

**Comments of Jim J. Tozzi
on behalf of the Center for Regulatory Effectiveness
concerning the NTP proposal to change the
listing of TCDD ("dioxin") in the Ninth Report on Carcinogens
to "known to be a human carcinogen"**

Before the RoC Subcommittee of the
NTP Board of Scientific Counselors

At the National Institute of Environmental Health Sciences
Research Triangle Park, North Carolina
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I am Jim J. Tozzi of Multinational Business Services, Inc. (MBS), and I am presenting comments on behalf of the Center for Regulatory Effectiveness (CRE) in Washington, D.C. MBS provides analytical support to CRE, which is comprised of a number of leading trade associations and companies that have an interest in the integrity of Federal Government processes that affect their interests and those of their customers and members.

Accordingly, my comments are directed mainly at the integrity of the NTP and Subcommittee review process. More specifically, although they are directed at dioxin, they are also aimed at the terrible government-wide precedent that could result.

My first point is that Dr. Olden directed that there be a formal "re-review" of the dioxin proposal after this Subcommittee's first review last October. Based on the Draft Background Document that has been distributed in support of the proposed listing change for dioxin, it appears that there has not been a re-review. Not a single word has been changed in the Draft Background Document. The Document does not even state that there has been a re-review, and the analysis and explanations have remained the same. All that has been done is to update the literature search in a Supplement to the Draft Background Document.

As it stood during the last review, and as it stands now, the Draft Background Document does not support the proposal to list dioxin as a "known human carcinogen". There is no finding of sufficient evidence from studies in humans which shows a causal relationship between the specific exposure and cancer. Instead, the Document relies on a hodgepodge of human, animal, and other data.

A substantial portion of the Draft Background Document consists of the 1997 IARC Monograph on dioxin and related compounds. But the IARC working group concluded that the human evidence for dioxin was "limited" rather than "sufficient", so the IARC conclusions support keeping the dioxin listing as "reasonably anticipated". The IARC working group included five U.S. agency scientists -- two from NIEHS, two from NIOSH, and one from EPA. At last year's review, Dr. Yamasaki from IARC opposed the proposed upgrade for dioxin.

In this review proceeding, the Subcommittee has one paramount charge, and that is that it must follow the definition of a “known human carcinogen” promulgated by Secretary Shalala and Dr. Olden. That definition states very clearly and without qualification that for an agent, substance or mixture to be listed as a “known human carcinogen” there must be “sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship. . . .”

The evaluation of the evidence in the Draft Background Document does not come close to satisfying this definition. There is no finding that the evidence comes within the definition, and instead the Document relies on an amalgamation of human, animal, and *in vitro* data accompanied by some biological hypotheses. The proposed listing upgrade is therefore completely unsupported and contrary to the legal criteria under which the Subcommittee must make its determinations. Therefore, the Subcommittee must vote against the proposal.

Voting against the proposal does not mean that there will not be sound scientific review of the possible hazards and risks of dioxin and related compounds and communication of those findings to the public. EPA has announced that it is approaching completion of its own re-review of dioxin and related compounds and will soon be submitting its analysis to outside scientific peer review. It can be expected that the review of EPA’s re-assessment will include review of the appropriate hazard description by a large number of scientists who are familiar with the dioxin database, including a number of expert epidemiologists.

EPA is due to release its new draft re-assessment and enter the external peer review phase in the coming year. It would be a poor use of taxpayer funds to embroil this Agency in a legal dispute over the validity of classifying dioxin as a “known human carcinogen”.

It is already established by the SOCMA judicial decision that a listing decision for the Report on Carcinogens is an agency action that is judicially reviewable. The Department would surely lose such a legal challenge because the rationale for the proposed listing change is so clearly in violation of its rules, thereby seriously damaging its credibility, as well as the credibility of this Subcommittee if it supported the nomination.

Therefore, I urge this Subcommittee to accept the recommendation made both by IARC and its representative to NTP that dioxin be classified as a reasonably anticipated carcinogen.

Thank you for your attention.