



JAN 5 2004

The Honorable J. W. Lee, M.D.
Director-General
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27
Switzerland

Dear Mr. Director-General:

The United States Government is pleased to once again provide the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) with comments on its Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (Report 916) which was co-released in final form by both Organizations in April 2003.

We in the United States Government are taking the opportunity now to review and provide additional comments on the 2003 version of the Report in view of the ongoing discussions within the governance venues of the WHO and FAO, particularly as it relates to WHO's global strategy on diet, physical activity and health. These comments focus on where the U.S. Government's policy recommendations and interpretation of the science differ from those of the WHO/FAO Report. While these comments are illustrative rather than comprehensive, we hope they will contribute to the global discussions that will take place within the WHO and FAO in 2004.

Our comments also reinforce our view that the role the WHO should play as a strict role as a technical agency of the United Nations to provide recommendations based on sound science to help guide Member States as they develop national public health policies appropriate to their own circumstances. Only by employing open and transparent processes that are science-based and peer-reviewed can the WHO and FAO produce a credible product. As we have said before, in our view, the WHO and FAO have not done so with Report 916.

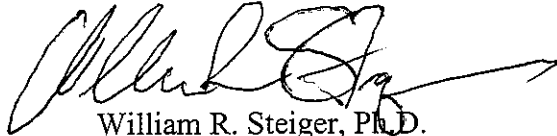
The comments in the enclosed document are an indication of the U.S. Government's continued commitment, under the leadership of Secretaries Tommy G. Thompson and Ann Veneman, to work with the WHO, FAO, and the international community to address the growing challenges of obesity and chronic diseases through evidence-based policies, better

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data and surveillance, and the promotion of sustainable strategies that focus on energy balance, individual responsibility, and strong public health approaches. As with our previous communications on Report 916, our comments represent a consensus reached within the U.S. Government through a full interagency-process.

My staff and I would be pleased to answer any questions or provide additional clarification on the enclosed document. You may reach me at (202) 690-6174. Lou Valdez, Deputy Director for Policy in the Office of Global Health Affairs, here in the Department of Health and Human Services, can also be an additional resource for you (telephone 301-443-1774 or e-mail mvaldez@osophs.dhhs.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'William R. Steiger', with a long horizontal flourish extending to the right.

William R. Steiger, Ph.D.
Special Assistant to the Secretary for
International Affairs

Enclosure

Copy to: Jacques Diouf, Ph.D.
Director-General
Food and Agriculture Organization

**Review of
“Diet, Nutrition and the Prevention of Chronic Diseases”
Report of a Joint World Health Organization (WHO)/Food and Agriculture
Organization (FAO) Expert Consultation (WHO Technical Report Series 916)
by the U.S. Departments of Health and Human Services and Agriculture**

Report 916, entitled *Diet, Nutrition and the Prevention of Chronic Diseases*, is a Report of a Joint WHO/FAO Expert Consultation, which met during the period of January – February 2002. A draft version of the *Report* was released in April 2002, and the final version was published and released in April 2003 by the Directors-General of the WHO and FAO in Rome, Italy. The United States Government (USG), through its Department of Health and Human Services (HHS), provided substantive comments on the 2002 draft version of the *Report* (April 2002).

HHS takes the opportunity now to review and provide additional comments on the 2003 final version of the *Report*, given the ongoing discussions within the governance venues of the WHO and FAO regarding the *Report* itself, and more broadly, the issues surrounding diet, nutrition, physical activity and health, including the WHO’s development of a global strategy on diet, physical activity and health. These comments delineate where the USG’s policy recommendations and the USG’s interpretation of the science differ from those of the WHO/FAO *Report*. They are illustrative rather than comprehensive and are not intended to identify all instances of such differences.

The United States supports the idea of a WHO global strategy on diet, physical activity and health. USG agencies are committed to working with the WHO, FAO, and their Member States in the development of such a strategy. However, the issues surrounding diet, nutrition, and the prevention of chronic diseases are extremely complex. In developing any regional or global strategy, it is incumbent upon United Nations organizations, governments and all stakeholders to ensure the strategy is based on the best possible scientific and public health evidence. Equally important, if countries are to embrace any resulting strategy and implement it effectively, the process for development and implementation must be transparent and participatory.

General Comments

USG agencies have a long history of using science-based reviews to develop public health policies. The success of such activities depends largely on the rigorous and critical nature of the scientific reviews and the development of policies consistent with the results of these reviews. This policy development is generally characterized by two basic traits:

- a) A comprehensive and systematic review of the available evidence. Individual studies are evaluated for scientific quality and merit, and the weight of the overall scientific evidence is based on a hierarchical plan in which intervention trials carry greater weight than observational studies. To the extent possible, this process is well-documented by using criteria accepted by the scientific

community. This approach promotes a transparent process in which stakeholders can take part and understand the decisions made.

- b) A separation of the scientific evaluation from the policy decisions. This separation is desirable to prevent the scientific review process from manipulation, or the appearance of manipulation, to support certain policy recommendations. The scientists should review and evaluate the available science without regard to policy decisions. Separately, the policymakers use this scientific review to develop policy decisions and initiatives.

A primary concern with the WHO/FAO *Report* is that it does not consistently meet these standards. The different evaluation approaches explain at least some of the inconsistencies between the conclusions of the WHO/FAO *Report* and current U.S. recommendations.

For example, under the U.S. Data Quality Act, USG agencies operate under guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated to the public. These guidelines require agencies to adopt a basic standard of quality as a performance goal and, take appropriate steps to develop a process for reviewing the quality of information before disseminating it, and to incorporate information quality criteria into agency information dissemination practices. Each agency is to ensure and establish quality at levels appropriate to the nature and timeliness of the information to be disseminated, and agencies may adopt specific standards that are appropriate to the various categories of information disseminated. Agencies are. Further, information quality is to be treated as an integral step in every aspect of the information development process. Excerpts from the HHS Agency Guidelines are located at ANNEX A.

The consultation process of the development of the WHO/FAO *Report* and the resulting *Report* itself would not meet these current U.S. data quality standards, as the process lacked a high degree of transparency, and the data and analytic results contained within the *Report* were not subject to formal, independent, external peer review, among other criteria.

Besides the questions about the evaluation of the scientific evidence, the WHO/FAO *Report* would have benefited from being strictly a review of the relevant science. In general, separation of the scientific review from policy development avoids the appearance of bias in interpreting data to support certain policy outcomes. This process also recognizes that both qualitative and semi-quantitative “judgment” must enter into policy recommendations and decisions (e.g. uncertainty, weight of evidence, and the balance of the risks and potential benefits of the policy options suggested in the current analysis) against sometimes-larger societal, economic, legal, and practical considerations. The WHO/FAO *Report* tends to mix policy and science conclusions, thus undermining this important principle designed to protect the integrity and credibility of the scientific review process.

The WHO/FAO *Report* also mixes policy recommendations not well-supported by evidence that address broad areas of trade, agricultural subsidies and advertising – areas which are outside the expertise of many of the experts who participated in the consultation and beyond the WHO and FAO’s mandates and competencies.

The numerous instances in which it appears that policy recommendations of the document are not supported with sufficient scientific evidence underscore the need for a research agenda and well-conducted studies with varied populations. The WHO and FAO are encouraged to focus on the research needed to develop the evidence required to implement strategies at the country level.

The WHO/FAO *Report* is in general agreement with the United States' perspective on the role of diet and inactivity with respect to the origins of chronic disease. However, several critical interactions are inadequately addressed or mischaracterized in the *Report*. These include (1) energy balance – balancing calories eaten with adequate physical activity; (2) personal responsibility and an individual's role in improving overall dietary choices and better integrating physical activity into individual lifestyles; and (3) the *Report's* conclusion that all current evidence suggests that the underlying determinants of non-communicable diseases and prevention solutions are largely the same for populations of developed and developing countries alike.

There is also an unsubstantiated focus on “good” and “bad” foods, and a conclusion that specific foods are linked to non-communicable diseases and obesity (e.g., energy-dense foods, high/added-sugar foods, and drinks, meats, certain types of fats and oils, and higher fat dairy products). The USG favors dietary guidance that focuses on the total diet, promotes the view that all foods can be part of a healthy and balanced diet, and supports personal responsibility to choose a diet conducive to individual energy balance, weight control and health.

Strength of Scientific Evidence

One key methodological difference lies in the framework used to evaluate the strength of scientific evidence. In the WHO/FAO *Report*, the highest level of evidence (i.e., “convincing evidence”) consists mainly of epidemiological studies. In U.S. evaluations, the greatest weight is given to intervention studies, followed by epidemiological studies. (See ANNEX B as an example.) Furthermore, epidemiological studies also have a weight-of-evidence hierarchy; for example, longitudinal studies receive greater weight than cross-sectional studies. Thus, the WHO/FAO *Report* might give a study greater scientific weight than it would receive in a similar analysis in the United States.

There are questions about the extent to which the scientific quality and relevance of individual studies cited in the WHO/FAO *Report* were evaluated. Typically, evidence-based frameworks systematically evaluate whether the design, conduct, interpretation, and reporting of study results were done in a manner that meets generally accepted principles of scientific quality. The WHO/FAO discussion of strength of the evidence does not discuss how, or if, study quality or data quality is considered. In some discussions, the cited references in support of some topics are mainly review articles rather than primary studies. Evaluation of the underlying primary research would allow a more transparent view of the pro and con arguments for a given health policy decision.

The conclusions in Section Five and the Annex on nutrient and disease relationships are not difficult to accept as observations, tentative conclusions, guidelines for intervention programs, or goals. However, to categorically state the strength of some of the evidence as “convincing” is not supported with scientific evidence.

For example, a key concern with the *Report* is that the definitions for the level of evidence are not always consistent with the level of evidence assigned to a particular risk factor. The “Strength of Evidence” criteria (Section 5) are one of the most -- if not the most -- critical components of the *Report*. The criteria for evaluating the strength of the evidence are described in the *Report*, but it is unclear what process was used to reach the reported conclusions and how specific recommendations were derived. Information as to what criteria were used to identify literature for review and the process for inclusion or exclusion of studies in support of the recommendations are also not included.

The definitions for the level of evidence are not always consistent with the level of evidence assigned to a particular risk factor. This is especially true for recommendations for the prevention of excess weight gain and obesity. As the *Report* points out, the historical reliance on the nutritional balance sheet does not provide reliable information on food consumption patterns needed to establish the link with chronic diseases. Despite this assertion, with which there is agreement, the *Report* still contains many of the inconsistencies upon which HHS commented in the April 2002 draft version of the *Report*. The most important problems are found in Table Seven (Page 63), although some of these points are incorporated into earlier sections of the text.

Links and Relationships Supported by Science

Clarity and transparency of the process used to develop the expert consultation’s recommendations and revisions would enhance the utility of the final version of the *Report*. For example, the assertion that heavy marketing of energy-dense foods or fast food outlets increases the risk of obesity is supported by almost no data. In children, there is a consistent relationship between television viewing and obesity. However, it is not at all clear that this association is mediated by the advertising on television. Equally plausible linkages include displacement of more vigorous physical activity by television viewing, as well as consumption of food while watching television. No data have yet clearly demonstrated that the advertising on children’s television causes obesity.

There are also questions about the scientific basis for several relationships stated in the WHO/FAO *Report*. These include the linking of fruit and vegetable consumption to decreased risk of obesity and diabetes, and the identification of adverse socioeconomic status, especially for women, as a causative factor for obesity.

The WHO/FAO *Report* also implies conclusions about several important relationships in the food production and supply systems that are not well supported by research. These include the role of international trade in affecting consumers’ diets and the environmental impacts of current food-production techniques.

The data are not conclusive to recommend the specific dose of physical activity for weight maintenance aside from those available for people who have lost weight and sustained those losses. In these individuals, 60 minutes of moderate physical activity daily is one of the four strategies commonly employed for weight maintenance after loss, in combination with a low-fat diet, eating breakfast, and weight-monitoring. Although it is true that the recommendation for 30 minutes of moderate physical activity on most or all days of the week is based on its health effects, there are few data that support the specific recommendation proposed in the Report for 60 minutes of physical activity to prevent obesity. The limited research that supports the 60 minutes recommendation should be acknowledged.

Data Sources and Methodology

The WHO/FAO *Report* relies solely on food supply data to evaluate changes in dietary intakes over time. We recognize that this type of exposure data is the only type of data available from all countries and regions of the world. However, the shortcomings of this approach are well known, and conclusions based on it should be examined carefully. The United States frequently uses report of food consumption by individuals as the basis for developing policies, rather than food supply data, because of known shortcomings in food supply data.

Data on food consumption patterns from individuals often provide different results for time trends than do food supply data. Using U.S. food consumption data, we find that fat intakes, as a percentage of total calories, have decreased over time. However, food supply data for the same time span suggest that fat intakes have increased. These discrepancies clearly stem from the fact that food supply data do not correct for what is not consumed, for example, for fats and oils that go into pet foods or are discarded, or oils used in deep fat frying.

In general, the USG believes that food consumption data are more reliable than food supply data. Therefore, while the authors of the WHO/FAO *Report* understandably used those data for which they had access, some of their conclusions differ from those developed using a different type of food intake database. This difference is clear from an analysis of the data, and should be considered before letting the difference in data modeling cause policy differences. In the end, the goal is to achieve the greatest public health impact by making sound decisions based on full analysis of the available data. Appropriate caution is urged in the heavy reliance that the WHO has placed on food supply data as a surrogate for intake assessments.

USG investigations into some of the public health matters addressed in this *Report* have differed in decisions about methodology and in the conclusions reached based on the evidence reviewed. For example in the United States, a recent Institute of Medicine (IOM)/National Academy of Science (NAS) determination against setting a recommended intake for "added sugars" conflicts with the identification of such a level in the WHO/FAO *Report*. The inconsistent conclusions reflect differences in evaluation criteria and processes used for the two reports.

For these reasons, in some cases U.S. scientific reviews and policy recommendations currently differ, and will continue to differ, from those in the WHO/FAO *Report*. There is recognition on the need to evaluate why these differences occur, and to work, to the extent possible, toward a common interpretation of the data and its uncertainties.

The USG shares with the WHO and FAO a determination to continue developing effective public health policies related to diet, physical activity, and chronic risk reduction. However, it is also recognized that, in those few cases where common interpretations of the data cannot be achieved, the USG will rely on its best evaluation of the scientific evidence to support policy decisions in both the domestic and international arenas.

Implementation of Strategic Actions for Promoting Healthy Diets and Physical Activity

The WHO/FAO *Report* calls on countries to develop national strategies to reduce the burden of chronic diseases that are related to diet and physical inactivity. The United States has numerous strategies that align with the recommendations in Section 6.4 of the WHO/FAO *Report*.

The United States already has mechanisms in place for evaluating health and making dietary recommendations for the nation. The *U.S. Dietary Guidelines for Americans* serves as a brief, but comprehensive, overview of authoritative nutrition advice. An external expert advisory committee reviews the scientific basis for the Guidelines. The *Dietary Guidelines* are designed to promote health and reduce disease risk for Americans based upon current scientific evidence. The *Dietary Guidelines* serve as a framework for many federal initiatives, and all federally issued dietary guidance for the general public is required to be consistent with the *Dietary Guidelines*. The Guidelines are updated every five years, and the advisory committee reviewing the science for the 2005 revision is now underway.

President George W. Bush launched a *HealthierUS* initiative in June 2002, based on the premise that increasing personal fitness leads to the improved health of our nation. *HealthierUS* has identified four key dimensions: be physically active each day, eat a nutritious diet, get preventive screenings, and make healthy choices. As part of *HealthierUS*, the President announced two new Executive Orders that direct key federal departments and agencies to develop plans to better promote fitness and health for all Americans.

Also as a part of the *HealthierUS* Initiative, the Departments of Education, Health and Human Services, and Agriculture have joined together to form the *Healthier Children and Youths* partnership. The three Departments are working together to encourage all youth to adopt healthy eating and physical activity behaviors. Another partnership associated with *HealthierUS* was established between the Departments of the Interior, Health and Human Services, and Agriculture, and the Army Corps of Engineers. These Departments are working together to promote the use of public lands and waters to enhance physical health.

At HHS Secretary Tommy G. Thompson has embraced the President's goal to build a healthier nation. *Steps to a HealthierUS* is a bold new initiative that advances the

President's *HealthierUS* goals and envisions a healthy, strong U.S. population supported by a health care system in which diseases are prevented when possible, controlled when necessary, and treated when appropriate. The *Steps to a HealthierUS* initiative aims to help Americans live longer, better, and healthier lives by reducing the burden of diabetes, overweight, obesity, and asthma, and addressing related risk factors - physical inactivity, poor nutrition, and tobacco use. *Steps* supports the President's initiative by giving the public and policy makers clear, scientifically proven steps to embrace prevention. The initiative encourages the development of innovative efforts to enhance access to services and change health outcomes within multiple communities including schools.

The centerpiece of this initiative, the *Steps* cooperative agreement, is a \$15 million program that will support innovative community-based programs that are shown to be effective in preventing and controlling chronic diseases.

Specific Scientific/Technical Comments

Although it is recognized that the final WHO/FAO *Report* was published and released in April 2003, the following specific comments demonstrate the continuing potential lack of clarity or lack of agreement on the scientific justification of statements contained within the *Report*. These issues will have an impact on countries, including the United States, that might attempt to implement actions consistent with the goals of the *Report*.

These specific scientific and technical comments are not intended to identify *all* instances in which the USG's policy recommendations and the USG's interpretation of the science differ from those of the WHO/FAO *Report*.

Section 1: Introduction

Page 1, Paragraph 2, line 7 - after "... in individuals" insert "and account for differences in disease rates among populations." The role of diet in explaining population-level differences in incidence of coronary heart disease is well-established, and adds importantly to the argument of the *Report* (See, for example, Keys, Seven Countries Study).

Page 2, Paragraph 2, lines 2-3 - Terms in the phrase "including obesity, diabetes mellitus, cardiovascular disease (CVD), hypertension and stroke, and some types of cancer" should have been re-ordered "ischemic heart disease and stroke, hypertension, diabetes, some types of cancer, and obesity" to reflect the relative importance of these conditions by the measure used generally throughout the *Report*, known as DALYs (disability-adjusted life years lost) (See Murray and Lopez, *Global Burden of Disease Study* and *World Health Report 2002*).

Section 2: Background

Page 4, Paragraph 2, lines 8-9 - As per comment on Page 1, Paragraph 2 above, ordering of these terms should be consistent with DALYs attributable to these conditions. (See Murray and Lopez, *Global Burden of Disease Study* and *World Health Report 2002*).

Page 6, Paragraph 1 and elsewhere in the document - The categories of risk factors for chronic diseases (non-modifiable, behavioral, and societal) appear inadequate to cover the

