Cancer Cluster Investigation for DeRoyal Industries Located in New Tazewell, Tennessee

Conducted and prepared by the Tennessee Department of Health.

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Executive Summary

Based on recent studies, the U.S. Environmental Protection Agency identified a higher than usual risk of cancer around the DeRoyal Industries facility located in New Tazewell, Tennessee, due to ethylene oxide (EtO) exposure.

The Tennessee Department of Health conducted a cancer cluster investigation to see if there were more cancer cases than expected in the area surrounding the facility.

This cancer cluster investigation provided no evidence for the clustering of high numbers of leukemia, Non-Hodgkin Lymphoma, breast, or stomach cancer near DeRoyal Industries, located in New Tazewell, Tennessee. Some clustering of cancer cases in areas away from the facility were identified. Since the clustering of cancer cases was located geographically away from the facility, the increase in cancer cases was unlikely associated with EtO exposure from the facility.

Detailed findings of this investigation are presented below.

About Ethylene Oxide (EtO) and DeRoyal Industries

Ethylene oxide (EtO) is a colorless, flammable gas that is a known carcinogen, meaning it can cause cancer.[11,12] EtO has been linked to leukemia, non-Hodgkin lymphoma (NHL), stomach, and breast cancers.[12] Usually, humans are exposed to EtO by breathing it in.[12]

DeRoyal Industries uses EtO to sterilize medical equipment. The U.S. Environmental Protection Agency (EPA) identified the community near DeRoyal Industries, located at 1135 Highway 33 in New Tazewell, Tennessee, as having a higher than usual risk of cancer due to EtO emissions from the facility.[5] While the facility is currently meeting EPA safety regulations, EPA has recently determined EtO is more harmful to human health than previously understood.[5,6,7] The EPA has proposed new regulations to help better protect individuals living, working, and going to school near facilities that use EtO across the nation.[7]

About Cancer Cluster Investigations

A cancer cluster is defined as "a greater than expected number of the same or etiologically related cancer cases that occurs within a group of people in a geographic area over a defined period of time."[2,9] The inclusion of "etiologically related" in the definition takes into consideration that some cancers develop similarly in terms of risk factors, causes, or origin. "For example, exposure to the sun can cause skin cancer." [2]

The purpose of a cancer cluster investigation is to see if there are more cancer cases than expected in a particular geographic area.

Even when an increase in cancers is identified, establishing a link between a potential environmental contaminant, such as EtO, and an increase in cancer rates is unlikely[10] because:

1. Cancer is not one disease, but a group of more than 100 diseases that may have different causes, latency periods before symptoms appear, presentations and effects on the body, and more.
2. Cancer is common. 1 in 2 men and 1 in 3 women will be diagnosed with cancer in their lifetime.[1]
3. Cancer is usually not caused by one thing, but is caused by a combination of things including:
    - Age
    - Gender
    - Behavior (e.g., smoking, drinking, diet, and exercise habits)
    - Genetics
    - Environmental factors
4. There is a natural variation in rates of cancer.
5. Other factors influence rates of cancer such as:
    - Access to healthcare
    - Rates of screening for cancer
    - Socioeconomic-related factors like education, income, and more

Limitations of cancer cluster investigations:

- Small sample sizes of cancer case counts can result in unstable age-adjusted incidence rate calculations.[10]
- Cluster investigations rely on geospatial analyses which are dependent on existing administrative borders, like zip codes, county lines, or census tracts.[10] The geographic borders, selected with high uncertainty, define the population in the study and make the study susceptible to "sharpshooter fallacy" or "clustering illusion" which refers to the idea of drawing a target after the bullets are shot.[8] Anytime data is collected, clusters may be seen. In some cases, patterns could be identified where there really are none and we might focus on the similarities while ignoring differences which can lead to false conclusions.[8]
- This is an ecological study, meaning that it analyzes groups of individuals. Because ecological studies do not analyze people individually, ecological studies cannot claim to determine a specific cause of disease.[10]

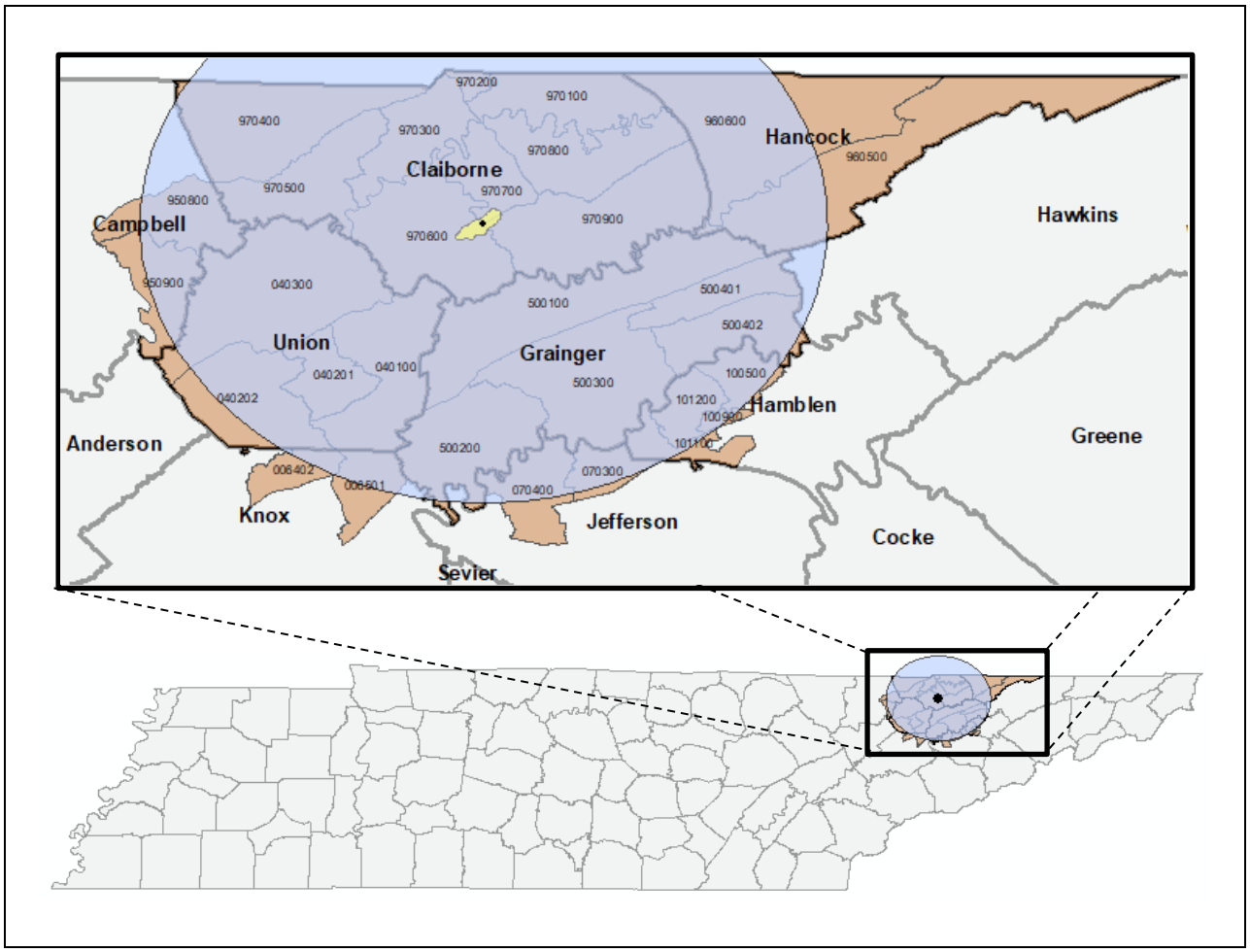
The DeRoyal Industries in New Tazewell Cancer Cluster Investigation

In this cancer cluster investigation, we looked for possible relationships between the proximity to the facility and the numbers of cancer cases in the surrounding area. To do this, we calculated age-adjusted incidence rates for new cases of leukemia, NHL, breast, or stomach cancer that were diagnosed from 2010 to 2019. It is necessary to use age-adjusted statistical measurements in cancer studies because age is a critical predicting factor of cancer. We used these age-adjusted rates to conduct geospatial statistical analyses called Hot Spot Analyses. These analyses looked for areas with elevated rates of cancer where the cancers appeared to group together (cluster), so-called “hot spots.” These analyses also identified areas with lower rates of cancer where the lower number of cancer cases appeared to group together, known as “cold spots.”

For statistical stability in Hot Spot Analyses, a sufficient sample size (population) is required. As mentioned in the limitations of cancer cluster investigations, administrative borders like census tracts are often used in these analyses but may not always best represent the study area. For example, this analysis required the inclusion of 30 census tracts to reach statistical strength. Because census tracts are based on population and the subject area of this investigation is very rural, to include 30 census tracts, the analysis had to look at a 22-mile radius around the facility. While the area of higher lifetime cancer risk identified by the EPA modeling only includes a small part of Claiborne County, the area of analysis had to expand into multiple counties (Campbell, Grainger, Hamblen, Hancock, Jefferson, Knox, and Union) to reach statistical strength.

Figure 1:

The black point on the map represents the facility's location. The light blue circle represents the 22-mile radius around the facility required for the analysis. The coral represents the census tracts in the study. The thick borders outline the county boundaries, and the thin borders outline the census tract boundaries. The area of higher lifetime cancer risk identified by the EPA modeling is in yellow.



Results

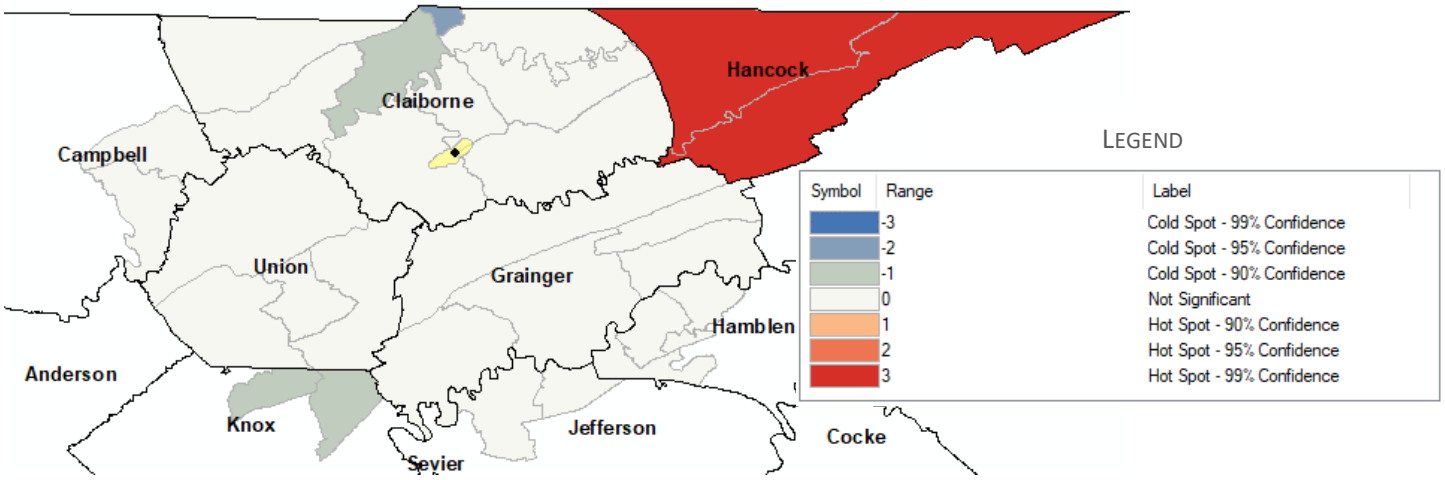
Figures 2a – 2d show the results of the hot spot analyses. The facility's location is represented by the black point. The area of higher lifetime cancer risk around the facility identified by the EPA modeling is in **yellow**.

Grey represents no clustering of cancer, **blues/greens** represent cold spots, and **reds/oranges** represent hot spots.

White represents areas outside of the study that were not analyzed.

Leukemia

Figure 2a

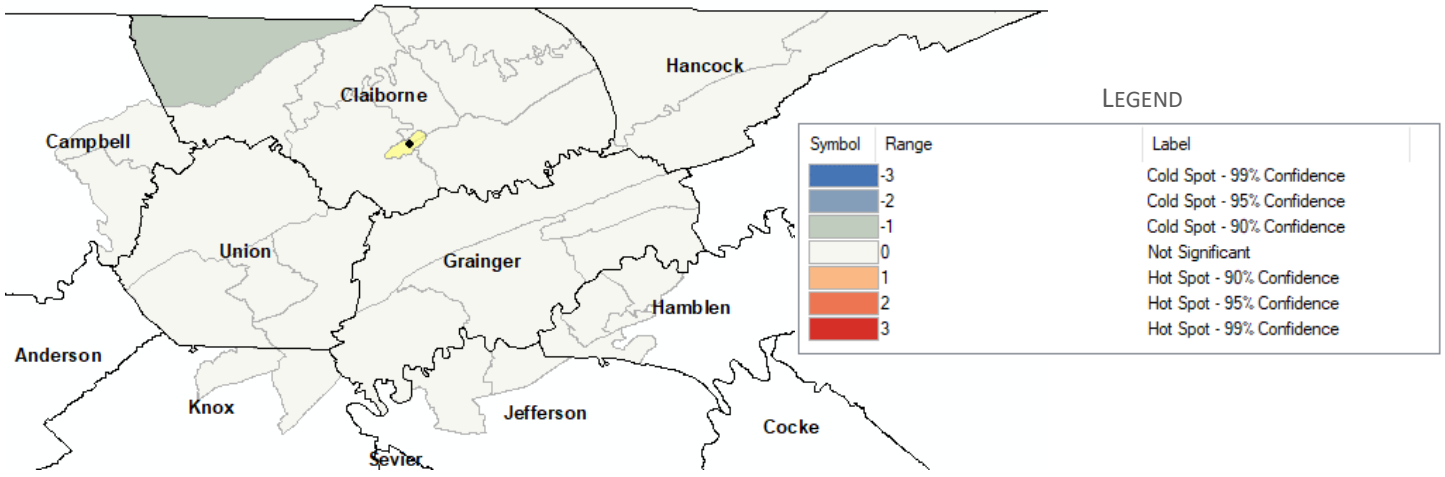


The analysis for leukemia identified hot spots and cold spots. Cold spots were identified to the north and south of the facility in Claiborne and Knox County. Hot spots were identified to the northwest of the facility in Hancock County, but these hot spots were over 15 miles away. These hot spots were outside of the EPA's higher cancer risk area, so it is unlikely the increase in leukemia cases is due to the facility's EtO emissions.

These results do not show clustering of leukemia cases near the facility.

Non-Hodgkin Lymphoma (NHL)

Figure 2b

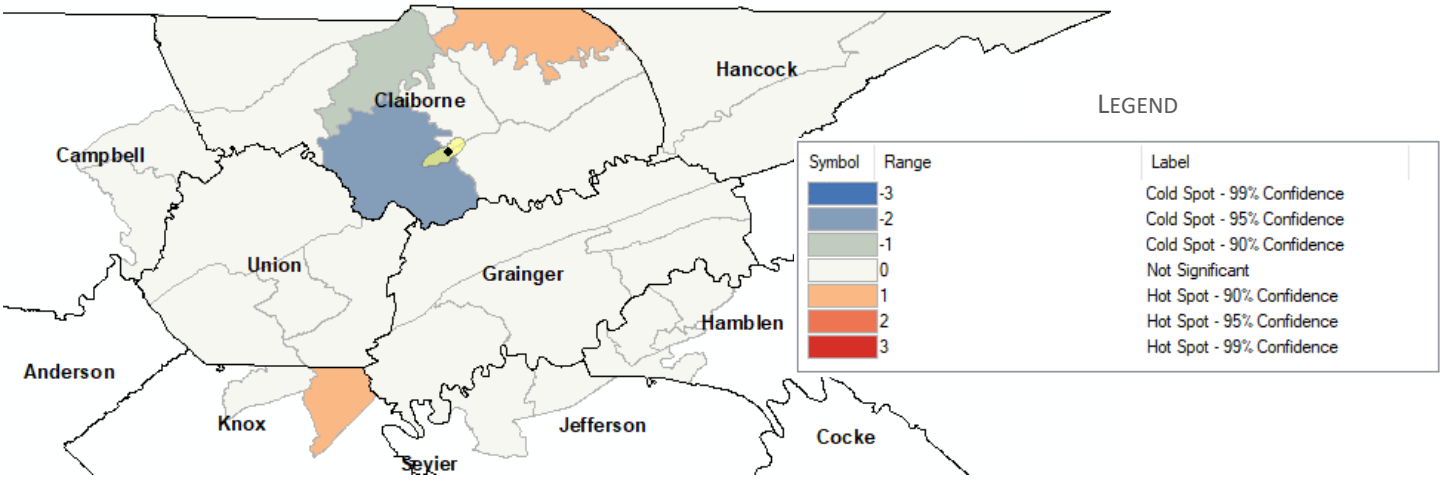


The analysis for NHL showed no hot spots. One cold spot was identified in the northwest region of Claiborne County (*See Figure 2b*).

These results do not show clustering of Non-Hodgkin's Lymphoma cases near the facility.

Breast Cancer

Figure 2c

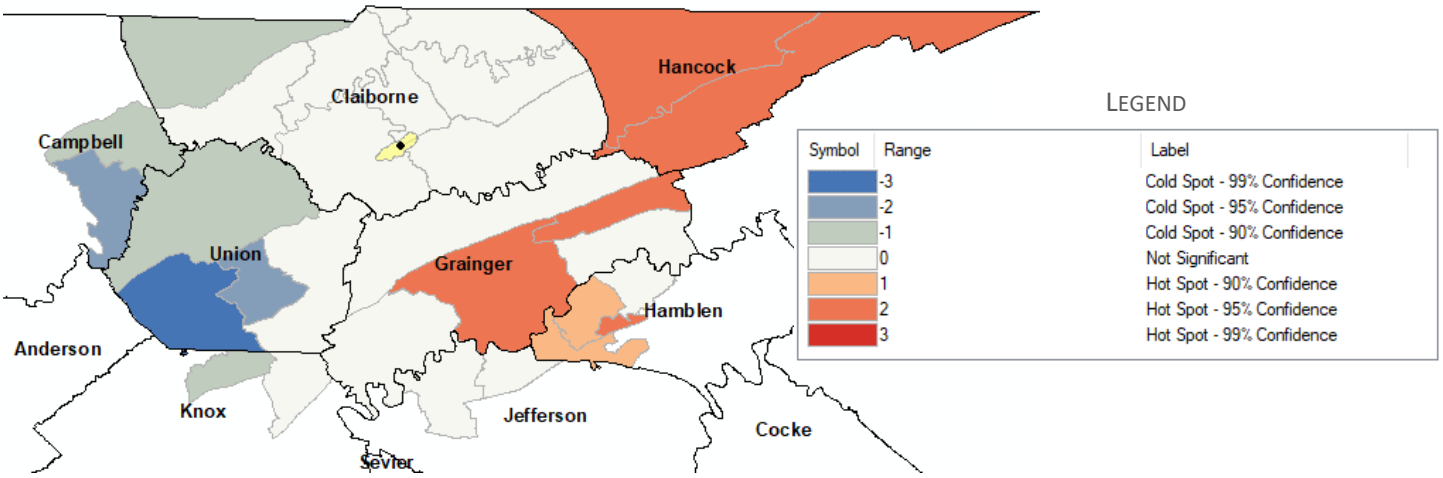


The analysis for breast cancer identified cold spots and hot spots. Cold spots were found very close to the facility in Claiborne County. Hot spots were identified further away from the facility in the northwest part of Claiborne County and in the northwest part of Knox County. The hot spots were outside of the EPA's higher cancer risk area, so it is unlikely that the increase in breast cancer cases was due to the facility's EtO emissions.

The location of the cold spots near the facility supports the conclusion the facility's EtO emissions are not causing excess numbers and/or clustering of breast cancer cases. The hot spots of breast cancer located to the north and south of the facility are too distant to be associated with EtO exposure from the facility. These results do not show clustering of breast cancer cases near the facility.

Stomach Cancer

Figure 2d



The analysis for stomach cancer cases showed no hot spots or cold spots near the facility. Hot spots

were found more than 10 miles east of the facility in Hancock, Grainger, and Hamblen County, but these regions are too far away to be affected by facility EtO emissions. Cold spots were found to the west of the facility in Claiborne, Campbell, Union, and Knox County.

These results do not show clustering of stomach cancer cases near the facility.

Summary of Results

In conclusion, the hot spot analyses did not provide evidence of clustering of leukemia, non-Hodgkin lymphoma, breast cancer, or stomach cancer near the facility during 2010-2019. Based on this conclusion, it does not appear the facility's EtO emissions are associated with higher rates of leukemia, non-Hodgkin's lymphoma, breast cancer, or stomach cancer.

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