



OUR BREATH CAUSES CANCER?

The formaldehyde that is naturally formed in our bodies is exhaled at concentrations of up to a few parts per billion.¹ Yet 0.008 parts per billion is the inconsistent and overly conservative cancer risk value proposed by the EPA's draft Integrated Risk Information System (IRIS) risk assessment – **meaning every human breath poses an unacceptable risk of cancer.**

Experience and science tell us this simply cannot be the case. In fact, The National Academy of Sciences (NAS) issued its scientific review of the IRIS risk assessment

and found that the “EPA's assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selection and evaluating studies.”²

The NAS further provided the EPA with both specific and general recommendations in line with the World Health Organization's guidelines.

The truth is, formaldehyde is a natural part of our world – and the illogical findings of IRIS are not.

Risk assessments should be based on the best available science – not antiquated assumptions.

For information regarding the government agencies supporting these policies, go to:

The U.S. Environmental Protection Agency (www.epa.gov)
The Integrated Risk Information System (www.epa.gov/IRIS)

¹The World Health Organization

²http://www.formaldehydefacts.org/newsroom/nrc_to_epa_formaldehyde_assessment_needs_significant_improvement



RISKY BUSINESS: OVERVIEW OF INTEGRATED RISK INFORMATION SYSTEM ASSESSMENT OF FORMALDEHYDE

IRIS Risk Assessment Level: 0.008 parts per billion

Naturally Occurring Level in Humans: 0.8 to 8.0 parts per billion

In the mid-1980s, the U.S. Environmental Protection Agency (EPA) created the Integrated Risk Information System (IRIS) to facilitate the development and dissemination of risk assessments for chemicals. This platform was intended as a tool to support and guide consistent risk management decisions.

Unfortunately, the IRIS program must be overhauled to improve its scientific rigor if it wants to be credible and an asset to risk managers. In fact, the NAS and other expert panels frequently criticize IRIS assessments for their poor scientific quality – a result of the IRIS’s reliance on overly conservative default assumptions and outdated scientific information. This often results in IRIS “safe levels” that are actually below naturally occurring background levels.

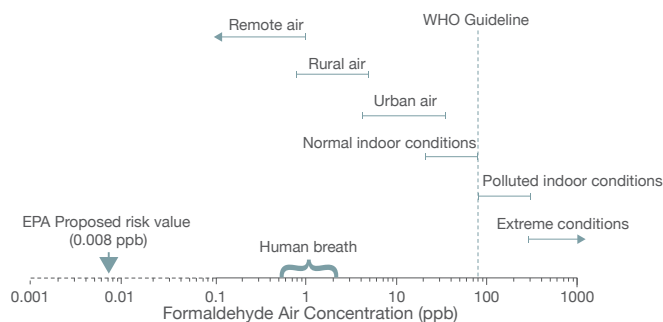
Formaldehyde, one of the simplest carbohydrate molecules, is a commercially valuable common building block compound made of hydrogen, oxygen and carbon. It is also abundant in nature. All organic life forms manufacture formaldehyde in varying amounts through metabolic processes. It is a food source for simple life forms, such as bacteria, and it does not persist in the environment, because it is either metabolized in the body or broken down by sunlight.

Applications for formaldehyde are diverse and far-reaching – as an anti-bacterial agent, preservative and highly versatile industrial building block. As the basis of a wide range of materials, formaldehyde-based technologies are an important part of the U.S. economy. Formaldehyde is a part of the glue that holds together important construction materials, such as particle board and plywood, without which modern, safe, affordable home construction would be impossible.

According to the large body of research available, the levels of formaldehyde to which most people are exposed are not high enough to cause adverse health effects. The World Health Organization (WHO) considers the carcinogenic risk of formaldehyde, when estimated from animal data, to be uncertain. This is due to the chemical’s nonlinear dose response curve, showing a disproportionately low risk at low concentrations. Further, WHO reports that humans produce formaldehyde in their bodies and exhale it at concentrations of up to a few parts per billion (ppb). The IRIS-proposed cancer risk value of 0.008 ppb would set a cancer risk value that is significantly

below the levels that naturally occur in the environment (see Figure 1). EPA’s proposed cancer risk value would suggest that human breath poses an unacceptable risk of cancer.

Figure 1: Formaldehyde Concentration in Various Environments



Source: Salthammer et al. 2010. Reprinted with permission; copyright 2010, American Chemical Society. Graphic adapted from NRC. 2011. Review of the EPA Draft IRIS Assessment of Formaldehyde, p.13.

While the extremely low level of formaldehyde in human breath is not a realistic health or environmental threat, at exposure levels between 120 ppb and 1,020 ppb, formaldehyde is known to irritate eyes, noses and throats and cause respiratory lesions.¹ Thus, to prevent sensory irritation in the general population, WHO recommends an air indoor quality guideline value for formaldehyde of 81 ppb (averaged over 30 minutes), which prevents both short-term and long-term health effects, including cancer.

Formaldehyde is extensively regulated, and mandatory government standards have been established to enable the safe production, storage, handling and use of this important building block chemical. Additionally, industry has voluntarily adopted product emission standards and developed low-emitting resins, contributing to a significant decline of indoor formaldehyde emissions in recent years.

In its press release on the report, the NAS determined that the EPA’s draft assessment was “not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies.”

Risk assessments should be based on the best available science – not antiquated assumptions.

To learn more about:

The Integrated Risk Information System – visit www.epa.gov/IRIS

Formaldehyde – visit www.formaldehydefacts.org

NAS publications – visit www.nap.edu

¹World Health Organization – WHO Guidelines for Indoor Air Quality: Selected Pollutants