996, there have been 508,673 reported cases of salmonellosis (Centers for Disease Control and Prevention, *Laboratory Confirmed Salmonella, Surveillance Annual Summary, 1993–1995 and 1996*). Based on CDC outbreak data, the three illness-causing serotypes most frequently reported—*Salmonella typhimurium*, *Salmonella heidelberg*,

and *Salmonella enteritidis*—are most often traced to poultry and eggs when a food vehicle is found. A food vehicle is found in only about 25 to 30 percent of cases.

Since the reporting of outbreak statistics to CDC is voluntary, it is estimated that there are an additional 20 to 100 cases of salmonellosis for every reported case, or some 800,000 to 4 million cases per year (R. Chalker and M. Blaser, “A Review of Human Salmonellosis: III. Magnitude of *Salmonella* Infection in the United States,” *Review of Infectious Diseases* 10(1) (1988): 111–124). The severity of the underreported cases as well as their statistical distribution is unknown and hence this analysis could not adjust for such probabilities. The estimate of 800,000 to 4 million is based on the number of cases reported to the CDC surveillance system through 1996 and is confirmed by the data for the 1988–92 period.

TABLE 1.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45°F RULE: LOW BENEFITS ESTIMATES

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in \$ (1996) ¹	Upper bound of health costs associated with column 1 in \$ (1996) ²
661,633 ³	\$225 million	\$900 million
Estimated Reduction in Egg-Related SE Cases due to 45°F Refrigeration ⁴		
Health benefits (number of cases avoided)	Lower bound of economic benefits associated with column (1) \$ (1996)	Upper bound of economic benefits associated with column (1) in \$ (1996)
10,189	\$3.47 million	\$13.86 million

¹ Jean C. Buzby and Tanya Roberts, “Guillain-Barré Syndrome Increases Foodborne Disease Costs,” *Food Review* (September-December 1997): 36–42. This report provides an estimate of costs of total human *Salmonella* cases from all food sources. The costs estimated in the table assume that egg-related SE cases represent 25% of total human salmonellosis cases. The report estimates the lower bound of the low estimate of health care costs at \$900 million.

² *Ibid.* The report estimates the upper bound of the low estimate of health care costs at \$3.8 billion.

³ FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The number shown in the chart is the estimated mean number of salmonellosis cases resulting from the consumption of SE-contaminated eggs. The estimated number of cases per year in the *Risk Assessment* ranges from 128,374 to 1.7 million.

⁴ FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The risk assessment model estimates that refrigeration of eggs at 45°F during storage and transportation will result in a mean reduction of 1.54% in human SE cases.

TABLE 2.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45° F RULE: HIGH BENEFITS ESTIMATES

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in \$ (1996) ⁴	Upper bound of health costs associated with column 1 in \$ (1996) ⁵
661,633 ⁷	\$1.2 billion	\$3.075 billion

TABLE 2.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45° F RULE: HIGH BENEFITS ESTIMATE
Continued

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in \$ (1996) ^a	Upper bound of health costs associated with column 2 in \$ (1996) ^a
Estimated Reduction in Egg-Related SE Cases due to 45°F Refrigeration ^b		
Health benefits (number of cases avoided)	Lower bound of economic benefits associated with column (1) \$ (1996)	Upper bound of economic benefits associated with column (2) in \$ (1996)
10,189	\$18.48 million	\$47.355 million

^a Jean C. Buzby and Tanya Roberts, "Guillain-Barré Syndrome Increases Foodborne Disease Costs," *Food Review* (September–December 1997): 38–42. This report provides an estimate of costs of total human Salmonella from all food sources. The costs estimated in this table assume that egg related SE cases represent 25% of all human salmonellosis cases. The report estimates the lower bound of the high estimate of health care costs at \$4.8 billion.

^b Ibid. The report estimates the upper bound of the high estimate of health care costs at \$12.3 billion.

^c FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The number shown in the chart is the estimated mean number of salmonellosis cases resulting from the consumption of SE-contaminated eggs. The estimated number of cases per year in the Risk Assessment ranges from 128,374 to 1.7 million.

^d FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The risk assessment model estimates that refrigeration of eggs at 45°F during storage and transportation will result in a mean percent reduction of 1.54% in human SE cases.

Tables 1 and 2 show an estimated number of annual human illnesses resulting from consumption of SE-contaminated eggs. This number is based on the mean estimated annual number of cases in the *Salmonella Enteritidis Risk Assessment* published by FSIS (June 12, 1998). This report estimates that the number of cases of illness resulting from consumption of SE-contaminated eggs ranges from 126,374 to 1.7 million per year. The Agency is using data from the risk assessment rather than the number of reported cases because, as noted above, it is estimated that there are an additional 20 to 100 cases of salmonellosis for every reported case. Tables 1 and 2 display the mean estimate because the mean is not unduly affected by a few moderately small or moderately large values, and this stability increases with the sample size. To estimate the economic value of the health costs of salmonellosis, the USDA's Economic Research Service (ERS) related illnesses and deaths to four types of severity groups of patients. The four severity groups were: (1) those who did not visit a physician, (2) those who visited a physician, (3) those who were hospitalized, and (4) those who died prematurely because of their illness (Jean C. Buzby and Tanya Roberts, "Guillain-Barré Syndrome Increases Foodborne Disease Costs," *Food Review* (September–December 1997): 36–42). Similar severity rates are also used in the risk assessment final report, e.g., treatment by a physician,

hospitalization, and mortality. Both sources use the CDC data on severity. Based on the avoidance of medical costs, ERS estimated the economic values of prevention of these cases. ERS calculated the range of low estimate of avoidance of all foodborne human salmonellosis-linked diseases and deaths, at \$900 million and \$3.6 billion respectively (in 1996 dollars). ERS calculated the range of high estimate of the health costs at \$4.8 billion and \$12.3 billion (in 1996 dollars). The wide variation in this range of estimates is attributed both to the wide range in estimates of the number of cases and the economic methods used for the analysis. The economic methods are the human capital method and the labor market method. The human capital method yields a lower estimated range of \$0.9 to \$3.6 billion because the cost of premature death in this analysis varies with age and ranged from \$15,000 to \$2,037,000 (in 1996 dollars). The labor market approach yields the higher range of \$4.8 to \$12.3 billion because it values the cost of premature death at \$5 million per person (in 1996 dollars) (Jean C. Buzby and Tanya Roberts, "Guillain-Barré Syndrome Increases Foodborne Disease Costs," *Food Review* (September–December 1997): 36–42). Since the ranges of estimates for salmonellosis-related costs estimated by Buzby and Roberts are based on salmonellosis from all food sources, it is necessary to adjust the estimates downwards to obtain only the cases of salmonellosis related to consumption of SE-contaminated eggs. The medical cost

data shown in the first rows of Tables 1 and 2 represent 25 percent of the ERS estimates because FSIS assumes that SE-contaminated eggs are responsible for approximately 25 percent of salmonellosis cases. This assumption is based on the percentage of SE cases reported to the CDC and the fact that eggs are responsible for the vast majority of these cases. As noted above, from 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was found. Also noted above, a food vehicle is found in only about 25 to 30 percent of cases. Given the level of uncertainty in this data, for estimation purposes, the Agency believes it is appropriate to assume that SE-contaminated eggs are responsible for 25 percent of total salmonellosis cases. Humphrey and Whitehead (1998) suggest that an egg's contents can become contaminated with SE before the egg is laid. They also note that after an infected egg is laid, SE contamination tends to grow inside the egg (T. Humphrey and A. Whitehead, "Egg Age and Growth of *Salmonella* Enteritidis PT4 in Egg Contents," *Epidemiological Infection* 111 (1993): 209–219). Humphrey suggested that refrigerating during storage can prevent such growth (T.J. Humphrey, "Growth of *Salmonella* in intact shell eggs: Influence of Storage Temperature," *Veterinarian Record* (1990): 1236–1292). Other measures for preventing growth include refrigeration during transportation and retail sales, reducing shelf life of eggs at retail, thorough

cooking, pasteurization, and processing shell eggs into frozen, liquid, or dry egg products (FSIS, *Salmonella Risk Assessment*, June 12, 1998; T. Hammack, et al., "Research Note: Growth of *Salmonella Enteritidis* in Grade A Eggs During Prolonged Storage," *Poultry Science* 334 (1993): 1281-1286).

In order to determine the benefits of refrigerating eggs at 45°F, it is necessary to determine the percentage of reduction in the number of egg-related deaths and illnesses from SE cases referred to above. To determine these benefits, this analysis relied on input from a risk assessment model. In June 1998, FSIS completed a risk assessment concerning shell eggs and egg products in response to an increasing number of human illnesses associated with the consumption of shell eggs. The risk assessment developed a model to assess risk throughout the egg and egg products continuum. The risk assessment model consists of five modules. The first module, the Egg Production Module, estimates the number of eggs produced that are infected (or internally contaminated) with SE. The Shell Egg Module, the Egg Products Module and the Preparation and Consumption Module estimate the increase or decrease in the number of SE organisms in eggs or egg products as they pass through storage, transportation, processing and preparation. The Public Health Module then calculates the incidences of illnesses and four clinical outcomes (recovery without treatment, recovery after treatment, treatment by a physician, hospitalization, and mortality) as well as the cases of reactive arthritis associated with consuming SE positive eggs.

Refrigeration of shell eggs at an ambient air temperature of 45°F or below during storage and transportation will retard growth of SE and hence is likely to reduce the associated illnesses and deaths. The risk assessment model estimates that refrigeration of shell eggs at an ambient temperature of 45°F or below can bring about a mean reduction of 1.54 percent in egg-related human illnesses associated with SE. This estimate has a 90 percent confidence interval, with a lower bound of 0 percent and an upper bound of 7 percent. Therefore, there is a range of possible outcomes. Although a 1.54 percent reduction in illnesses associated with SE is the most likely outcome, the regulation could result in no reduction in illnesses or in a reduction as high as 7 percent. This estimate and its confidence interval are based on a model with the assumption that eggs are

maintained at an ambient temperature of 45°F after processing through transportation to retail, or other, end users. This result also assumes complete compliance with the regulation. The effect of the regulation was modeled by adjusting the baseline model (consisting of the Production, Shell Egg Processing/Transportation, Preparation/Consumption, and Public Health modules) to reflect the regulation's effect. The model adjusted the following temperature variables in the Shell Egg Processing/Transportation module: Storage temperature after processing at off-line processor, Storage temperature after processing at in-line processor, Temperature during transportation to egg users. In the baseline model, these variables were modeled as extending from a low of 41°F, in the case of the storage temperature after processing at in-line processors, to a high of 90°F. The baseline model assumes that eggs are handled under a variety of different temperatures. In modeling the regulation, these variables' distributions were truncated at 45°F. Therefore, all eggs were exposed to ambient temperatures of 45°F or less after packing in the regulation model. The effect of the regulation was calculated as the difference in simulated total human cases between the baseline model and the regulation model. The percent reduction in human illnesses was then calculated by dividing this difference in human cases by the simulated total human cases from the baseline model. It must be noted that the estimated mean reduction in SE illnesses of 1.54 percent referred to above was estimated in a separate run of the model for this rule performed by FSIS scientists and is not included in the risk assessment final report. As noted above, the risk assessment final report estimates the benefits that would result from maintaining an ambient temperature of 45°F throughout processing and distribution (that is, from pre-packing and through retail) and the benefits of maintaining the internal temperature of eggs at 45°F throughout processing and distribution.

The last rows in Tables 1 and 2 show the reductions in SE cases associated specifically with refrigeration of shell eggs based on the mean value of 1.54 percent reduction in cases referred to above. These are the incremental social benefits of the rule. These estimates range from a low of \$3.47 million to \$13.86 million in Table 1 to a range of \$18.48 million to \$47.355 million in Table 2 (in 1998 dollars). Requiring refrigeration of eggs at an ambient air temperature of 45°F does not address all

the food safety risks posed by shell eggs. Responses to the ANPR will assist FSIS and FDA in the development of a comprehensive, farm-to-table food safety strategy that will address a variety of food safety measures in addition to ambient air temperature. Actions taken subsequent to the analysis of alternatives identified in the ANPR may provide additional benefits associated with further reductions in foodborne illness associated with the consumption of shell eggs.

As noted above, FSIS and FDA have published an ANPR concerning SE in shell eggs (63 FR 27502; May 19, 1998). The number of cases in Tables 1 and 2 are larger than those reported in the ANPR (63 FR 27504) because the figures in the ANPR are based on outbreaks reported to the CDC, while the data on Tables 1 and 2 take into account the fact that many of the cases are unreported. In addition, the cost of illnesses in Tables 1 and 2 differ from those in the ANPR (63 FR 27504) because the estimates in the ANPR were based on 1991 data. FSIS used 1996 data for the cost and benefit analysis in these regulations.

Incremental Social Costs

The incremental social costs associated with the rule include the first year fixed capital costs and the annual recurring costs of compliance to be incurred by the industry. The first year costs would include the costs of replacing or retrofitting refrigeration units, compressors, and coils. These capital costs are required for storing shell eggs at 45°F or below after washing and packing. The capital costs to the industry would also include the costs of replacing or retrofitting transportation vehicles that have refrigeration units capable of producing air at 45°F or below. The annual recurring costs would encompass the energy costs of maintaining ambient temperatures in storage facilities and transportation vehicles at 45°F or below. These capital and recurring costs would be incurred either by shell egg producers or by their contractors for storage and transportation. When the storage or transportation services are contracted out, however, it is very difficult to separate the costs associated with shell eggs because these contractors store or haul not only shell eggs but also several other products.

An additional element of the social costs would be the incremental budgetary costs, if any, to USDA for enforcing this regulation. The Agency has not determined how it will enforce this rule. AMS may check the ambient temperature of shell egg storage

facilities and the labeling of shell egg containers during its surveillance of egg handlers and during grading activities. FSIS compliance officers may check the ambient temperature of shell egg storage facilities and transportation vehicles and the labeling of shell egg containers once the eggs leave the plant. For example, while compliance officers are checking meat and poultry products in commerce outside inspected establishments or at uninspected facilities, if such facilities store shell eggs, compliance officers may also check temperatures at these locations and verify that the labeling of egg containers meets the requirements in this rule.

Whether AMS or FSIS checks the temperature of shell egg storage facilities and transport vehicles and verifies that the labeling of egg containers meets the requirements in this rule, these activities are likely to be in addition to other Agency activities conducted at the same location. Checking temperatures and labeling will increase the time required for AMS or FSIS personnel to conduct their oversight activities. However, FSIS is unable to determine the amount of additional time that will be required. Therefore, the Agency is unable to estimate the additional costs (e.g., personnel costs and costs of equipment such as thermometers) that will be required for monitoring compliance with the requirements in this rule.

The costs of compliance to the industry are not likely to be excessive for three reasons. First, the rule exempts small producers with flocks of 3,000 layers or less. There are approximately 80,000 such small egg producers that would not be required to comply with the refrigeration and labeling provisions of this rule.

Second, of the approximately 700 producers currently registered with USDA as of July 1998, 329 are major producers with flocks of 75,000 or more who produce about 94 percent of U.S. table eggs. Most of these producers are members of United Egg Producers (UEP), an organization that provides a variety of services to member egg producers. The UEP already has a quality assurance program that recommends refrigerating eggs at 45°F or below as quickly as possible after washing and grading and that the same temperature be maintained during transportation. A letter from UEP indicated that many of these producers have already started refrigerating at 45°F or below. Therefore, these producers are unlikely to incur additional costs of compliance. (This aspect is elaborated later in a section on the Regulatory

Flexibility Act (RFA).) It is likely that most producers that are not members of UEP or are not major producers have also begun refrigerating shell eggs during storage and transportation because of State requirements (discussed below). With regard to producers that are not members of the UEP or are not major producers, specific information regarding whether they store and transport shell eggs at 45°F is not available. The structure of egg industry is changing toward greater concentration of large producers. For example, the number of producers registered with AMS has declined from about 1,200 in 1992 to approximately 700 in July, 1998. The resulting concentration of larger producers who refrigerate their supplies is likely to have reduced the costs of compliance.

Third, many States have already enacted laws requiring specified ambient air temperatures for shell egg storage and transportation. Approximately one-half of all States require 45°F or less for storage and transportation. Approximately ten of these States have adopted 45°F refrigeration requirements since 1992. Some of these States are large producers. Many States also require that shell eggs be refrigerated at 45°F at retail. Approximately ten States retain the 60°F traditionally required under USDA grading standards. Approximately one dozen States have no refrigeration requirement for shell egg storage and transportation. Costs of compliance for the shell egg producers in the States already requiring refrigeration at 45°F are not likely to increase significantly. Some of the States that require 45°F refrigeration of shell eggs during storage and transportation are among States in which major producers are located, e.g., Ohio, Pennsylvania, and Georgia. However, there are States with major producers and other producers that do not require 45°F refrigeration during storage and transportation of shell eggs. The Agency requests information concerning the costs these regulations may impose on producers who are currently not refrigerating shell eggs at 45°F during storage and transportation. The Agency also requests information concerning the size of these establishments.

The rule proposed on October 27, 1992 for refrigerating shell eggs at 45°F or below estimated the first-year capital investment costs at \$40.67 million (57 FR 48571). The annual recurring operating costs were estimated at \$10 million. The capital investment costs involved replacing or retrofitting existing refrigeration units with larger

compressors or coils. The recurring annual operating costs involved the energy costs of maintaining ambient air temperatures in storage facilities and transport vehicles at 45°F or below. These cost estimates were based on data obtained from a survey of 80 (7 percent) out of the 1200 shell egg processing plants located throughout the country representing about 25 percent of production. 59 plants (75 percent) responded to the survey. The Agency was unable to evaluate the comments regarding the specific large costs of acquiring trucks and equipment because the survey did not contain such detailed data.

The costs to comply with this final rule will be lower than the costs estimated for the proposed rule in 1992 because about ten States (e.g., Arkansas, Florida, Georgia, Louisiana, Ohio, Oregon, Rhode Island, and Texas) have already adopted refrigeration requirements at 45°F or below for storage and transportation since 1992. These States represented 29 percent of shell egg production in 1996. FSIS updated the 1992 estimates to account for inflation and changes in State laws. The Agency requests specific information concerning costs that will be incurred in States that have not enacted refrigeration requirements.

The costs estimated in 1992 were not adjusted upward for any of the comments to the proposed rule because about 10 States have implemented the 45°F refrigeration requirements since 1992. Since about ten out of fifty States representing 29 percent of production have implemented the rule since 1992, this analysis reduced the capital and recurring costs estimated in 1992 by 29 percent. This adjustment reduced the capital and recurring costs to \$28.40 million and \$7.1 million respectively. Therefore, costs were reduced based on shell egg production data. FSIS reduced costs based on production data because the 1992 costs were estimated and reported on a production basis (see 57 FR 48571-48572). The fact that the number of producers has declined since 1992 may further lower the costs to the industry because a smaller number of larger producers tend to have lower costs due to scale economies.

The updated costs referred to above were adjusted upwards because of inflation over the last six years. To adjust for this increase, FSIS increased the \$28.40 million capital costs by 8 percent (based on U.S. Department of Commerce, Bureau of Economic Analysis, price index of transportation and related equipment index, 1997 = 100, 1992 = 108.5). This adjustment increased the capital cost estimate from

\$28.40 million to \$30.67 million, or \$31 million approximately.

The updated recurring costs of compliance, estimated at \$7 million per year in 1992, were assumed to comprise mostly energy costs of refrigeration. These estimates were increased for inflation over the last six years to \$7.63 or \$8 million approximately (based on U.S. Department of Commerce, Bureau of Economic Analysis, Price Index of Electricity and Gas, 1992 = 100, 1997 = 108.98, or by 9 percent). FSIS requests alternate cost estimates and data to support these estimates from

commenters who disagree with the Agency's cost estimates.

The estimated costs of compliance and the associated social benefits of this rule are likely to be realized over the next twenty years. Therefore, these costs and benefits were discounted over this time span by using a 7 percent mid-year discount rate recommended by the Office of Management and Budget.

Table 3 reports FSIS estimates of the discounted costs and benefits of the rule under alternative assumptions about cost of salmonella induced foodborne illness. Depending on the assumption used, the estimated net benefits range

from -\$79.6 million to \$401.30 million. Under the assumption that the cost of foodborne illness varies with age, the net benefits from the rule range from -\$79.6 million to \$34.2 million. Alternatively, if it is assumed that the cost of premature death is \$5 million per person, the net benefits from the rule are higher, from \$84.9 million to \$401.3 million. In light of the uncertainty surrounding the benefit estimates and refinements to costs, FSIS cannot make a definitive statement about the net benefits associated with the rule.

TABLE 3.—DISCOUNTED BENEFIT-COST ESTIMATES OF REFRIGERATING SHELL EGGS
(Fixed Costs=\$31 million, Recurring Costs=\$8 million)

	Lower bound of low est.	Upper bound of low est.	Lower bound of high est.	Upper bound of high est.
Recurring benefits: (\$ million)	3.47	13.86	18.48	47.36
Discounted Benefits*: (\$ m.)	38.03	151.88	202.51	18.83
Discounted Costs*: (\$ m.)	117.83	117.83	117.83	17.83
Net Discounted Benefits: (Row 2-Row 3) (\$ m.)	-79.80	34.17	84.68	101.30
Benefit-Cost Ratio: (Row 2:Row 3)	0.32	1.29	1.72	4.41

*Discount Rate=7%, Time Period=20 years.
Source: Tables 1 and 2.

The preceding costs are likely to be passed on to consumers by the industry because of the elasticity of demand and supply of eggs. The demand for shell eggs is very inelastic, i.e., an increase in the price of shell eggs is not likely to reduce significantly the demand for them. For example, Kuo reports that the price elasticity of demand for shell eggs is only (-0.11), i.e., an increase in price by one percent is associated with only 0.11 percent decrease in quantity of shell eggs demanded (Huang S. Kuo, *A Complete System of U.S. Demand for Food*, USDA/Economic Research Service, Technical Bulletin No.1821, 1993, Appendix B and C).

The inelastic demand is due to the fact that there are no good substitutes for eggs that consumers might use when prices of shell eggs are increased. Also, a typical consumer spends an insignificant proportion of the food budget on shell eggs and consumes a limited number of eggs.

The supply of shell eggs is very elastic because this industry has hundreds of producers who can increase the supply of eggs with little increase in costs. This prevents price increases by any single producer and no producer can increase prices without losing significant market share. Therefore, egg prices have been stable, if not declining, for several years. For example, wholesale egg prices declined from 91.5 cents/dozen in 1996 to 83.8 cents/dozen in 1997. In the first

quarter of 1998, this price declined to 82.5 cents/dozen. The average retail price of grade A large eggs was \$1.1063/dozen in 1997 (U.S. Department of Labor/Bureau of Labor Statistics). Per capita consumption of eggs increased only slightly, from 237.8 eggs in 1996 to 239.3 eggs in 1997.

Regulatory Flexibility Act (RFA)

The Administrator has determined that this rule will not have a significant economic impact on a substantial number of small entities. As noted above, this rule exempts from compliance small producers with flocks of 3,000 layers or less. Most of the establishments not exempt from this rule are small establishments with employment of 500 or less. Also, the compliance costs are likely to be spread over a large volume of output that will be produced over the life cycles of these capital assets (e.g., refrigeration equipment). For example, according to the National Agricultural Statistics Service, 5.456 billion dozen eggs were produced between January 1, 1997 and December 31, 1997. During that time, the wholesale price for table eggs, estimated by ERS, was 83.8 cents per dozen, and the gross industry receipts were estimated at \$3.96 billion. Therefore, the compliance costs would represent less than a penny per dozen eggs or less than one percent of revenues. Since these first year costs

include nonrecurring capital costs for storage facilities and refrigerated vehicles, the impact on the industry would be substantially less in subsequent years. For example, the recurring costs in the subsequent years were estimated at \$9 million per year. This cost would represent primarily the energy cost of generating refrigeration and the maintenance and replacement costs of storage facilities. The relative impact on small producers would be insignificant also because the current structure of the shell egg industry is more concentrated than in 1992. For example, currently there are only about 700 producers, compared to about 1,200 producers in 1992. The smaller number of producers with increased output is likely to have resulted in a greater concentration of larger firms in the industry. These larger firms are more likely to absorb the compliance costs relative to smaller firms. FSIS notes that increased costs will not be evenly distributed across the industry because some producers are currently storing and transporting shell eggs at 45 °F, while others are most likely storing and transporting shell eggs at higher temperatures.

The shell egg industry would be able to "pass through" this cost in the form of higher prices to consumers because, as noted earlier, demand for this product is very inelastic and the supply

of shell eggs is highly elastic. The inelasticity of the demand follows from the fact that household expenditures on eggs are a small share of household budgets and because substitutes for eggs—at least in some applications—are limited. The high elasticity of supply is based on the fact that there are hundreds of shell egg producers in the U.S. with relatively flat marginal cost curves. Thus, producers expand egg production with little increase in average costs.

The rule would not be burdensome to other small entities such as State and local governments because they are not in the business of storage and transportation of shell eggs. However, to the extent State and local governments are consumers of eggs, they will pay a little more for eggs.

Alternatives to the Rule

FSIS considered several alternatives to this rule. FSIS found the alternatives, which are described below, to be inferior to this rule because of their expected benefits and costs, administrative burden, efficiency, and equity.

No Action

This alternative would continue the current practice of no Federal requirement for refrigeration of shell eggs. The public health benefit would be zero because this alternative would not reduce *Salmonella* related illness. FSIS considered and rejected this alternative because, as noted above, the EPIA amendments mandate promulgation of this rule. In addition, as noted earlier, the Appropriations Committee has withheld \$5 million of the FSIS appropriated funds for Fiscal Year 1998 until a final rule is promulgated to implement the refrigeration and labeling requirements included in the 1991 EPIA amendments. A loss of \$5 million in the Agency's appropriation is likely to impair FSIS's inspection activities, and degrade food safety in general.

Sliding Scale Approach

This alternative does not require maintenance of a specific ambient temperature, such as the 45°F rule does. Under this approach, a specific "sell-by" date is mandatory, which would vary depending on the temperatures at which eggs are maintained. To provide an incentive for processors to chill eggs before shipping, yet retain flexibility to accommodate reasonable alternatives to an absolute temperature requirement, a regulation might prescribe a range of "sell-by" dates based on the egg temperature achieved by the packer. Such an approach is under

consideration by the European Union but is not recommended for the U.S. because of differences in climate, and vast distances in the U.S. relative to within or even between countries in Europe. This alternative would be burdensome to the industry and difficult to implement because it would require detailed recordkeeping by the industry. Some public health benefits would be expected and would depend on the sell-by date/temperature matrix. Industry costs would depend on the matrix and which temperatures producers select. Finally, this alternative would be very difficult to enforce since USDA inspectors would have to keep track of hundreds of shell egg producers and billions of dozens of eggs.

State Rules Instead of Federal Rule

FSIS considered the alternative of actively encouraging State governments to promulgate their own laws instead of a Federal rule but did not adopt it for several reasons. First, as noted earlier, about half of all States currently have laws requiring refrigeration of shell eggs at 45°F. On the other hand, some States do not have any refrigeration requirements for shell eggs. Other States require refrigeration during storage but not during transportation. Some States require refrigeration of shell eggs at temperatures greater than 45°F. In contrast to these inconsistencies and non-uniformities, with the exception of shell eggs packed by egg handlers with 3,000 or fewer hens, this rule requires that all shell eggs packed in containers for the ultimate consumer be refrigerated during storage and transportation at 45°F or below. The public health benefits of this alternative are expected to be zero, since this alternative is essentially the same as no action except that States would be put on notice that they should deal with public health risks from eggs.

In view of the disparities within and across the States, FSIS determined that it would not be appropriate to defer to the States.

Summary and Conclusions

This section analyzed compliance of this rule with Executive Order 12866. It estimated discounted social benefits of the rule and juxtaposed them against discounted capital and operating costs of compliance with the rule. The analysis concluded that potential net social benefits may result from this rule.

This section also analyzed compliance of this rule with the Regulatory Flexibility Act. It is concluded that the costs of compliance are not likely to have a significant

economic impact on a substantial number of small entities because the industry's cost of compliance amounts to less than a penny per dozen egg. Demand for eggs is inelastic, and the supply of eggs is highly elastic. In short, the egg producers could easily "pass through" the costs of compliance to consumers without losing their market shares. Other small entities such as local and State governments are also not likely to be adversely affected by this rule because they are not in the business of producing, storing, or transporting shell eggs. To the extent that they are large buyers of eggs, they would be adversely impacted by the estimated increase in price of a penny per dozen eggs.

Finally, this section analyzed several alternatives to the rule. These alternatives included: (1) no action, (2) sliding scale approach, and (3) State rules instead of a Federal rule. These alternatives were rejected because of their costs, administrative burden, efficiency, or equity.

Paperwork Requirements

The paperwork and recordkeeping activities associated with this rule are approved under OMB control number 0583-0106.

List of Subjects in 7 CFR Part 59

Eggs and egg products, Exports, Food grades and standards, Food labeling, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is amending 7 CFR Part 59 as follows:

PART 59—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

1. The authority citation for part 59 continues to read as follows:

Authority: 21 U.S.C. 1031-1056.

2. Section 59.5 is amended by adding alphabetically the definitions for "Ambient temperature" and "Ultimate consumer" and revising the definitions for "Container or Package" and "Egg handler" to read as follows:

§ 59.5 Terms defined.

* * * * *

Ambient temperature means the air temperature maintained in an egg storage facility or transport vehicle.

* * * * *

Container or Package includes for egg products, any box, can, tin, plastic or other receptacle, wrapper, or cover and for shell eggs, any carton, basket, case, cart, pallet, or other receptacle.

**PROPOSED AMENDMENT TO
TITLE 119
PROPOSED LEGISLATIVE RULE
SECRETARY OF TAX AND REVENUE
Series 301
REGISTRATION OF TELEMARKETERS**

DRAFT

§119-301-1. General.

1.1. **Scope.** -- This rule establishes telemarketing registration fees and factors Secretary of tax and Revenue considers when assessing civil administrative penalties.

1.2. **Authority.** -- The authority for this rule is W. Va. Code §§ 29A-3-15, 46A-6F-301 and 46A-6F-303.

1.3. **Filing Date.** -- January ____, 1999.

1.4. **Effective Date.** --

1.5. **Official Citation.** -- The official citation of this rule is title 119, series 301 of the West Virginia Code of State Rules. Sections of this rule may be cited as 119 W.Va.C.S.R. § _____, or 119 C.S.R. § _____.

§ 119-301-2. Registration fees.

2.1 **General.** -- The Secretary of Tax and Revenue may charge reasonable application and renewal fees. These fees are deposited in the *Telemarketer Registration Fund* created in the State Treasury and used to administer and enforce the registration requirements of article 6F, chapter 46A of the Code and this rule.

2.2 **Fees.** --The Secretary hereby establishes the following fees:

2.2.1 **Initial application fee** -- \$250.00

2.2.2 **Renewal fee** -- \$250.00

2.2.3 Discount. – If the telemarketer registers at the Secretary's web site, or renews its registration at the Secretary's web site, the applicant will be allowed a \$50 discount.

2.3 Refund of fee.

2.3.1 No refund will be given, or credit established, for all or a portion of the registration fee if during the registration year the registrant: (a) goes out of business, (b) stops doing telemarketing activity in this State, or (c) has its telemarketing registration certificate revoked or suspended.

2.3.2 No refund will be given, or credit established, for all or a portion of the registration fee when the claim is for any other reason, except that a refund will be made if payment of the fee, or any portion of the fee, was erroneous at the time it was paid.

§119-301-3. Failure to register or meet security requirement; remedies.

3.1 Civil administrative penalty. – Any person subject to this rule is subject to imposition of a civil administrative penalty of not more than \$5,000 per violation if the person does any of the following:

3.1.1 Acts as a telemarketer without first registering with the Secretary as required by section 46A-6F-301 of the Code;

3.1.2 Acts as a telemarketer without first meeting the security requirements set forth in section 46A-6F-302 of the Code, unless the telemarketer is exempt from the security requirements;

3.1.3 Acts as a telemarketer after failing to maintain a certificate of registration as required by section 46A-6F-301 of the Code;

3.1.4 Acts as a telemarketer without furnishing the security required by section 46A-6F-302 of the Code;

3.1.6 Acts as a telemarketer without maintaining the amount of security required by section 46A-6F-302 of the Code;

3.1.7 Includes any material information on a registration application, or on a renewal application, that is false or misleading; or

3.1.8 Misrepresents that the telemarketer is registered with the Secretary.

3.2 Considerations. – When determining the amount of penalty to assess, the Secretary must take the following into account:

3.2.1 The seriousness of the violation;

3.2.2 Any good faith efforts of the telemarketer to comply with applicable requirements of article 6F, chapter 46A of the Code and this rule;

3.2.3 Any benefit obtained by person due to the act or omission;

3.2.4 The past history of the telemarketer in filing the initial application for registration and subsequent renewals;

3.2.5 Whether the cause of the delinquency was unavoidable, or was due to negligence or an intentional act of the telemarketer or an agent of the telemarketer;

3.2.6 The opportunity and degree of difficulty to correct erroneous or incomplete information in the initial application or a renewal application;

3.2.7 The cooperativeness and efforts made by the telemarketer or an agent of the telemarketer to correct the erroneous or incomplete information for which the penalty is to be imposed, in whole or in part;

3.2.8 The cost to the Secretary and time involved in investigation and correspondence prior to the time the erroneous or incomplete information is actually corrected;

3.2.9 Any good faith belief by the telemarketer that it was exempt from the registration requirements of section 46A-6F-301 of the Code, or the security requirements of section 46A-6F-302 of the Code, or exempt from the requirements of both sections;

3.2.10 The lack of actual knowledge by the telemarketer of the registration and security requirements of sections 46A-6F-301 and 302 of the Code;

3.2.11 The telemarketer's business reputation and history, if offered by the telemarketer;

3.3 Notice of civil administrative penalty. -- The telemarketer shall be notified by certified mail or personal service of any alleged violation of section 46A-6F-301 or 302 of the Code. This notice must include:

3.3.1 A reference to the provision(s) of W. Va. Code §§ 46A-6F-301, 302 and 303 that that the person allegedly violated;

3.3.2 A concise statement of the facts alleged to constitute the violation;

3.3.3 A statement of the amount of penalty sought to be imposed; and

3.3.4 A statement of the alleged violator's right to a hearing the violator desires to contest the proposed civil administrative penalty.

3.4 Request for hearing. -- The alleged violator shall have 20 calendar days after receipt of the notice within which to file with the Secretary a written request for a hearing. If no hearing is requested, the notice becomes a final order after the 20th calendar day.

3.4.1 Computation of time. -- If the 20th calendar day falls on a Saturday, Sunday or legal holiday in this State, the written request is timely if it is filed on the next day that is not a Saturday, Sunday or legal holiday in this State.

3.4.2 Service. -- A written request for a hearing is filed timely when the request is delivered to the Secretary in person on or before the last day for filing, or the request is deposited in the United States mail, postage prepaid, addressed to one of the following addresses; or the request is sent by other means recognized as service by the courts of this State:

W.Va. Secretary of Tax and Revenue

Office of Telemarketing Registration

P.O. Box 963

Charleston, WV 25324-0963

W.Va. Secretary of Tax and Revenue

Office of Telemarketing Registration

Building 1, Room W-300

Charleston, WV 25305-0842

3.5 Hearing and appeal procedures.

3.5.1 When a request for hearing is filed timely, the Secretary shall inform the alleged violator of the time and place of the hearing.

3.5.2 The Secretary may appoint a hearing examiner to conduct the hearing and then make a written recommendation to the Secretary concerning the assessment of a civil administrative penalty.

3.5.3 The hearing shall be conducted in accordance with the provisions of article 5, chapter 29A of this Code.

3.5.4 Within 30 days following the hearing, the Secretary shall issue and serve on the alleged violator a written decision that explains the rationale for any assessment of an administrative penalty.

3.5.5 An adverse decision may be appealed to the courts as provided in section 4, article 5, chapter 29A of this Code.

3.5.6 No notice of a civil administrative penalty shall become due and payable until after the procedures for review of the notice as set out in this section have been completed.

Section 2.1 Definitions

On page 8 of the rule, in subsection (mm) under definition of pharmacist-in-charge:

Delete number 2 and substitute in lieu thereof the following:

"2. The pharmacist-in-charge has the responsibility for the practice of pharmacy, as defined in this rule, at the pharmacy for which they are pharmacist-in-charge. The permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the permit holder on administrative and operational matters but following such advice shall not be legally required."

Delete number 3 and substitute in lieu thereof the following:

"3. Works at least 30 hours a week with the pharmacist-in-charge working at least three days per week in that pharmacy, including the use of any accrued annual or sick leave."

Delete number 4.

Section 20.1 Duties and responsibilities of pharmacist-in-charge

On page 78 of the rule, in subsection (b) add the following two subsections:

"1. The pharmacist-in-charge has the responsibility for the practice of pharmacy, as defined in this rule, at the pharmacy for which they are the pharmacist-in-charge. The permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the permit holder on administrative and operational matters but following such advice shall not be legally required."

"2. The pharmacist-in-charge shall notify the permit holder of potential violations of any statute, rule or court order existing within the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall reduce to writing the above and submit to the permit holder with a copy to the Board of Pharmacy. No pharmacist-in-charge shall be sanctioned by the Board for any violation of any statute, rule or court order if they have previously given such notice to the permit holder. The permit holder shall be responsible for such violations."

On page 78 of the rule, in subsection (b) (2), delete words "develop or adopt" in line 1.

On page 79 of the rule, in subsection (b) (3), replace the word "establishing" in line 1 with the word "implementing."

Section 14.8 Professional Work Environment

On page 48 of the rule, delete subsection (a) substitute in lieu thereof the following:

"(a) No pharmacist may work more than twelve (12) hours within a twenty-four (24) period

without at least eight (8) hours off duty in that 24 hours, except in a case of emergency when a pharmacist calls off work, the pharmacist on duty may work more than twelve (12) hours in order to keep the pharmacy open. The pharmacists would have to document the date and amount of time worked beyond the twelve (12) hour limit along with the reason for the extended hours of work and make it available to the Board.”

On page 49 of the rule add the following subsection (c):

“The pharmacist on duty or the permit holder shall notify the pharmacist-in-charge whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.”



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Cecil H. Underwood
Governor

Joan E. Ohl
Secretary

MEMORANDUM

TO: The Honorable Michael Ross
Co-Chairman
Legislative Rule-Making Review Committee

The Honorable Mark Hunt
Co-Chairman
Legislative Rule-Making Review Committee

FROM: Henry G. Taylor, M.D., M.P.H. *Henry G. Taylor*
Commissioner, Bureau for Public Health

DATE: January 8, 1999

RE: **Emergency Rules for Emergency Medical Services 64 CSR 48**

Please find enclosed correspondence related to emergency rules filed during the last Legislative Session. The West Virginia EMS Advisory Council voted to support the emergency ruling and the eventual passage of the proposed strike throughs, as requested by the Legislature. Attached are minutes of the meeting. Although requested on two separate occasions, only a few comments from the various fire associations and departments were returned.

If you have any questions pertaining to this action, please feel free to call me.

Enclosures

pc: Secretary Joan E. Ohl
David Forinash
Dr. Bill Ramsey
Mark King
Mary Huntley

BUREAU FOR PUBLIC HEALTH

Commissioner's Office

Building 3, Room 518, State Capitol Complex
Charleston, West Virginia 25305-0501
Telephone: (304) 558-2971 FAX: (304) 558-1035



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Cecil H. Underwood
Governor

Joan E. Ohl
Secretary

January 8, 1999

The Honorable Michael Ross
Co-Chairman, Legislative Rule-Making Review Committee
West Virginia Senate
State Capitol Building, Room 203W
Charleston, West Virginia 25305

The Honorable Mark Hunt
Co-Chairman, Legislative Rule-Making Review Committee
West Virginia House of Delegates
State Capitol Building, Room 215W
Charleston, West Virginia 25305

Dear Senator Ross and Delegate Hunt:

As you know, the Bureau filed emergency rules at the request of the Legislature to relieve fire departments from provisions pertaining to EMS Agency licensing. The EMS Advisory Council has been aware of this filing from the beginning, but would not vote on the issue until much discussion over several meetings.

Although there were very few comments provided back to the Office of EMS, there was significant discussion with participation by the fire community. The Council did take a stand on the proposed rules on December 3, 1998, voting unanimously to support the strike-through language as requested (see attached meeting minutes). Additional discussion will be held with the fire community to seek out a final solution on the rapid response issue.

BUREAU FOR PUBLIC HEALTH

Commissioner's Office

Building 3, Room 518, State Capitol Complex
Charleston, West Virginia 25305-0501
Telephone: (304) 558-2971 FAX: (304) 558-1035

The Honorable Michael Ross
The Honorable Mark Hunt
January 8, 1999
Page Two

Lastly, Joe Altizer, staff for the Legislative Rule-Making Review Committee, asked that a letter from you to the Committee explain this action. He needs the letter before the Committee meets on Tuesday, January 12th. Thank you very much for your assistance in this matter.

Sincerely,



Henry G. Taylor, M.D., M.P.H.
Commissioner

Attachments

cc: Dr. Bill Ramsey
Mark King
Denny Nurkiewicz

MINUTES EMS ADVISORY COUNCIL

December 3, 1998
Bureau for Public Health

Members in Attendance

Paul Seamann
James Noice
Frank Rodgers
Joyce White
Lois Lipscomb
Allen Holder
Mike St. Clair
David Maynard
David Anderson

Liaisons in Attendance

James Fife-Region III/IV
Ox Johnson-Region V
James Miller-Region VIII/IX
P.C. Pancake-Region II
David McClure-Region 10/11

Members Absent

John Riddle
William Pierce
Rick Wellman
Joanna Craigo

Guests in Attendance

Robert Wilson
Roger Bibbee
F. Gary Collis
Jerry Kyle

Wayne Lewis
Denny Nurkiewicz
Marianne Perry
Joann Fleming

William Ramsey
James Donathan
Mark King

Chair Paul Seamann called the meeting to order at 11:03 a.m. in the 1st floor conference room on 1411 Virginia Street, East.

Mark King introduced Robert Wilson as the new Training Director of the Office of Emergency Medical Services. Guests were welcomed.

After presentation of the minutes of the meeting held on September 17, 1998, a motion was made by Joyce White, seconded by Lois Lipscomb, and accepted by the Council to approve the minutes as presented.

A moment of silence was held for Thomas Spaulding, a paramedic from Putnam County killed in the line of duty

A general discussion was held on the EMS Legislative Rules Revision changes, the process of emergency filing, and the concerns of the fire community. A motion was made by Dave Maynard and seconded by Mike St. Clair to accept the strikethroughs of the EMS rules as written. After another lengthy discussion was held on the strikethroughs, a vote was called for with 9 favoring and 0 opposing the motion.

The next item on the agenda was an update by Denny Nurkiewicz on the PCS Sprint negotiations and the 911 tracking project, both of which are progressing very smoothly.

The AED Legislation was the next item up for discussion. Dr. David Anderson gave an update on the upcoming legislation for AEDs, pointing out that an important piece of the legislation is the inclusion of the EMS system in the bystander program on page 4 and that it be a registered program. The issue of medical oversight was considered as extremely important.

A report on the Critical Care Transport Task Force was given by Dr. David Anderson for Joe Lynch. The Task Force will be meeting to come up with guidelines for this form of service. There has been some very good preliminary work.

Dr. Ramsey's report:

- * Need to make sure hospitals and association are on board to work on Critical Care Transport Task Force guidelines.
- * He thanked the AED Task Force for a very efficient and quick document.
- * He gave updated information on medical direction issues which included internet addresses for regional medical directors, orange mailing labels for regional medical directors, monthly teleconferencing, clarifying statewide DNR protocols, new procedures for the statewide protocols, region V medical command, re-emphasis on the statewide trauma system, recertification issues, and paramedics in the ED.

Next item on the agenda was a call for a Certification Task Force by Mark King to work with the State Office, EMS Coalition, CTC on the process of certification, rules and regulations, picture card/bar graph identification card and National Registry issues. Suggestions to serve on this Task Force were: Paul Seamann (EMS Coalition), Gail Dragoo (regional program director), Patty Reger (RESA/Education Association), Jerry Kyle, and fire association. Dr. David Anderson suggested that Mark or Dr. Ramsey send a communication to restate that certification stands as is until otherwise notified.

Liaison reports:

- | | |
|---------------|--|
| Region II | Mr. Pancake reports that they are satisfied in their region. |
| Region V | Ox Johnson reported that the regional medical command issue is resolving very smoothly. A trauma center site visit was held at Jackson General Hospital. Pleasants County EMS may be going out of business on 1/1/99 but a Task Force has been appointed to look at solutions. |
| Region VI/VII | Dr. Anderson reported that certification issues are a problem but should be resolved with the communication from Mark. |

Region VIII/IX

Jim Miller asked for a licensure update of EMS agencies and the status of the hiring of the programmer in OCRHS.

Region X/XI

David McClure reported that the issues in their region are medical command and trauma center designation.

Other Business:

Allen Holder asked about the governor reappointments to the Advisory Council. Members are to remain status quo until notified otherwise.

Lois Lipscomb reported on the ex fisaco membership on the Educational Association. There is not anything in the bylaws that addresses this issue, but they will bring it up at the January meeting.

Meeting adjourned at 12:56 p.m.

PROPOSED CHANGES TO WEST VIRGINIA LEGISLATIVE RULE - DIVISION OF HEALTH, EMERGENCY MEDICAL SERVICES - 64 C.S.R. 48

- A) **2.6. Basic Life Support (BLS).** — A basic level of out-of-hospital and interfacility emergency medical services provided when a patient requires BLS services or continual medical supervision. Basic life support can be performed by ALS personnel as well as EMT-B, EMSA-LPN, EMT-FR EMSA-FR or as stated in this rule.
- B) Recall definition as re-written:
- 2.29. Fire Department Rapid Response.** A recognized fire department that is licensed as an EMS agency to provide Rapid Response-BLS or Rapid Response-ALS service as indicated in this rule. Nothing in these rules shall be deemed to prohibit members of a recognized fire department from providing basic first aid, CPR, manpower, or appropriate assistance in time of emergency. Recognized fire departments and their members providing these basic response services shall not be required to obtain licensure under these rules.
- C) Recall Definition as re-written:
- 2.41. Recognized Fire Department.** Any organization established for the purposes of providing fire suppression, fire protection, and related activities that is recognized by the West Virginia State Fire Commission.
- D) Recall stricken provision of 5.1:
- Fire department rapid response organizations shall meet the following specific standards of this rule: 5.3.a. - Off-Line Medical Direction; 5.3.c. - Quality Assurance; 5.4. - Communications; 5.5. - Rapid Response; 5.6. - Disaster Capability; 5.8. - Personnel; 5.9. - Training; 5.11.c. - Facilities; 5.11.d. - Equipment; 5.11.e. - Supplies; 5.12.b. - Mission and Organization; and 5.12.c. - Management Training.
- E) Recall and modify stricken provision of 6.1:
- The commissioner shall issue a license at no cost for EMS agencies such as, but not limited to, recognized fire departments seeking licensure as Rapid Response - BLS or

Rapid Response - ALS service provided the fire department rapid response service does not charge a fee for services rendered. Fire department rapid response services shall comply with application and documentation requirements of activities and practices as noted in Section 64-48-3, 64-48-4, 64-48-5, and 64-48-6 of these rules. EMS agencies providing Rapid Response service for a fee shall be subject to payment of all fees and inspections as otherwise required by these rules. Nothing in these rules shall be deemed to prohibit members of a recognized fire department from providing basic first aid, CPR, manpower, or appropriate assistance in time of emergency. Recognized fire departments and their members providing these basic response services shall not be required to obtain licensure under these rules.

F) Modify 14.1.a.3. to read as follows:

14.1.a.3. For individuals who are not affiliated with an EMS agency or Recognized Fire Department, final certification credentials and the ability to provide service according to the Office of EMS "Standards of Practice for EMS Personnel" will not be granted until such time as the individual becomes affiliated with either an EMS agency and its associated medical director or a recognized fire department.

G) Modify 14.2.a.7 to read as follows:

14.2.a.7. For individuals who are not affiliated with an EMS agency or Recognized Fire Department, final certification credentials and the ability to provide service according to the Office of EMS "Standards of Practice for EMS Personnel" will not be granted until such time as the individual becomes affiliated with either an EMS agency and its associated medical director or a recognized fire department.

H) *Delete Definition and Reference to RESCUE found at 2.40.*

I) Modify 5.3.a.

5.3.a. Off-Line Medical Direction. All EMS agencies shall have a county or squad medical director. In those instances where an EMS agency is unable to acquire the services of a locally-licensed physician to perform as the squad or county medical director, the Office of EMS shall appoint the regional medical director to serve on an interim basis

as the squad or county medical director. The appointment of the regional medical director shall continue until such time as the EMS agency is able to acquire the services of a locally-licensed physician.

REGISTRATION OF PUBLIC
AT
COMMITTEE MEETINGS
WEST VIRGINIA LEGISLATURE

Committee: _____ Date _____

Please print or write plainly.

NAME	ADDRESS	REPRESENTING	Please check (X) if you desire to make a statement.
Marionne K. Stone Street	100 Dee Drive	WVHCA	
Tom Susman	Chas	WV Behavioral Health Care	Providers X
Randall Lewis	P.O. Box 225 ^{WV} Teays	WURWA	

DOH - Behavioral Health Consumer
adopted Rita explained
Anderson Approve as mod

Office of Air Quality - Hazardous Waste Treatment
Joe explained pasture
adopted Karen Watson, Counsel OAQ responded to q's
Anderson Approve as mod.
linch
adopted Remove the amendment

DOH - Behavioral Health Client Rts
Ltr of withdrawal
adopted
Anderson
Anderson
Anderson Reconsider action on DOH - Behav Health
move to front of agenda

DOH - Public Water
Anderson Approved as mod

DOH - Infectious med waste
adopted Rita explained
Anderson Approve as mod

DOH - EMS
Kelly Blackwell - seem to have agreement
Anderson
Anderson
Anderson Should rec withdrawal
Req withdrawn

DOH - Benchmarking

● Rawman Approve w/tech mods

Accountants

Barry Kerber - AG willing to make tech mods
@ substantive mods

Faircloth
adopted Approve as mod

linch
moves
adopted Staff directed to prepare reports & draft bills
and put each members names on the bills

Agriculture - Eggs

Faircloth will work w/agency

DOH - Behavioral Health - Consumer

will work later
move as mod. fixed

Anderson
adopted

January 12, 1999

9:00 - 11:00 a.m.

Legislative Rule-Making Review Committee
(Code §29A-3-10)

Senate Finance Room

Earl Ray Tomblin, ex
officio nonvoting member

Robert S. Kiss, ex
officio nonvoting member

Senate

House

Ross, Chair
Anderson, Vice Chair
Bowman
Macnaughtan
Boley
Buckalew

Hunt, Chair
Linch, Vice Chair
Compton
Jenkins
Faircloth
Riggs

Pharmacy

I explained 3 mods dist. by the Bd
mod requested by Bd

Approve as mod

Richard Stevers responded to questions.
Doug Douglas, Bd of Pharmacy, responded
to questions

adopted
Anderson
Riggs
adopted

Tax - Telemarketers

I explained proposed mod

Adopt proposed mod

Approve as mod

adopted
Anderson
" adopted

DOH - EMS

Joe explained

Mark King - EMS responded to q's from the C
Kelly Blackwell, Chief Bridgeport FD addressed
the C; responded to q's
Foot of the agenda

Linch