

## **Global Green and Healthy Hospitals & Sustainable Health in Procurement Project**

\*International network of:

- Hospitals
- Health Care Facilities
- Health Systems
- Health Organizations

Dedicated to reducing environmental footprint and promoting public and environmental health

### **\*Ten interconnected goals for the health sector to address and promote greater sustainability and environmental health**

- Leadership**-Promoting Environmental Health
- Chemicals**-Substitute Harmful Chemicals with Safer Alternatives
- Waste**-Reduce, Treat and Safely Dispose of Healthcare Waste
- Energy**-Implement Energy Efficiency and Clean, Renewable Energy Generation
- Water**-Reduce Hospital Water Consumption and Supply Portable Water
- Transportation**-Improve Transportation for Patients and Staff
- Food**-Purchase and Serve Sustainability Grown, Healthy Food
- Pharmaceuticals**-Safely Manage and Dispose of Pharmaceuticals
- Buildings**-Support Green and Healthy Hospital Design and Construction
- Purchasing**-Buy Safer and More Sustainable Products

GGHH Network Comprised of 1,193 Members in 58 Countries, including USA, Belgium, Manila and Strategic partners in South America, Australia, Nepal and South Africa

Goal to protect public health from climate change, protect public health from climate change.

### **Dr. Peter Orris, MD, MPH Synopsis and Points**

He is a Professor and Chief of Service at the Occupational Health Service Institute within the University of Illinois Hospital and Health Sciences System, USA. His work has been critical to worldwide environmental health movement. He has advised communities worldwide of the dangers of toxic chemical health exposures.

## Quotes from Peter Orris:

### Ethylene Oxide: Health

#### Effects

\*History of what has been happening with EtO since 1980's

\*EPA did sampling in our area discovering an industrial sterilization company has been exposing people to cancer

\*The synonyms for ethylene oxide are listed and some of them are just trade names that are used by different companies.

-EO, ETO, EtO, anprolene, dihydrooxirene, 1,2-epoxyethane, oxacyclopropane, oxane, oxidoethane, oxirane, dimethylene oxide, ethene oxide

\*The uses of ethylene oxide began to be used as an antimicrobial pesticide in 1948. It was used primarily and built up in usage in hospitals for sterilizing hospital equipment including medical supplies, for bandages, sutures, etc.

\*It is additionally used and was used to treat spices and seasonings. This is an area that we have very little information about and would be very interested in others that might have more information about the continued use of ethylene oxide for this purpose. It used to treat commercial food processing, handling and storage. It is used as a disinfectant fumigant on a variety of food stuffs. And the primary use of ethylene oxide is as a precursor to the creation of ethylene glycol for, as a de-icer on airplanes and as a coolant in automobiles and trucks

\*The production exceeds 11 million tons a year, globally. It is a colorless gas at room temperature and normal pressure. It's in liquid when it is under higher pressure and cooled. It has a high odor threshold, so one is not able to smell it at low levels of concern. It is extremely flammable and there is a history of explosive events related to the material and it has an atmospheric persistence of 50 to 60 days as its half-life and therefore, a prolonged period of several months.

\*Most of it is used in the creation of ethylene glycol on an industrial level. It is a direct alkylating agent that disrupts the DNA of microorganisms and that's how it primarily has its sterilizing effect.

\*EPA allowed ETO to be used in fumigating items retrieved from congressional offices that were potentially contaminated with Anthrax.

\*EPA allowed ETO to be used the Department of Justice to test the fumigation process for mail received by the DOJ that may be potentially contaminated with Anthrax.

\*There are standards, both internationally and for us in the United States and consensus standards within the industry, about the use of ethylene oxide. None of these standards nor the estimate of the residuals have taken into account potential communities exposures related to the carcinogenic effect.

\*Routes of exposure of most interest to us are inhalation exposure. It is heavier than air, as some of the hydrogen sulfides are as well and therefore can cause asphyxiation both in factories and in the surrounding communities at low levels.

\*The main alternative that has been proposed and is recognized by the U.S. Food and Drug Administration as a potential alternative is hydrogen peroxide. And hydrogen peroxide seems to work equally well. Not a known human carcinogen but from an engineering point of view, the industry has raised a couple of questions that are not able to be answered as yet. And that is, first of all, ethylene oxide penetrates multiple materials better than the ethylene oxide does. I'm sorry, better than the hydrogen peroxide does. And second of all, it would appear that, increasing the size of the sterilizing chambers outside of what is now used in hospitals with hydrogen peroxide presents some engineering problems on both the chemical and mechanical engineering end that industry would say has not been solved.

\*The problems with their arguments that they have to use ethylene oxide is, that while they're using it for some 50-80% of sterilization done on these kinds of health care products and devices, they have not tested whether or not the safety, whether or not this hydrogen peroxide as a safer alternative, will work as well. What is concern is, the manufacturer applies in the U.S. to the U.S. FDA, they give them the results of their studies. Their studies are generally done with ethylene oxide alone. They demonstrate that they can bring down a six long decrease in the microorganisms present and the EPA approves that process then, as an adequate sterilization process. But unless there is pressure brought to bear on these manufacturers, they will not attempt to go out and develop the alternative technologies that may be necessary for some of the products that have difficulty being sterilized with hydrogen peroxide, or in fact, gamma radiation or others. Dr. Peter Orris: And that's what we really need to create and that is a demand that we see alternative testing, so that we know that yes, in fact, this particular type of product cannot be sterilized with anything but ethylene oxide. At the moment industry has not produced that and industry within its own processes, does not do that testing because from their point of view, they have an effective sterilizer that has been in use for 50 years. And the only increased expense in production would be if they're going to try alternative products because nobody has raised yet, the demand that these kinds of releases, should not be going on in communities around these sterilizing production processes.

\*How long does it stay in the body? That is an interesting question because of the concern about several month of exposure or several month duration. In the environment in the body it's very quick, in its half life of 45-60 minutes, so totally eliminated in a day or two. Not a constant exposure if it isn't coming from the outside.

\*The acute exposure from ethylene oxide causes numbness and tingling in the fingers and toes. It's a neurologic toxin. It also causes a feeling of being high, drunk, causes problems with higher concentration in thinking and is an irritant to the upper respiratory tract. These are all at quite substantial levels. Often above the level that you can smell. But the upper respiratory tract irritation, as you can see from this chart, will occur before you are aware that this is happening through the smelling of the ethylene oxide.

\*Chronic exposure causes both peripheral and central nervous system chronic damage occurs renal, hematologic, reproductive and carcinogenic are prominent aspects of low level ethylene oxide exposure.

\*Spontaneous abortions have been noted in hospital sterilization workers and dental hygienists who had an exposure as well. But these are again significantly higher levels that we're concerned about with respect to the communities.

**Are you aware of any state or government officially recommending the elimination and substitution of ethylene oxide? The second question is, is the testing of exposures and exposure limits up to manufacturers or is there a role for government agencies to help in the testing for alternatives sterilizing agencies?**

Well let's take the second first. This is set up differently in different countries of course, but as part of a licensing process it ought to be the expense of the manufacturer to produce these studies which then need to be reviewed by the government agency. And in fact, here in the U.S. that's what happens. The FDA, Food and Drug Administration reviews the reports from the manufacturers about their recommended and tested approaches to sterilizing the products they produce.

The problem with that is that they go to their tried-and-true tested methodology without concern about developing methodologies that are friendlier to exposure to both the workers and the communities. As to the government agency's approach, in Illinois the new governor after the elections, closed down this sterilizing facility in the western suburbs in Chicago and there is now open debate going on about exactly how the law should be written with respect to one of the obligations of that sterilizing facility in terms of what kind of internal controls, how far away from residential areas and a variety of other aspects.

On a global level, both NIOSH and OSHA and EPA in the U.S. for known human carcinogens recommends that we move to safer substitution with other products if technically feasible. And that would be covering the ethylene oxide as well. The furthest the FDA has gone in that matter in 2016 is to come out with an advisory, that they feel that hydrogen peroxide is a well-known and usable alternative.

That led most hospitals to phase out the use of ethylene oxide and there were very few hospitals any longer, about 10 hospitals in the state of Illinois. About 5% of the hospitals still use ethylene oxide. But again that's the smaller capabilities where mostly ethylene oxide is used today is for these large industrialized production processes determined by the manufacturers.

**Should we be asking manufacturers that use ethylene oxide to do their own air testing outside facilities to ensure they're not off-gassing into the environment, like Sterigenics was; and for those products, and this is a U.S. FDA approved question; that where products don't have an approved alternative for sterilization as part of their manufacturing licensing, what kinds of questions can we ask the manufacturer or processor to ensure that they're using CPO as safely as possible?**

Right now the contracting groups that do this sterilization, their trade agency has come back and said, we have to do it, the FDA makes us do it. It's the only approved process. Yes, but it's the only approved process because it's the only process that they ask for approval for, or rather the manufacturers did.

Now how to make this process that is by definition not an enclosed process, because you must take the materials out of the sterilizer and put the materials into an aerator, how we can make that process safer, is an industrial hygiene question. But I can tell you that through all of the changes that have been recommended for hospitals and with respect to changing the way that the sterilizers are constructed, etc., and exhausted. Still, they lose ethylene oxide into the atmosphere and we don't know the lower levels, we are unable to say, here's a safe level of a known carcinogen because we believe in general that every exposure increases the risk of this.

So that is our problem with respect to, for instance, Sterigenics, which is the company that we're concerned about in Willowbrook. When they put in even more controls than they had before, when this issue was raised, they resampled and they discovered that the levels were the same in the general community. There are undoubtedly other exposures to this as well that we have to define that have not yet been defined.