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How Natural Variations Became Environmental Crises: The Numbers Racket

By Frank Schnell — February 15, 2016

George Washington may be the only popularly elected ruler in history who, when his supporters offered to crown him King, relinquished his power instead. Politically speaking, that was a very *unnatural* thing to do.

Historically, federal agencies have not surrendered their power, even after their congressional mandates were accomplished. Instead, they have invented new problems to solve, thereby justifying their continued existence.

The Environmental Protection Agency (EPA) was created by Congress in 1970 to write and enforce regulations designed to protect the environment and, by extension, human health. The Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of the Centers for Disease Control (CDC), was created by Congress ten years later (1980) as a non-regulatory public health information agency that analyzed the public health implications of environmental data provided by EPA and others, and wrote Public Health Assessments for concerned citizens at contaminated sites.

Although ATSDR has always been a non-regulatory agency, it has also always been a compliant stepchild of the EPA, largely because, for most of ATSDR s history, EPA was the source of both its funding and many of its personnel, especially in upper management. More importantly, both political agencies have always been more responsive to the environmental lobby than to the scientific facts, and the legitimate needs of the American People.

The Numbers Racket:

EPA and ATSDR promulgate dose-specific health guidelines (variously called MRLs, RfDs, and RfCs) which represented safe levels of ingestion and inhalation exposure to various chemicals. Both agencies also promulgate media-specific comparison values (variously called EMEGs, and RMEGS) which represented safe levels of exposure to various chemicals in various environmental media such as air, water, soil, and fish. Health Guidelines are expressed in units of dose (mg/kg b.w./day), while comparison values are expressed as environmental concentrations, e.g., parts per

billion (ppb) in air or drinking water and parts per million (ppm) in soil or fish.

Dose-specific health guidelines are converted to media-specific comparison values by simply multiplying the former by the quotient of body weight over intake rate. (Rocket science this is not.)

When they were originally created, both federal agencies had legitimate problems to solve. But, EPA quickly became a victim of its own success. As the environment became cleaner, there were fewer and fewer real environmental problems to address. So, they began inventing them, initially by just making their dose-specific health guidelines and media--specific comparison values smaller to create the impression of increased risk.

This was an on-going process so that officially safe levels of exposure gradually went from conservative, to ultra-conservative, to completely ridiculous. (As a toxicologist at ATSDR between 1993 and 2013, I privately referred to the agency s MRLs and EMEGs as funny numbers.)

The most common health guidelines are EPA s RfDs (Reference Doses for ingestion exposure) and RfCs (Reference Concentrations for inhalation exposures), and ATSDR s MRLs (Minimal Risk Levels). They are typically derived by simply dividing a threshold dose for a sensitive effect (i.e., a NOAEL or LOAEL) by safety factors that typically range from 10 10,000. (A LOAEL is a Lowest-Observed-Adverse-Effect-Level; a NOAEL is a No-Adverse-Effect-Level.) Using this safety factor approach, one can give the impression that a chemical poses a greater risk to human health by simply selecting a less serious (or even non-adverse) LOAEL or NOAEL for the numerator, or by increasing the safety factor used in the denominator, or both.

But, there is a limit to how large you can make an arbitrary safety factor without attracting unwelcome attention and looking silly. Consequently, you won t see any safety factors larger than 10,000. The preferred method for inflating apparent risk today is to base the RfD or MRL on what I personally referred to as bogus LOAELs. When I retired from ATSDR, many of the agency s funny numbers for celebrity chemicals like dioxins, PCBs, arsenic, lead, trichloroethylene and formaldehyde were based on such bogus LOAELs for non-adverse effects well within normal ranges.

Many of these bogus LOAELs were even based on effects that were not actually a consequence of the experimental exposure. And, if you remove both the A and the E from LOAEL all you have left is a LO (twitter jargon for Laugh Out Loud).
But, wait, there s more. Once you are already deriving health guidelines using bogus LOAELs for non-adverse effects within normal ranges, and excessively high safety factors, you have to come up with newer and more creative ways to further inflate the risk that is implied by health guidelines and comparison values.

Currently, that is being accomplished by eliminating altogether LOAELs, NOAELs, and even the Concept of Dose. In 2005, ATSDR set an unfortunate precedent by eliminating all 32 pages of tabulated LOAELs and NOAELs from the agency s Toxicological Profile for Lead. Those doses were replaced by Internal Lead Doses Associated with Health Effects from Selected Studies (my italics).

Two of the most important determinants of the effect that a substance will have on an organism is

(1) the body weight of that organism and (2) the frequency of the exposure. That s why Dose is typically expressed in milligrams of the substance per unit body weight per frequency of exposure, e.g., mg/kg/day. It is an established scientific fact that larger, longer-lived mammals like humans tend to be more resistant to the adverse effects of a given chemical than are smaller, shorter-lived mammals like rats.

Larger body weights effectively dilute the final concentration of the toxicant at the cellular level; slower ventilation rates effectively reduce the frequency of exposure; and, longer-lived mammals tend to have more efficient immune systems and other defense mechanisms. (That s why they live longer.)

In 1994, however, EPA came up with a new way to evaluate inhalation exposures that took into account neither body weight nor exposure frequency. (See EPA s October 1994 *Methods for Derivation of Inhalation Reference Concentrations and Application Dosimetry*) Instead, *the ratio of the blood*: gas partition coefficient of the chemical for the laboratory animal species to the corresponding value in *humans* ($(H_{b/g})_A/(H_{b/g})_H$) was used to convert a relevant (or not) NOAEL or LOAEL concentration in air into a so-called Human Equivalent Concentration or HEC.

The biological relevance of such a convoluted process would be suspect, even if sufficient data on chemical-specific blood: gas partition coefficients in animals and humans existed. But, only for only a few dozen different chemicals do blood: gas partition data exist for *both* rats and humans, and the blood: gas coefficient is *smaller* in humans than in rats almost 90% of the time. (See Table 8 on page 94 of Gargas et al, Toxicology and Applied Pharmacology, 98, 87-99 (1989).)

This would make the resulting HEC *larger* than the animal NOAEL or LOAEL (in ppm). In other words, this method would suggest that human exposure to a given chemical would almost always have *less* of an adverse impact than the same exposure would in rats. (Consider, for example, the very different effect that a squirt of RAID would have on a roach versus a human being.)

This is precisely what one would expect in any realistic comparison of the effect of the *same* inhalation exposure concentration of the*same* chemical in humans versus much smaller, faster breathing, and shorter-lived animals. But, it is precisely the *opposite* of the result that EPA wanted. The long-standing *policy* at EPA and ATSDR has been that humans are *more* susceptible than laboratory animals are to a given chemical exposure. (But, of course, *policy* is not the same thing as science.)

EPA got around this problem by introducing a purely *political policy* into the new method according to which *the value of 1.0 is used for the ratio if* $(H_{b/g})_A > (H_{b/g})_H$. In other words, if the available partition coefficient data in rats versus humans would yield an HEC that is*larger* than the corresponding animal exposure (as one would intuitively *expect* to be the case the *majority* of the time), then no conversion at all actually takes place. Rather, the HEC is, by default, set *equal to* the value in the much smaller, faster breathing, & shorter lived animal.

This intentional disregard for the effect of radically different body weights is particularly puzzling when one considers that, as long ago as 1949, it was already known that more than 30 physiological & somatic parameters were proportional to body weight (E.F. Adolph, Science, June 10, 1949, Vol. 109, pp 579-85).

If all this is confusing, it was *meant* to be. Because, when something unintelligible is expressed mathematically and claims to be scientific, the tendency is for people to *assume* that it is just over their heads and accept it uncritically.

All that really matters is that EPA s HEC method for evaluation of the risk associated with equivalent inhalation exposures will always make the health risk of that inhalation exposure in humans appear *equal to or larger* than that in rats, even though, in reality, the *opposite*is generally the case.

It is bad enough that EPA and ATSDR intentionally and cynically manipulate the value their official, safe exposure levels for the express purpose of deceiving the general public and keeping the fear alive. To make matters even worse, the general public commonly misinterprets those bureaucratically generated safe levels of exposure as legitimately established *thresholds* of effect, i.e., as strict demarcations between harmless and hazardous levels of exposure. (*Valid* NOAELs and LOAELs for sensitive effects do *approximate* such thresholds, but *not* after they are divided by safety factors of *one or more orders of magnitude* to yield official exposure guidelines.)

Environmental activists encourage this misconception by characterizing exposures above EPA s and ATSDR s conservative exposure guidelines and comparison values as dangerously elevated, unsafe, or variations thereof.

In the next article [1], I show how natural variations became manufactured crises before numbers were so easy to get - by using the language of science against science.

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