Dear Dr. Beck,

Attached is a public comment on Risk Assessment in MS-Word containing a figure in PNG format. My son Horst put it together for me and this is the reason I forwarded it to you.

Kindly acknowledge that you received and successfully opened all 4 pages including the figure.

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Real Science to Regulate Chemicals

A public Comment on OMB's Proposed Risk Assessment Bulletin 2006

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Cancer Risk assessment, as used by the EPA, makes up risks that do not exist. It confuses people with Junk Science so they cannot understand chemicals regulation.

Risk Assessment falsely justifies the extreme Superfund program but has proven impractical to regulate the really toxic pesticides, arsenic and radon. These remain regulated 100 times less stringently by a pre-EPA regulation based on real science.

This policy reflects a major collapse of our democratic system under an environmental fear campaign and the first use of Junk Science. A review was mandated many years ago but never happened.

We here urge a TRUTH COMMISSION, without fault finding, so the American Public, after 30 years of misinformation, can participate in an informed debate.

How Junk Science became the Official Environmental Science

In the 1960s and 70s Congress responded to an environmentalist fear campaign about cancer risks from trace exposures (the "no threshold" concept) first with the Delaney Amendment and then with the creation of the EPA. No evidence for these new risks existed. We were told that we "cannot afford to wait for the scientific evidence". Congress rushed ahead without science advice and without the feasibility of such regulation. In retrospect, Congress legislated Junk Science with these two hasty legislations and made it inevitable that the Government would eventually sponsor Junk Science and false science advice. No one has found a way admit and correct this error.

EPA, given unsupervised control over environmental science defined the "No Threshold" concept the basis of its Risk Assessment and then used its funding power to create a pliant new scientific specialty: environmental epidemiology, completely dependent on EPA's funding. This establishment supports EPA's Risk Assessment in the face of heavy criticism that "No Threshold" Risk Assessment violates basic standards of science.

Real Toxicity and the Critics of Junk Science

Criticism of what became known as Junk Science (1) has clarified over the last years. An investigative study by Gary Taubes in the journal SCIENCE describes how epidemiologists routinely misinterpret negative results as "Risk" (2). The EPA Science Advisory Board, created by Congress to advise it, reported several times that "evidence

does not permit estimation of Risk" (beyond the scientifically established Lowest Effective Dose (3). A peer-reviewed editorial calls for the correction of false science advice by the National Academy in support of the use of the "No Threshold" (4). None of these serious accusations has been answered.

All epidemiological studies, particularly those on Atom Bomb Survivors and victims of arsenic poisoning in developing nations support the long-known Lowest Effective Dose, if they are correctly interpreted (4). The newly discovered Toxic Stress Response, controlling all toxic effects, now provides a molecular explanation of why toxicity is limited at the Lowest Effective Dose (5). This line of research has inherently greater precision and, most importantly, is not burdened by contoversy as is epidemiology.

The National Cancer Institute was once a major sponsor of research in Chemical Carcinogenesis, or cancer causation. It has quietly ended this sponsorship, as controversy over Risk Assessment grew. Chemical Carcinogenesis is no longer an NCI funding line item. Publications in this field have practically disappeared from the journal CANCER RESEARCH. The American Health Foundation, the major private institute for carcinogenesis research, has closed its doors.

Risk Assessment Proves Impractical to Regulate Older Chemicals

Arsenic, pesticides and radon are chemicals with real toxicity that were already regulated in 1970 when EPA was created. In 1942 the U.S. Department of Health regulated arsenic based on its Lowest Effective Dose plus a modest Margin of Safety. Congress recently reaffirmed this regulatory approach (6) but EPA has never acknowledged its existence as a lawful alternative to Risk Assessment.

It turns out that Risk Assessment could never be applied to arsenic, pesticides and radon because the resulting standards would be hundred times too stringent to be practical (see figure). EPA has therefore left those standards unchanged, or in the case of arsenic, made only a minute change (7).

The result is a patchwork of old and new that completely contradicts the need for extreme Risk Assessment-based regulation. As shown in the attached figure the SUPERFUND program would not be needed if Superfund chemicals were regulated like arsenic, pesticides or radon. Nuclear waste would become manageable. The public has never been told about this huge failure real toxicity. The public is completely unaware that the science and the legislative basis for more reasonable regulation exist but are concealed to protect the extreme, or 100 times more stringent, SUPERFUND regulation.

Cost of Junk Science

The cost of Risk Assessment-based regulation, not counting basic pre-EPA regulation, has been estimated at 100 billion some years ago (9). Added over one generation, this amounts to the cost of a Harvard education for one child per family.

The Government has always insisted that “the polluter pays”. That is completely false. Industry passes the complete cost of regulation on to the consumer. Some profit additionally from the regulatory enterprise. Industry is no longer a political weight in favor of reasonable regulation. The public is completely misinformed about the cost and who pays it.

We are concerned about an additional cost of Junk Science. Controversial new pharmaceutical treatments to reduce the risk of future disease are based on the same controversial interpretations that originated in environmental epidemiology.

Return to Real Science in Regulation

As the enclosed figure shows, Risk Assessment calculations are already based on the undisputed LOWEST EFFECTIVE DOSE. Simply dropping the calculations below the lowest effective dose will restore the toxicity assessment used by the U.S. Department of Health to regulate arsenic in 1942. EPA implicitly acknowledged the wisdom of that regulation when it left arsenic regulation almost unchanged in 2001 (8).

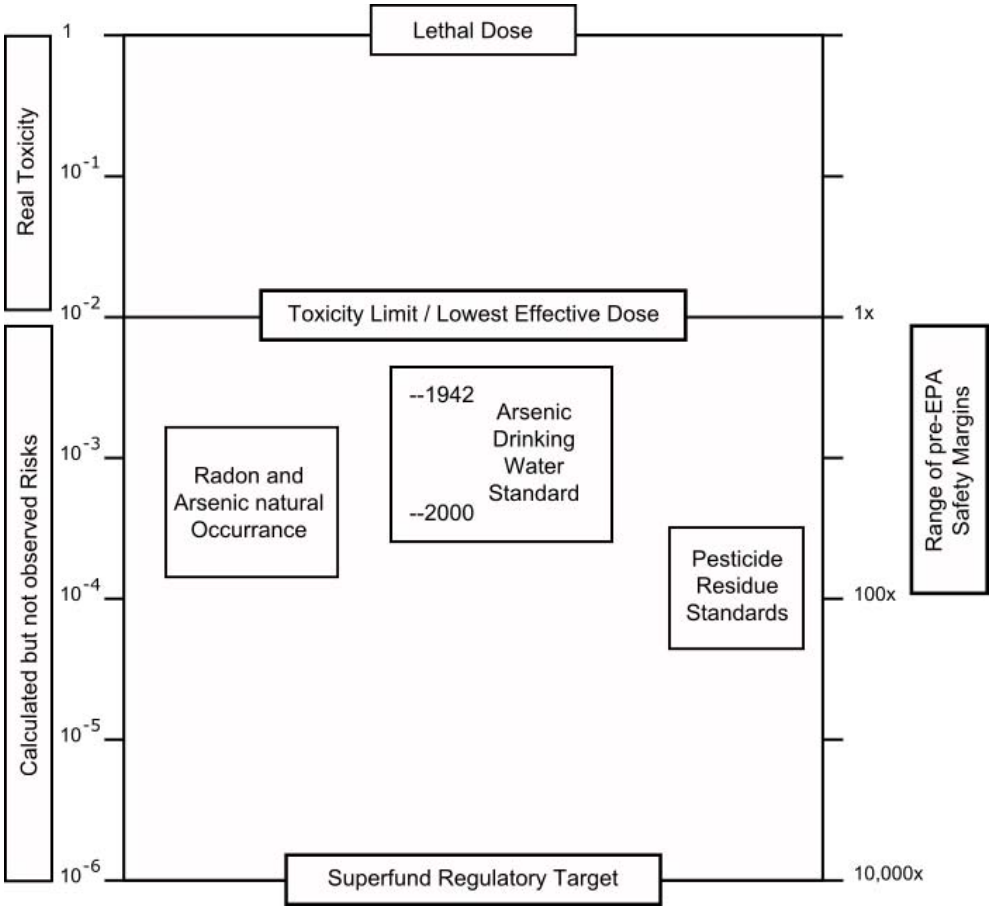
Congress has quietly reaffirmed this use of real science plus a safety margin in the 1996 Clean Water Act but has not directed the EPA to use that approach. The legal basis and the science exist for a change right now. But we do not advocate haste now.

We are dealing with a major failure of our democratic system under the combined onslaught of special interest and Junk Science. In the 1960s our political system was unprepared to deal with this new phenomenon. Forty years later the public is still completely misinformed.

We recommend a Truth Commission, fairly representing critics, to lay out the facts without attributing blame. Long suppressed facts must be presented. The public must be given time to adjust deeply held beliefs. An extended public debate as recommended by EPA Adminstrator Reilly is needed (9). Only then should the Government review the regulation of chemicals.

References

1. Huber PW: Galileo’s Revenge: Junk Science in the Court Room
2. Taubes, G: SCIENCE 269:164-169 (1995)
3. EPA Science Advisory Board /DWC/01/001; DWC/95/015
4. Stöhrer G, Callis C, et al; Regul.Toxicol Pharmacol 25:89-90 (1997)
5. Doull and Klaassen. Textbook of Toxicology
6. Safe Drinking Water Act 1996 Sect 1412 b3A
7. FR 40 CFR Parts 9, 141 and 142 ;1/22/2001
8. OECD, Paris 2001: Cost of Environmental Regulation
9. Reilly, W: Why I Propose a National Debate on Risk. EPA J 17:2-5(91)



Logarithmic representation of approximate relative toxicities, exposures and regulations