The Center for Regulatory Effectiveness

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September 8, 2003

Director General LEE Jong-wook World Health Organization 20 avenue Appia 1211 Geneva 27 Switzerland Director General Jacques Diouf Food and Agriculture Organization of the United Nations Viale delle Terme di Caracalla 00100 Rome, Italy

Dear Directors General:

I am writing to bring your attention to the Data Quality Act, a statute recently enacted in the United States. This statute directed the U.S. Office of Management and Budget to issue guidelines establishing the quality standards of objectivity, utility, and integrity for information that U.S. Government agencies disseminate.

It appears that the World Health Organization (WHO) and the U.N. Food and Agriculture Organization (FAO) will have to apply the standards in this Data Quality Act to medical and other scientific studies resulting from expert consultations convened by WHO/FAO in order to permit U.S. Government agencies to be legally able to rely on them or accept on their own basis any recommendations based on them.

The U.S. Office of Management and Budget guidance explains that: if an agency [of the U.S. Government], as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these [OMB] guidelines. As the U.S. Department of Agriculture (USDA) states in its data quality guidelines: These [USDA] guidelines apply not only to information that USDA generates, but also to information that USDA disseminates that was provided by or obtained from outside parties and which USDA adopts, endorses, or uses to formulate or support a regulation, guidance, or other agency decision or position. As the guidelines issued by the U.S. Department of Health and Human Services (HHS) state: The [Data Quality] Guidelines apply to substantive information disseminated by OPHS [Office of Public Health and Safety] offices and representing OPHS/HHS views.

As our enclosures explain, our specific concern is with WHO Technical Report 916, Diet, Nutrition and the Prevention of Chronic Diseases. USDA and HHS have publicly stated an

intent to base what they would include in the upcoming 2005 Dietary Guidelines for Americans in part on this WHO Report.

As our enclosures further explain, before USDA and HHS will be legally able to rely on any of the facts and analyses supporting the scientific recommendations stated in the WHO Technical Report 916, USDA and HHS will have to carry out a predissemination review (that needs to include the public involvement of all stakeholders) to identify specifically in what ways this WHO Report fails to meet the U.S. Government s data quality standards. After that review, either USDA and HHS or WHO will have to supplement this WHO Report with corrections before USDA and HHS will be able to base policy guidance on any scientific recommendations and associated facts and analyses stated in the WHO Report.

As our letters to USDA and HHS indicate, we recommend that the Secretaries of USDA and HHS write to the World Health Organization (WHO) and the U.N. Food and Agriculture Organization (FAO), the sponsors of the WHO Report. We further recommend that the Secretaries of USDA and HHS need to point out that the U.S. Government (and its agencies) cannot base their policy decisions on any facts and analyses supporting scientific recommendations stated in a WHO Report, such as this one, until the facts and analyses supporting scientific recommendations in WHO reports can be shown, through a predissemination review, to meet the U.S. Government s data quality standards. We also recommend that the Secretaries of USDA and HHS offer to work together with WHO and FAO to assist WHO and FAO institutionalize a group within WHO and FAO to assure that the medical and other scientific studies cited by any and all expert consultations convened by WHO/FAO meet the U.S. Government s data quality standards.

Thank you for considering this matter. We would appreciate being advised of any action that you take.

Sincerely,

Jim J. Tozzi Member, CRE Advisory Board

Enclosures

cc: Under Secretary Eric M. Bost, USDA Assistant Secretary Kim R. Holmes, State Mr. Carter Blakey, HHS