

From: andre menache <andre_menache@yahoo.com>
To: <fkammerer@oehha.ca.gov>
Date: 8/18/2010 2:30 AM
Subject: Green Chemistry Initiative

Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Pre-regulatory draft document on HAZARD TRAITS, ENDPOINTS, AND OTHER RELEVANT DATA

Let me begin by saying that you are to be commended for this excellent forward-looking initiative.

The following suggestions represent my contribution to the informal comment period

on the pre-regulatory draft regulation which ends on September 13, 2010.

I have studied the current draft document. It refers in several sections to toxicity in "humans or animals", when referring specifically to the protection of human health.

I would like to suggest that all reference to the need for animal data be removed when referring to the protection of human health, e.g. the section on Carcinogenicity states:

endocrine, genital, hematopoietic, integumentary, musculoskeletal, nervous, respiratory, special senses, and urinary systems as well as any other systemic neoplastic lesions observed in human or animal studies."

I base this suggestion on the following:

1. Animal tests are not reliably predictive for humans. Sadly, the field of regulatory toxicology consistently confuses the concept of "prediction" with the concept of "retrospective analysis" and tries to equate the two. Penicillin is safe in mice and rats but generally lethal for hamsters and guinea pigs. All four of these species are rodents. If one species of rodent is not reliably predictive for another, how can we justify relying on animal tests for humans?

Formaldehyde was discovered in 1859, yet it has taken the US health authorities 150 years to finally propose that this commonly used laboratory chemical be classified as a known human carcinogen (Department of Health and Human Services, 2009).

The confusing and inconsistent data obtained from animal tests has largely contributed to this delay in protecting public health.

2. Based on the above, I would therefore like to suggest replacing the phrase "humans or animals" (whenever it appears in the draft document)

with the following:

"evidence-based human data"

Sincerely,

Andre Menache BSc(Hons) BVSc MRCVS
Director Antidote Europe
<http://www.antidote-europe.org>

"Endpoints include, but are not limited to those indicating malignant and benign neoplasia of alimentary, cardiovascular