UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 14 2002

OFFICE OF
GENERAL COUNSEL

Charles J. Fromm, Esq.
Multinational Legal Services, PLLC
11 Dupont Circle, Suite 700
Washington, DC 20036

Re: *Tozzi v. EPA*, D.D.C. Civ. No. 00-2604

Dear Mr. Fromm:

On behalf of the Environmental Protection Agency, I am addressing certain concerns that your clients have raised in the above-captioned litigation. You have indicated that, upon your receipt of this letter, plaintiffs will voluntarily dismiss the above lawsuit, with prejudice, with each party to bear its own costs and fees. The agency acknowledges that a copy of this letter will be filed with the court as an exhibit to the parties' joint stipulation of dismissal.

The Deputy Administrator's December 20, 2001 memorandum to EPA senior management (copy attached) states, in part:

> Effective immediately, the draft July 1999 draft revised *Guidelines [for Carcinogen Risk Assessment]* will serve as interim guidance to EPA risk assessors preparing cancer risk assessments, superseding all previous versions of the *Guidelines*. ... Thus, while the July 1999 draft revised *Guidelines* will be the basis from which we move forward to finalize the *Guidelines*, any final cancer risk assessment may take a different approach depending on evolving science, the facts of a particular case, or comments from peer reviewers, the public or others.

EPA hereby confirms that the draft July 1999 *Guidelines* supersede all previous versions of the *Guidelines*, including the 1986 and draft 1996 guidelines.

EPA is in the process of finalizing its report, "Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related

Compounds" ("dioxin reassessment"). In the event that EPA decides to describe TCDD or other dioxins as carcinogenic to humans in the final dioxin reassessment, the agency will send a written notice by facsimile (at 202-939-6969) to the offices of Mr. Jim Tozzi by noon (Eastern) of the day preceding public release of the final dioxin reassessment.

Sincerely,

Roland Dubois
Senior Attorney

Attachment

cc: William H. Farland (w/ att.)
Linda J. Fisher (w/ att.)
Jim Tozzi (w/ att.)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 20 2001

OFFICE OF THE
ADMINISTRATOR

MEMORANDUM

SUBJECT: Finalizing the Agency's *Guidelines for Carcinogen Risk Assessment*

TO: Assistant Administrators
Associate Administrators
Regional Administrators
Science Policy Council

In 1996, the Agency proposed revisions to its 1986 *Guidelines for Carcinogen Risk Assessment (Guidelines)*. Since the 1996 proposal, we have benefitted from extensive public comment and scientific peer review, including three reviews by the Agency's Science Advisory Board (SAB). EPA staff have conducted outreach meetings with stakeholder groups and organized workshops to discuss the scientific aspects of the proposed revisions. Recently, the Science Policy Council (SPC) discussed key steps that constitute the critical path for finalization of the *Guidelines*.

Actions

The Agency is now poised to move forward to issue final *Guidelines* in 2002. However, to finalize the *Guidelines*, we must ensure that: (1) the SAB and public comments are addressed; (2) significant outstanding science policy issues are resolved; and (3) outreach to Agency stakeholders (both inside and outside of the federal government) is part of the process. SPC members are uniquely positioned to assist in the timely accomplishment of these tasks. I am, therefore, establishing the following groups:

(1) Formation of a Core Writing Group

The Agency has been well served by the Risk Assessment Forum's (RAF's) Cancer Guidelines Technical Panel in developing previous drafts of the *Guidelines*. Their efforts addressed many of the issues that have arisen as the science has evolved and science policies have been formulated. This Technical Panel developed the current July 1999 draft revised *Guidelines* and received input and encouragement from the SAB on several occasions. The Technical Panel members have been Drs. Jeanette Wiltse (Co-Chair), Vanessa Vu (Co-Chair), Karl Baetcke, James Cogliano, Vicki Dellarco, Richard Hill and Arnold Kuzmack.

To address several remaining issues and to help bring the *Guidelines* to completion, I am establishing a Core Writing Group to work directly with the SPC. The Core Writing Group will

be led by Dr. James Cogliano (ORD), who recently replaced Vanessa Vu as Co-Chair of the RAF Technical Panel, and will consist of Drs. Michael Firestone (OCHP), Al McGartland (OPEI), Margaret Stasikowski (OPPTS), Jeanette Wiltse (OW) and William Wood (RAF Staff Director). Interactions between the Core Writing Group and the RAF Technical Panel will be facilitated by Dr. David Bennett (OERR), RAF Chair. The Core Writing Group is purposefully designed to be small and dedicated to this task. Thus, Dr. Cogliano is being detailed to work full time on this issue over the next six months. All other members of the Core Writing Group indicated their willingness and availability to invest the time necessary to get the job done.

The Core Writing Group, working in consultation with the RAF's Technical Panel, is charged with developing a revised, final internal review draft of the *Guidelines* that represents Agency consensus on critical science issues, fully considers the comments from the SAB and the public, and reflects science policy concerns which are key to successful implementation of the *Guidelines*. The issues to be addressed by the Core Writing Group include, but are not limited to, (1) the nature and use of default assumptions; (2) definition and application of hazard descriptors; (3) identification of carcinogenic mode(s) of action and, in particular, consideration of relevancy for children; and (4) guidance on the use of the margin of exposure analysis.

The Core Writing Group will report directly to an *Ad Hoc* SPC Cancer Guidelines Advisory Committee (discussed below). The goal is to have revised *Guidelines* ready for SPC review by the end of April 2002, followed by interagency review, and then final Agency clearance.

(2) Formation of an *Ad Hoc* SPC Cancer Guidelines Advisory Committee

To ensure timely resolution of major science policy issues and to assist in the development of final Agency cancer guidelines, I am establishing an *Ad Hoc* SPC Cancer Guidelines Advisory Committee. This committee will be chaired by Dr. William Farland, Interim SPC Co-Chair and Acting ORD Deputy Assistant Administrator for Science. The Committee will consist of William Muszynski (Region 2), Michael Shapiro (OSWER), Ramona Trovato (OCHP) and Vanessa Vu (OPPTS). While all SPC members are expected to assist in the effort to bring the *Guidelines* to completion, I am expecting the *Ad Hoc* Committee to work closely with the Core Writing Group to resolve issues that need SPC attention and ensure that the positions taken in the *Guidelines* are reflective of the broader SPC membership.

(3) Development of an Outreach Strategy

To bring these efforts to completion in an open and participatory manner, it is important that we develop an outreach strategy to promote interaction with key Agency constituencies who have a large stake in the *Guidelines*. It is our intent that there be "no surprises" when the final *Guidelines* are released. These stakeholder groups include Agency federal advisory committees (e.g., the Children's Health Protection Advisory Committee and the SAB), industry and public interest groups. I am asking that Dr. Carl Mazza (OAR) organize a small group of SPC members or their representatives to carry out this outreach effort. An essential component of this effort was publication of a *Federal Register* Notice on November 29, 2001 that informs the public of our

intent to finalize the *Guidelines* and provides a 60-day opportunity for the public to provide additional information or comment on experience gained in applying the draft *Guidelines*.

Interim Use of the July 1999 Draft Revised Guidelines for Carcinogen Risk Assessment

Effective immediately, the July 1999 draft revised *Guidelines* will serve as interim guidance to EPA risk assessors preparing cancer risk assessments, superceding all previous versions of the *Guidelines*. The draft revised *Guidelines* and other supplementary material are available at www.epa.gov/ncea/raf/cancer.htm. As with all previous versions of the cancer risk assessment guidelines, the predominant guidance provided in the July 1999 draft revised *Guidelines* is for risk assessors to use the best science and risk assessment techniques available to them at the time a risk assessment is conducted. Thus, while the July 1999 draft revised *Guidelines* will be the basis from which we move forward to finalize the *Guidelines*, any final cancer risk assessment may take a different approach depending on evolving science, the facts of a particular case, or comments from peer reviewers, the public or others.

I know I can count on each of you to continue to support this important Agency effort and to provide timely, cogent advice to each of these three groups. Through a strong coordinated effort, I am confident we can finalize the Agency's *Guidelines for Carcinogen Risk Assessment* in 2002.

Linda J. Fisher
Deputy Administrator

cc: SPC Steering Committee
Kerry Dearfield
Lisa Matthews