

EPA’s Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments (External Review Draft) Constitutes a Case of Deadly Obfuscation

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5.2.3.1.2.1. Cheng et al. (2006, 523122)

The following statement concerning the shape of the cancer risk model developed in the Cheng, 2006 study is set forth in the draft US EPA report named above.

"The resulting predicted cancer-mortality risk is approximately linear with daily oral intake at low doses."

This means that dose response is approximately linear for background levels of exposure, which validates the use of a linear model in the 2003 draft of the US EPA dioxin reassessment.

5.2.3.1.2.2. Warner et al. (2002, 197489)

As stated in, 5.2.3.1.2.2. Warner et al. (2002, 197489), US EPA did not develop a cancer risk slope factor using the exposure response data for a cohort of 981 women, which was analyzed in the above named study. The agency's failure to develop a cancer risk slope factor was attributed to the magnitude of the exposures of this cohort. The failure to develop a slope factor using this study maintains a continuing deficiency of the EPA's effort to estimate dioxin exposure cancer risk, that being the lack of inclusion of data for exposure of females.

5.2.3.2. Dose-Response Modeling Based on Animal Bioassay Data

The following statement concerning the results of modeling animal data pursuant to developing cancer risk slope factors is found in the report in question.

"Based on these results, EPA believes that a credible value for the BMDLHED derived from the animal studies lies in the range shown in Table 5-17 between 3.1×10^{-2} and 1.1×10^{-3} ng/kg-day. These values, which correspond to oral slope factor values of 3.2×10^5 and 9.4×10^6 per mg/kg-day, respectively, encompass the range at which elevated cancer risks can be detected for the most sensitive species, sex, and endpoints in the animal bioassay data."

The numerical range of animal cancer risk slope factors described above encompasses the human cancer risk slope factor developed by US EPA and set forth in the 2003 draft of the dioxin reassessment. US EPA has wasted several years of time and large amounts of money, the salaries of the many scientists that worked on this project, to come up with one more way of supporting its development and selection of the human cancer risk slope factor set forth in the 2003 draft of the dioxin reassessment.

The entire 1800 plus pages of the US EPA's Reanalysis... Report are mere obfuscation. Cut through the complex mathematics and assumptions and all that is left is the record of an endeavor to consume time. The period of time that passes before finalization of a dioxin reassessment based upon state of knowledge science is important to the food industry. During this period of time the food industry can continue to profit from the sale of animal fat foods. This period of time is also important to the chemical corporations, Dow and Monsanto, which have dioxin clean up and health care problems. This period of time postpones the coming of the day when these corporations will be held responsible for clean up to cancer outcome protective soil contamination standards and for health care that addresses the magnitude of dioxin exposure cancer risk. How long will US EPA deny the public the straightforward analysis of science that leads to public health protective actions? How long will US EPA continue to be controlled by the interests of the food industry and the chemical corporations? The current US EPA is a cancer causing problem for all Americans. Based upon that Agency's long history of dishonorable acts, it should be eliminated.

Viva the Revolution!

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County Governments in New York State Must Use Science to Prevent Cancer Caused by Dioxins and Other Carcinogenic POPs in US Food Supply, June 5, 2010, Donald L. Hassig, Director, Cancer Action NY

On May 6th of 2010, a report titled, "Reducing Environmental Cancer Risk: What We Can Do Now", the 2008-2009 Annual Report of the President's Cancer Panel, dated, April, 2010 was provided to the public.

This report was produced by the President's Cancer Panel, which was created by an act of Congress in 1971. The Panel is charged with monitoring the National Cancer Program. In the Cancer Panel's letter to President Barak Obama, which accompanies this document, the cochairs of the Panel wrote:

"The Panel was particularly concerned to find that the true burden of environmentally induced cancer has been grossly underestimated. With nearly 80,000 chemicals on the market in the United States, many of which are used by millions of Americans in their daily lives and are un- or understudied and largely unregulated, exposure to potential environmental carcinogens is widespread. One such ubiquitous chemical, bisphenol A (BPA), is still found in many consumer products and remains unregulated in the United States, despite the growing link between BPA and several diseases, including various cancers."

Despite the fact that this report constitutes the best effort of federal government thus far to address the matter of reducing cancer incidence at a time when cancer exists at epidemic levels in the United States, the report fails to come close to providing Americans with a state of scientific knowledge set of cancer prevention recommendations. It is outrageous that the President's Cancer Panel would choose not to make currently existing scientific knowledge concerning the presence of carcinogenic persistent organic pollutants (POPs) in the animal fat portion of the US food supply known to the American public. The US government still lags far behind the scientific and activist communities and does not deserve the respect of Americans due to its continuing failure to use scientific knowledge to prevent cancer. The President's Cancer Panel should consider the fact that it too is failing to fully inform the public about highly significant parts of cancer causation.

Addressing the contamination of the US food supply with carcinogenic POPs is a much more contentious and difficult matter than dealing with exhaust exposures to benzene, and indoor air exposure to formaldehyde which has volatilized from building products. The President's Cancer Panel chose to start with benzene and formaldehyde because they would encounter less push back by doing so. Despite the fact that the Cancer Panel has been so careful about the pollutant carcinogens that it chose to tackle, push back has been significant. The American Cancer Society and the Komen Foundation have already attacked.

Most of the agencies of federal government are engaged in promulgating information far different from that set forth in the Cancer Panel's report. The US Environmental Protection Agency, the US Food and Drug Administration, the Agency for Toxic Substances and Disease Registry, a part of the Centers for Disease Control and Prevention and the National Cancer Institute all seek to create the illusion that the food supply of the United States is safe. Familiarity with the scientific research literature leads one to conclude otherwise. The above named government entities are almost entirely controlled by the chemical industry and the food industry. These parts of government twist science into a message that serves the interests of the corporate powers. The public education pieces on the subject of dioxins that are found on the websites of the government agencies listed herein set forth false information that is utilized to mislead the public concerning the matter of dioxins in the food supply and the cancer risk imposed by these contaminants.

During the last days of the month of May, the US EPA made available to the public a draft report titled, "EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments (External Review Draft)". This is a draft US EPA report about a final

National Academy of Sciences report about a draft US EPA dioxin reassessment. The draft report is over 1800 pages in length. It contains a vast amount of mathematical information. The entire purpose of the draft report is to delay finalization of the US EPA dioxin reassessment. There is very little that is new and substantive in the draft report. It is an attempt to create confusion concerning the population level cancer outcome estimates, which are based in the dioxin exposure cancer risk analysis studies that have been published in the peer-reviewed scientific literature. US EPA and the corporate powers that control EPA are uncomfortable with the quantity of cancer risk that the science associates with dioxin exposure at current levels of food supply contamination. Thus, US EPA spreads confusion in an effort to please the corporate overlords.

US EPA is failing to fulfill its responsibility to the public by delaying producing a final dioxin reassessment. Chemical companies including Dow and Monsanto have much at stake due to their clean-up and health care liabilities. If EPA concludes that dioxin exposure imposes the quantity of cancer risk that is demonstrated by the state of knowledge science, the dioxin clean-up standard will need to be sufficiently stringent to protect against unacceptable cancer risk. The chemical corporations with dioxin and PCB clean-up problems can avoid huge costs by forcing US EPA to underestimate dioxin exposure cancer risk. Additionally, the food industry wishes to continue selling animal fat with relatively stable demand. These corporations pressure US EPA to underestimate dioxin exposure cancer risk and also to delay finalization of the dioxin reassessment. Finalization of the dioxin reassessment would trigger the next regulatory step of establishing a standard for safe dioxin levels in foods. The food industry wants to hold off that day as long as possible because current dioxin levels in food are not safe.

The US EPA is controlled by corporate interests to the extent that it is incapable of acting to protect public health as directed by current scientific knowledge concerning dioxin exposure and cancer outcome at the population level. The "Reanalysis..." report is merely a time buying device utilized to please the corporate stakeholders.

New York State's county public health departments must step in to use existing scientific knowledge to prevent cancer by educating residents concerning strategies for reducing exposure to carcinogenic POPs. During the course of the past year Cancer Action NY has worked to educate the health care policy makers of many counties in New York State. Extensive information constituting state of knowledge science on the subject of dioxin exposure cancer risk has been provided to the following government officials: James Crucetti, MD, Commissioner of the Albany County Public Health Department, Christine Compton, MD, prevention consultant to the Albany County Public Health Department, all members of the Albany County Board of Health, Sarah Rowden, chair of the Clinton County Legislature's Health Committee, all of the members of this committee, Paula Calkins

LaCombe, Director of the Clinton County Public Health Department, all members of the St. Lawrence County Legislature, Dr. Susan Hathaway, Director of the St. Lawrence County Public Health Department, Kate Browning, Chair of the Suffolk County Legislature's Health and Human Services Committee, and the members of this committee, Jack Proud, chair of the Oswego County Legislature's Health Committee and the members of this committee, Pam Mackesey, Chair of the Planning, Development and Environmental Quality Committee of the Tompkins County Legislature, and all of the members of this committee, as well as all of the members of the Tompkins County Legislature, James Nabywaniec, Chair of the Health and Human Services Committee of the Jefferson County Legislature, and all of the members of this committee. Cancer Action NY has requested that these county governments take on the public educational project of educating their residents concerning carcinogenic POPs exposure cancer risk and exposure reduction. Pursuant to motivating such action by these counties, we are suggesting that they consult with David O.Carpenter, MD., Director of the SUNY Albany, Institute for Health and the Environment. Hopefully, all of these county public health leaders will make use of the expert guidance that has been long provided and is always available to them from Cancer Action NY and our colleagues such as Dr. Carpenter. The time has come for local government to take action on the science to prevent cancer.

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US EPA Demonstrates Intention to Further Delay Finalization of Dioxin Reassessment Thereby Depriving the Public of the Cancer Prevention Benefits of Timely Utilization of Scientific Knowledge, Cancer Action NY, May 16, 2010

It is clear that US EPA intends to prolong the finalization of the dioxin reassessment just as the Chlorine Chemistry Council, the American Chemistry Council, the National Cattleman's Beef Association, the National Milk Producers' Federation, and the National Poultry and Food Distributors Association have advocated. US EPA failed to meet its own deadline of December 2009 for release of its report on the NAS/National Research Council report setting forth recommendations for revision of the dioxin reassessment. EPA should be focusing on finalizing the dioxin reassessment, not reporting on a report.

From what is stated below it appears that EPA plans to commence a new review of the scientific literature based upon a recently conducted literature search on the subject of dioxin dose-response. This would be preliminary to developing a new quantitative cancer risk assessment. In a matter of such complexity it is relatively easy for US EPA to do the bidding of the above named corporate associations without appearing to be acting counter to the public interest. However, one only needs to weigh the state of knowledge science to come to the conclusion that publication of a final dioxin reassessment is a critically necessary step

toward protecting the American public from exposure to carcinogenic persistent organic pollutants (POPs). US EPA should have finalized the dioxin reassessment years ago and be currently assessing the cancer risk imposed by exposure to the entire suite of POPs that contaminate animal fat produced and marketed in the United States.

Many Americans and citizens of other nations that consume animal fat produced in the United States have developed cancer due to the failure of US EPA to finalize the dioxin reassessment. Had the dioxin reassessment been finalized long ago, much greater progress would have been made on reducing human exposure to all carcinogenic POPs. The people of the Earth should go into the streets to demand accountability for this cancer epidemic that was made in the United States due to the controlling influence of corporations over government regulatory agencies such as US EPA and US FDA.

The following set of questions on the subject of quantitative cancer risk assessment for dioxin exposure was submitted by Cancer Action NY to the US EPA's National Center for Environmental Assessment in February of 2010. The answers were provided several months later.

1. Has US EPA made available to the public on a date after December 1, 2009 any report setting forth the US EPA response to the NAS report which called for supplementation of the dioxin reassessment with discussion of certain sources of uncertainty in that reassessment? EPA has not released such a report to the public at this time. EPA is thoroughly considering the recommendations of the NAS in its technical evaluation of the TCDD dose-response data and, as part of this consideration, EPA has undertaken and published an updated literature search that identified new TCDD dose-response studies. EPA requested and received public comments on the literature search results, which augmented this effort.

EPA also held a public kickoff workshop in February 2009 that included the participation of external experts in TCDD health effects, toxicokinetics, dose-response assessment, and quantitative uncertainty analysis. These experts discussed potential approaches to TCDD dose-response assessment and considerations for EPA's response to NAS. The literature search results and workshop summary can be found at the following URL:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=205603>

EPA expects to release a Draft Response to Comments Report for public review and comment and independent external peer review in the next few months. This draft report will address key recommendations of the NAS report.

2. If such a report has been made available to the public, please provide access to the report.

When released, the availability of the Draft Response to Comments Report and the start of the public comment period will be announced in the Federal Register. The draft report will be posted on EPA's Web site at: www.epa.gov/ncea .

3. Part III of the dioxin reassessment includes a risk characterization. What is the purpose of producing a risk characterization for dioxin exposure?

Risk characterization is the final phase of the health risk assessment paradigm set forth by the National Academy of Sciences in 1983. The goal of any risk characterization is to qualitatively describe the nature of the risks posed by a compound, develop a quantitative estimate of the risk (if practical) taking specific exposure information into account, and characterize the uncertainties associated with such an estimate.

4. Can the risk characterization set forth in the dioxin reassessment, which includes a determination of a cancer risk slope factor, be used to calculate population level cancer risk?

The dose-response curve for dioxin is not linear. Consequently one cannot simply multiply the oral slope factor at high exposures to calculate a population risk. The calculation must be done with an understanding of the non-linearities in the dose-response curve across the full range of doses experienced.

5. Based upon the risk characterization set forth in the dioxin reassessment, what is the estimated number of cancer cases that will be caused by dioxin exposure in the US during the upcoming 70 years? EPA has not developed such estimates.

6. Will the next draft of the dioxin reassessment include research published during the past several years (but not included in the most recent draft) which describes the predisposing to increased cancer susceptibility effect of gestational dioxin exposure on female rats? EPA has conducted and published a thorough literature search as a component of its technical evaluation of the TCDD dose-response data. EPA requested and received public comments on the literature search results, which augmented this effort. The literature search results can be found at:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=205603> .
EPA is still evaluating these data.

7. Will the next draft of the dioxin reassessment include an

explanation of how the gestational exposure referred to above might be expected to influence the numbers of cancer cases caused by dioxin exposure?

The EPA is still evaluating the TCDD dose-response data identified through the literature search. It is difficult to say whether this kind of analysis will be possible.

8. Will the next draft of the dioxin reassessment include a discussion of the varied effects of dioxin exposure depending upon the life stage at which the exposure takes place?

Per the NAS's explicit recommendation, EPA is expected to develop an oral reference dose for non-cancer effects from chronic exposure. By definition, the RfD addresses all life stages.

9. If gestational dioxin exposure imposes increased cancer susceptibility in humans just as it has been found to do in female rats could this increased cancer susceptibility be involved in causing girls as young as 10 years of age to develop breast cancer?

It is likely that our current state of the science will not be robust enough for us to be able to make such a determination.