

War On Science: Bogus Human Carcinogens

By Frank Schnell — March 10, 2016



In the last 15 years, EPA has invented three bogus human

carcinogens: dioxin, formaldehyde, and TCE.

Prior to the late 1990s, EPA's cancer Risk Assessment Guidelines (CRAGs) required sufficient evidence of a cause-and-effect relationship in humans before a substance could be classified as a "known human carcinogen". However, during the late 1990s, EPA modified its CRAGs to allow itself to classify substances as known human carcinogens *without* sufficient epidemiological evidence to support such a decision.

The new CRAGs were specifically designed to enable the agency to classify the "celebrity" pollutant dioxin as a human carcinogen, using the agency's speculative policies (e.g., the so-called TEF approach to the risk assessment of "dioxin-like" compounds) as surrogates for the missing evidence of carcinogenicity in humans.

Dioxin had been a "celebrity" pollutant ever since it came to public attention during the Vietnam War. The chemical's status followed, not from its known toxicity in humans (which was largely limited to chloracne, a serious skin condition associated with heavy exposures), but from its association with the second most divisive war in American history. EPA's determination to classify it as a human carcinogen had little to do with toxicology and everything to do with the politics of pollution.

In 2000, based on the new *draft* CRAGs - they were not published final until 2005 - "dioxin" (2, 3, 7, 8-TCDD) was re-classified as EPA's first *bogus* human carcinogen. The dioxin-specific modifications to EPA's CRAGs were not really applicable to any other chemicals, but that didn't matter. EPA's foot was in the door, and science *officially* no longer mattered.

In 2010, formaldehyde (HCHO) became the second bogus human carcinogen to be created by EPA, based on the unsupported and biologically implausible assumption that this chemical could cause nasopharyngeal and lymphopietic cancers in humans by inhalation. As was the case with dioxin, it was the political opportunity provided by a high-profile event rather than any scientific evidence that promoted formaldehyde from a common chemical with a long history of safe use to a "known human carcinogen." In this case, the precipitating historical event was Hurricane Katrina in 2005 and the subsequent health scare that surrounding the allegedly "toxic" trailers provided by

FEMA for the displaced survivors of the storm. And, again, as was the case with dioxin, the alarmist claims were totally inconsistent with the scientific facts.

Those facts are as follows:

HCHO is *not* a systemic, developmental, or genotoxic hazard in humans.

It is rapidly metabolized to formic acid, thence to CO₂, with a half-life in blood of only 1.5 minutes.

Systemic effects are possible only with levels of exposure that overwhelm the organism's metabolic capacity.

Only laboratory animals can be chronically exposed to such high, irritating levels of HCHO.

The adverse health effects (both acute & chronic) of inhaled formaldehyde in humans occur only at the portal of entry & are essentially limited to eye & nose irritation. Compared with endogenous production, exogenous exposure is so *low*, & metabolism is so *rapid*, that measured formaldehyde levels in the blood and tissues do not even change with exposure, e.g., with inhalation exposure as high as 15 ppm or ingestion of foods containing high levels of formaldehyde.

The lowest cancer effect level (CEL) for formaldehyde-induced nasal tumors in rats is 10,000 ppb, 6 hr. /day, 5 days/wk., for 24 months (i.e., most of a rat's lifetime). Under the same conditions, 2,000 ppb had no effect. Even short-term exposure to such high levels of formaldehyde would be intolerable to human beings.

In response to a congressional request, the National Research Council of the National Academies of Science (NAS) performed a review of EPA's evidence that formaldehyde was a human carcinogen. NAS found "no clearly established framework for establishing causation on the basis of the weight or strength of evidence."

Yet, officially, formaldehyde is still called a "known" human carcinogen.

On September 28, 2011, trichloroethylene (TCE) became the third bogus human carcinogen created by EPA. The highly publicized TCE contamination of groundwater at Camp Lejeune, NC, and the panoply of reported health effects implausibly associated with drinking that water, provided EPA (and ATSDR) with the opportunity to elevate this common chemical with a long history of safe use to the level of a known human carcinogen.

In 1989, EPA had withdrawn its cancer assessment and RfD for TCE because the evidence of serious adverse effects in humans was inconclusive. The chemical remained "under review" for the next 22 years, during which time no persuasive evidence of human carcinogenicity materialized.

This was no surprise to toxicologists for several reasons:

- (1) TCE was a very weak mutagen in mice and rats;
- (2) the rodent cancer data were irrelevant to humans because the former involved a species-specific mechanism of action (peroxisome proliferation) which did not occur in humans; and;
- (3) the proximate carcinogen in rodents was generated only at very high doses of no relevance to

the human condition. Metabolism of the relatively low doses that occur in humans does not yield a proximate carcinogen.

In 1989, all of these scientific facts mattered, even to the EPA.

COPYRIGHT © 1978-2016 BY THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Source URL: <https://www.acsh.org/news/2016/03/10/bogus-human-carcinogens>