

Secretary's Order No.: **2009-A-0004**

RE: Proposed Amendment to existing State of Delaware Air Regulation 1138: *Emission Standards for Hazardous Air Pollutants for Source Categories, Section 9.0: Hospital Ethylene Oxide Sterilizers*

Date of Issuance: January 14, 2009

Effective Date of the Amendment: February 11, 2009

I. Background:

A public hearing was held on Wednesday, December 3, 2008, at 6:00 p.m. at the DNREC Air Quality Management Office, 715 Grantham Lane, New Castle, Delaware, to receive public comment on the proposed amendment to existing Delaware Regulation 1138, *Emission Standards for Hazardous Air Pollutants for Source Categories*. To serve as a brief background for this promulgation, it should be noted that Congress sought to reduce cancer and non-cancer health risks due to the exposure to hazardous air pollutants (HAPs) in the 1990 Amendments to the Clean Air Act. Under Section 112(k) – Area Source Program, Congress mandated that the EPA identify 30 or more HAPs that posed the greatest threat to public health in urban areas, and to identify the small (i.e., “area”) sources that emit any of those pollutants.

In 1999, the EPA identified 33 HAPs that posed the greatest threat to public health. Since that time, the EPA has identified over 60 area source categories for which standards are to be promulgated. The EPA promulgated its first of these area source standards in 2006, and they are under Court-ordered deadlines to complete all promulgations by

June 2009. In December 2007, the EPA promulgated another area source standard affecting a Delaware source: the hospital ethylene oxide sterilizer standard under 40 CFR Part 63 Subpart WWWW.

The purpose of this proposed amendment to Regulation 1138 (Section 9.0) is to provide increased protection for Delaware citizens against a variety of adverse health effects, which includes problems in the proper functioning of the brain and nerves and the irritation to the eyes, skin, and mucous membranes as a result of exposure to ethylene oxide. In addition, ethylene oxide is classified as a probable human carcinogen based on cancer data, which shows increased incidences of leukemia, stomach cancer, and cancers of the pancreas. The proposed amendment will provide greater consistency between Delaware's air toxics standards and the recently promulgated federal standard (Subpart WWWW), on which this proposed amendment is heavily based. Moreover, this amendment proposes to include several more protective requirements that either currently exist in Delaware air permits, or are in similar air toxic standards found in Regulations 1138.

Of note is the fact that no members of the public attended this hearing on December 3, 2008 to voice concerns with regard to the aforementioned amendment to Delaware's existing Regulation 1138. Neither were there any comments, either written or oral, received from the public during either the pre-hearing or post-hearing phase of this

proceeding. Proper notice of the hearing was provided as required by law.

After the hearing, the Hearing Officer prepared her report and recommendation in the form of a Hearing Officer's Memorandum to the Secretary dated January 12, 2009, and that Report in its entirety is expressly incorporated herein by reference.

II. Findings:

The Department has provided a reasoned analysis and a sound conclusion with regard to this proposed regulatory action, as reflected in the Hearing Officer's Memorandum of January 12, 2009, which again is attached and expressly incorporated into this Order. Moreover, the following findings and conclusions are entered at this time:

1. The Department has jurisdiction under its statutory authority to make a determination in this proceeding;
2. The Department provided adequate public notice of the proceeding and the public hearing in a manner required by the law and regulations;
3. The Department held a public hearing in a manner required by the law and regulations;
4. The Department has reviewed this proposed amendment in the light of the Regulatory Flexibility Act, and has determined it to be lawful, feasible and desirable, and that the revisions as proposed should be applied to all Delaware citizens and

members of the regulated community equally in order to provide increased public health to Delaware's citizens, as well as to provide greater consistency between current state air toxics standards and the recently promulgated federal standard on which this proposed amendment is based;

5. Promulgation of this proposed amendment would update Delaware's requirements to be consistent with the federal requirements, thus bringing Delaware into compliance with EPA standards;
6. The Department has an adequate record for its decision, and no further public hearing is appropriate or necessary;
7. The Department's proposed regulatory amendment to Delaware's existing Regulation 1138, as published in the November 1, 2008 *Delaware Register of Regulations* and set forth within Attachment "A" hereto, is adequately supported, not arbitrary or capricious, and is consistent with the applicable laws and regulations. Consequently, it should be approved as a final regulation, which shall go into effect ten days after its publication in the next available issue of the *Delaware Register of Regulations*; and
8. The Department shall submit the proposed regulation as a final regulation to the *Delaware Register of Regulations* for

publication in its next available issue, and shall provide written notice to the persons affected by the Order.

III. Order:

Based on the record developed, as reviewed in the Hearing Officer's Memorandum dated January 12, 2009, and expressly incorporated herein, it is hereby ordered that the proposed amendments to existing Delaware Regulation 1138, *Emission Standards for Hazardous Air Pollutants for Source Categories*, be promulgated in final form in the customary manner and established rule-making procedure required by law.

IV. Reasons:

The promulgation of the aforementioned amendments to existing State of Delaware Regulation 1138 will bring Delaware into compliance with Federal standards by updating Delaware's requirements, where appropriate, to be consistent with the same, and will also result in better public health standards for Delaware's citizens.

In developing this regulation, the Department has balanced the absolute environmental need for the State of Delaware to promulgate regulations concerning this matter with the important interests and public concerns surrounding the same, in furtherance of the policy and purposes of 7 Del. C., Ch. 60.

/s/ John A. Hughes
John A. Hughes
Secretary

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MEMORANDUM

TO: John A. Hughes, Secretary

FROM: Lisa A. Vest, Hearing Officer

RE: Proposed Amendment to existing State of Delaware Air Regulation 1138: *Emission Standards for Hazardous Air Pollutants for Source Categories, Section 9.0: Hospital Ethylene Oxide Sterilizers*

DATE: January 12, 2008

I. Background:

A public hearing was held on Wednesday, December 3, 2008, at 6:00 p.m. at the DNREC Air Quality Management Office, 715 Grantham Lane, New Castle, Delaware, to receive public comment on the proposed amendment to existing Delaware Regulation 1138, *Emission Standards for Hazardous Air Pollutants for Source Categories*. To serve as a brief background for this promulgation, it should be noted that Congress sought to reduce cancer and non-cancer health risks due to the exposure to hazardous air pollutants (HAPs) in the 1990 Amendments to the Clean Air Act. Under Section 112(k) – Area Source Program, Congress mandated that the EPA identify 30 or more HAPs that posed the greatest threat to public health in urban areas, and to identify the small (i.e., “area”) sources that emit any of those pollutants.

In 1999, the EPA identified 33 HAPs that posed the greatest threat to public health. Since that time, the EPA has identified over 60 area source categories for which standards are to be promulgated. The EPA

promulgated its first of these area source standards in 2006, and they are under Court-ordered deadlines to complete all promulgations by June 2009. In December 2007, the EPA promulgated another area source standard affecting a Delaware source: the hospital ethylene oxide sterilizer standard under 40 CFR Part 63 Subpart WWWW.

The purpose of this proposed amendment to Regulation 1138 (Section 9.0) is to provide increased protection for Delaware citizens against a variety of adverse health effects, which includes problems in the proper functioning of the brain and nerves and the irritation to the eyes, skin, and mucous membranes as a result of exposure to ethylene oxide. In addition, ethylene oxide is classified as a probable human carcinogen based on cancer data, which shows increased incidences of leukemia, stomach cancer, and cancers of the pancreas. The proposed amendment will provide greater consistency between Delaware's air toxics standards and the recently promulgated federal standard (Subpart WWWW), on which this proposed amendment is heavily based. Moreover, this amendment proposes to include several more protective requirements that either currently exist in Delaware air permits, or are in similar air toxic standards found in Regulations 1138.

Of note is the fact that no members of the public attended this hearing on December 3, 2008 to voice concerns with regard to the aforementioned amendment to Delaware's existing Regulation 1138. Neither were there any comments, either written or oral, received from

the public during either the pre-hearing or post-hearing phase of this proceeding. Proper notice of the hearing was provided as required by law.

II. Summary of Hearing Record:

At the time of the hearing on December 3, 2008, Jim Snead, Engineer IV with the Air Quality Management Section of DNREC, offered the Department's 26 exhibits pertaining to the proposed amendment to Delaware's existing Regulation 1138. Since no members of the public or the regulated community attended this public hearing, a hard copy of Mr. Snead's prepared PowerPoint presentation was entered into the record as well.

For the sake of brevity, and for the Secretary's full understanding of this action, a copy of the handout provided at the public hearing (which includes a hard copy of the Power Point presentation prepared by the Department, the formal exhibit listing, a summary data sheet on ethylene oxide from the EPA, and a strikeout copy of the proposed regulations themselves) is attached hereto as Attachment "A", and is expressly incorporated herein.

It should be noted that the Department adhered to all appropriate Delaware statutes and the regulatory development process during the development of this proposed regulation. Additionally, the Department completed its review of this proposal under the Regulatory Flexibility Act, and determined that this proposed amendment promulgation is lawful, feasible and desirable, and that the revisions as proposed should be applied to all Delaware citizens and members of the regulated community

equally in order to provide increased public health to Delaware's citizens, as well as to provide greater consistency between current state air toxics standards and the recently promulgated federal standard on which this proposed amendment is based.

Again, the Department received absolutely no public comment in this matter, nor was the Air Quality Management Section asked by any business entity to incorporate such comment into the formal hearing record of this matter.

III. Conclusions and Recommendations:

Based on the above discussion, I conclude that the Department has provided appropriate reasoning regarding the need for the proposed amendment of existing Delaware Regulation 1138, *Emission Standards for Hazardous Air Pollutants for Source Categories*, and has thoroughly addressed public health issues and taken the steps necessary to protect the public health of the citizens of Delaware. Accordingly, I recommend promulgation of this proposed regulation in the customary manner provided by law.

Further, I recommend the following findings:

9. The Department has jurisdiction under its statutory authority to make a determination in this proceeding;
10. The Department provided adequate public notice of the proceeding and the public hearing in a manner required by the law and regulations;

11. The Department held a public hearing in a manner required by the law and regulations;
12. The Department has reviewed this proposed amendment in the light of the Regulatory Flexibility Act, and has determined it to be lawful, feasible and desirable, and that the revisions as proposed should be applied to all Delaware citizens and members of the regulated community equally in order to provide increased public health to Delaware's citizens, as well as to provide greater consistency between current state air toxics standards and the recently promulgated federal standard on which this proposed amendment is based;
13. Promulgation of this proposed amendment would update Delaware's requirements to be consistent with the federal requirements, thus bringing Delaware into compliance with EPA standards;
14. The Department has an adequate record for its decision, and no further public hearing is appropriate or necessary;
15. The Department's proposed regulatory amendment to Delaware's existing Regulation 1138, as published in the November 1, 2008 *Delaware Register of Regulations* and set forth within Attachment "A" hereto, is adequately supported, not arbitrary or capricious, and is consistent with the applicable laws and regulations. Consequently, it should be approved as a

final regulation, which shall go into effect ten days after its publication in the next available issue of the *Delaware Register of Regulations*; and

16. The Department shall submit the proposed regulation as a final regulation to the *Delaware Register of Regulations* for publication in its next available issue, and shall provide written notice to the persons affected by the Order.

 /s/ Lisa A. Vest .
LISA A. VEST
Hearing Officer