



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 Members 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:

- ① 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.

② 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.

③ 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.

④ 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 of 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

factors that deserve attention. To these categories are added pathological conditions such as obesity, hypertension, and diabetes. This categorization omits the lipid risk factors (e.g., total cholesterol, low density lipids (LDL) cholesterol, high density lipids (HDL) cholesterol, and triglycerides), which play a crucial role in the development of coronary heart disease (CHD), but which do not fall neatly into any of the categories cited. Elsewhere in the document (for example on page 43, top bullet, "Intervening throughout life") the text introduces the term "biological risk factors," and notes that this term includes hypertension, obesity, and dyslipidemia. Clearly high LDL cholesterol and other dyslipidemias deserve a prominent place in the roster of risk factors for CHD and cardiovascular disease (CVD), and the categorization offered early in the *Report* should have been modified to encompass the lipid risk factors.

Age, sex, and genetic susceptibility are listed as non-modifiable, while risk factors for age and sex are listed as modifiable. Some of the latter are noted as "biological factors," but most of them have genetic components, e.g., dyslipidemia, hypertension, and hyperinsulinaemia.

Page 6, Paragraph 1, lines 2-3 - A consistent use of terms indicating the adverse circumstance would have been preferred. For example, "diet" → "dietary imbalance" and "alcohol consumption" → "excessive alcohol consumption" in parallel with "physical inactivity" and "tobacco use." "Dietary imbalance" and "unbalanced diet" are terms used elsewhere in the *Report*, either of which could be used here and explained if this is the point of first use, as "dietary imbalance – chiefly the relative excess of animal fats and total calories and the absolute excess of salt over desirable amounts."

Page 6, Paragraph 2 Sentence 2 - "Traditional, largely plant-based diets have been swiftly replaced by high-fat, energy-dense diets with a substantial content of animal-based foods." It is not clear to which countries this statement applies or the timeframe for such changes. The term "swiftly" could be subject to multiple interpretations. References for this statement and clarity on countries and timeframes for such dietary changes would have been useful.

Page 6, Paragraph 2, last sentence and Paragraph, line 2 - The phrase "chronic disease epidemic" needs explanation. The term "obesity epidemic" is widely used and accepted, but other chronic diseases are not usually referred to as being epidemic. It is not clear in which countries or for which chronic diseases there are epidemics.

Page 6, Paragraph 2, lines 7 and 8 - "But diet, while critical to prevention, is just one risk factor." This sentence inappropriately diminishes the importance of diet in causation of cardiovascular diseases. It would be more accurate to state, "Diet is critical to the prevention of multiple chronic diseases and is the primary cause of epidemic ischemic heart disease and stroke." (See, for example, Stamler, *Established Major Risk Factors* and Marmot and Elliott, *Coronary Heart Disease: From Aetiology to Public Health*.)

Page 6, Paragraph 2, last line: “This epidemic is now emerging....” It would be more consistent with the evidence and with the thrust of the entire *Report* to have stated, “This epidemic is now established...”

Page 6, Paragraph 3, line 3 - “but the developing countries are lagging behind....”
Actually, all countries are lagging behind, but especially the developing countries.

Page 8, Paragraph 2, line 18 - In view of recent challenges to the Barker work, “potential” and “reported” should have been inserted to read: “It also has major potential public health implications in view of the reported increased risk ...”

Page 8, Paragraph 3, line 4 - “emerging” → “occurring” on the basis discussed above.
(See Page 6, Paragraph 1, lines 2-3.)

Pages 9 through 10, Section 2.3 - “An integrated approach to diet-related and nutrition-related diseases.” – This section does not address an integrated approach as the heading indicates. It does not distinguish between “diet-related” and “nutrition-related” diseases (terms used in the heading). Also, three of the references cited in this section (35-37) are quite old (1968, 1989, and 1988).

Page 9, Paragraph, Section 2.3, last sentence - The sentence says there is complementarity in terms of public health approaches to prevent chronic diseases and those designed to prevent other diet-related and nutrition-related diseases. This conclusion does not logically follow from the preceding sentences. The distinctions between chronic disease, diet-related disease, and nutrition-related diseases are not made. Perhaps the intent was to consider chronic diseases and diet-related or nutrition-related diseases as the same, but it is not clear.

Page 9, Paragraph 2, Section 2.3 - “High-income countries accustomed to programmes designed to prevent chronic disease can amplify the effectiveness of the programmes by applying them to the prevention of nutritional deficiency and food-related infectious disease.” The meaning of this sentence and its logic are not clear. High-income countries generally do not need programs directed to nutritional deficiency.

The term “food-related infectious disease” is not defined. It is also not clear what diseases are being discussed.

Section 3: Global and regional food consumption patterns and trends

Pages 13-29, Section 3 - This section is entitled “Global and regional food consumption patterns and trends”; however, the information that is provided is largely from food availability and food supply data (i.e., from food balance sheets), mixed with some food consumption data from food consumption surveys. Food availability/supply data should not be referred to as “consumption” data. The food availability/supply data should have been presented separately from food consumption data.

Page 13, Paragraph 2, next to last sentence – The sentence “Changes in diets, patterns of work and leisure – often referred to as the “nutrition transition” - are already contributing...” is found here and elsewhere in the *Report*. The apparent citation for this statement (although not cited in this sentence) is a reference by Drewnowski and Popkin, 1997, entitled “The nutrition transition: new trends in the global diet.” The term “nutrition transition” is not a term that is often used, nor does it seem to have a specific definition.

Page 14, Paragraph 1, last sentence - “In the remainder of this chapter, therefore, the terms “food consumption” or “food intake” should be read as “food available for consumption.” The remainder of the chapter uses both of the terms “food availability/supply” and “food consumption” to mean “food availability/supply.” It also uses “food consumption” to mean “food consumption” as from individual intake of food surveys. To mix both types of data and label them by inappropriate names results in confusion.

Pages 15-21, Table 1, Figure 1, Figure 2, and Table 4 - These tables and figures include projected food/nutrient availability data for 2015 and 2030, yet not explanations as to how the projections were made.

Page 18, Paragraph 2, sentence 1 and elsewhere - The “fat-to-energy ratio (FER)” is defined as “the percentage of energy derived from fat in the total supply of energy (in kal).” This value is not a ratio. It is simply the percent of calories derived from fat.

Page 20, last Paragraph - The second sentence refers to “cold chains” but does not define this term.

The third sentence makes a general statement that is not substantiated, “Compared with the less diversified diets of the rural communities, city dwellers have a varied diet rich in animal proteins and fats, and characterized by higher consumption of meat, poultry, milk and other dairy products.” This is likely not true in many cases, such as many poor people in both urban and rural areas, many of whom do not have especially diverse diets and have little money to spend on food.

Page 23, last Paragraph, last sentence - This sentence says that fruit and vegetable consumption increased to 369 grams per capita per day in China in 1992, but does not indicate what it increased from -- what the intake was in prior years. Without this additional information, the increase is hardly noteworthy.

Page 26, top line, “Annual cereal use per person (including animal feeds)...” - The meaning is not clear. Does “use” refer to availability or consumption? What does “including animal feeds” mean? Is this the amount of cereal fed to animals that is somehow accounted for as per person availability? This information causes confusion and not useful in terms of true cereal consumption.

Page 26, next to last line – The term “off-take rates” with regard to animal carcasses requires a definition.

Page 27, Paragraph 2, Sentence 1 - “In developing countries, demand is predicted to grow faster than production...” It is not clear what the demand is for. The food products should be explained – is it for meat, milk, and other animal products?

Page 27, Paragraph 4, last sentence - “...pursue form of management conducive to sustainable exploitation, ...” The term “sustainable exploitation” appears to be an oxymoron and requires definition.

Page 27, line 3 from end and elsewhere - The term “noncommunicable diseases” is used here and in many other places in the *Report*, yet it is not defined. Is this a synonym for “chronic diseases” or does it include chronic disease and other diseases? It is preferable to use only one term for “chronic diseases” throughout the text. The *Report* title uses “Chronic Diseases” rather than noncommunicable diseases.

Page 28, bullet 1 - “There is need to monitor how the recommendations in this *Report* influence the behavior of consumers, and what further action is needed to change their diets (and lifestyles) towards more healthy patterns.” While this may a good suggestion, this issue is not addressed elsewhere in the *Report*. How would recommendations be monitored?

Section 4: Diet, nutrition and chronic diseases in context

Page 31, lines 3 through 6 - “Both undernutrition and overnutrition are negative influences in terms of disease development, and possibly a combination is even worse; consequently the developing world needs additional targeting.” It is not clear if this refers to undernutrition and overnutrition in the same persons or the same geographical areas. Some explanation is needed to indicate the logic as to why a combination of undernutrition and overnutrition will lead to increased disease development, and the *Report* should have provided references for the statement.

Page 31, Section 4.2.1 - “The four relevant factors in fetal life are...” It is not clear what these relevant factors refer to. Are these factors for disease and/or injury to infants?

A more balanced approach to this section would have been useful. While the literature on animal studies supports the concept of fetal programming, human studies have had significant methodological flaws. The authors should have at least acknowledged this in their text and included other references instead of only citing Barker. Some references to consider include the following:

- Joseph KS, Kramer MS. Review of the Evidence on Fetal and Early Childhood Antecedents of Adult Chronic Disease. *Epidemiologic Reviews* 1996; 18 (2):158-174.
- Susser M. Ordeals for the fetal programming hypothesis. The hypothesis largely survives one ordeal but not another. *BMJ* 1999; 318:885-886.
- Leon DA Fetal growth and adult disease. *Eur J Clin Nutr* 1998 (52)1:S72-78, S78-82. Symonds ME, et al. Limitations of models used to examine the

influence of nutrition during pregnancy and adult disease. *Arch Dis Child* 2000; 83:215-219.

- Godfrey K, Robinson S. Maternal Nutrition, placental growth and fetal programming. *Proceedings of the Nutrition Society* 1998;57:105-111.

The *Report* should have addressed the importance of the periconceptual period (embryonic development/organogenesis). It is important to begin to look at both the periconceptual period and intrauterine environment for clues to the origins of chronic disease.

Pages 31-32 - Fetal development and the maternal environment. High birth weight also relates to an increase in obesity in later life. Effects of increased birth weight may also be seen in childhood. It should have been mentioned in this discussion.

Pages 34-38 - The life course. Cholesterol and other lipid risk factors for CVD are not mentioned in the sections on childhood and adolescence and should be. Studies have demonstrated that elevated cholesterol in childhood and adolescence is associated with an accelerated rate of atherosclerosis and an increased risk for dyslipidemia and CHD in adulthood.

Page 34, Paragraph 4, sentence 1 - The term "relative weight" is used, but not defined.

Page 38, Paragraph 1, sentence 1 - "The "obesogenic" environment appears to be largely directed at the adolescent market, making healthy choices that much more difficult." There is no citation or explanation for this statement. Others might argue that the obesogenic environment is available to all.

Section 5: Population nutrient intake goals for preventing diet-related chronic diseases

There is no mention of the possible role of dietary supplements (e.g., multivitamin/mineral preparations) in meeting certain nutrient requirements for at-risk populations.

Pages 54-55, Section 5.1.2 - The criteria presented for ranking the strength of evidence are too liberal for the designated labels. The quality of evidence ranked as "convincing" falls far short of that descriptor. (See Annex A of these comments for an example of HHS evidence categories).

The U.S. comments to the Draft *Report*, as submitted to the WHO and FAO in July 2002, suggested that the rating of evidence needed to be reformulated.

With that done, approaches delineated in the *Report* could have been investigated in an appropriate manner to establish those that will produce desired outcome(s) and those that will not. It is unfortunate that the WHO and FAO have chosen to ignore this suggestion.

Pages 54-55 - For the categories of "convincing," "probable," "possible," and "insufficient" evidence, it appears that the criteria should be separated by "and" or "or." It is not clear if only one criterion is sufficient, or if all are needed for each category.

The Strength of Evidence criteria is one of the most, if not the most, critical component of this *Report*. Yet, as currently formulated, it is not always clear, and is unlikely to enjoy scientific consensus.

For example, under “convincing” evidence, it would seem that the availability of randomized controlled trials (RCTs) of sufficient size, duration, and quality showing consistent effects should be the primary factor and, therefore, mentioned first in the paragraph. Consistency with and among epidemiological studies is a secondary, although very important, consideration, particularly when the epidemiological studies are particularly relevant and persuasive (e.g., prospective cohort studies in the population). “Probable” strength of evidence would seem to require several clinical studies as a minimum, although because of limitations in size, etc., they do not merit a “convincing” status. Additionally, there should be a sufficient body of epidemiological studies that are particularly relevant and persuasive - not just “epidemiological studies.” The “possible” category should have a significant number of prospective studies, as conclusions from case-control and cross-sectional studies are likely to be less relevant and persuasive.

Page 56, Table 6 and elsewhere – The *Report* should provide and cite a definition of “dietary fiber” that has been generated and vetted through a scientifically defensible process. An example would be the IOM’s process for development of a definition of dietary fiber (Panel on the Definition of Dietary Fiber, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board. *Dietary Reference Intakes: Proposed Definition of Dietary Fiber*. National Academy Press, 2001, pp. 74).

Page 56, Table 6 - Ranges of population nutrient intake goals. The goal for total fat intake is stated as 15 to 30 percent of energy, and the goal for carbohydrate intake as 55 to 75 percent of energy. Average intakes at or near the lower bound of the range for total fat and at or near the upper bound for carbohydrate are likely to lead to increased triglyceride and decreased HDL levels in some populations, thereby increasing CHD risk.

Page 56, Table 6 - The population nutrient-intake goals for sodium chloride (sodium) [<5 grams/day (<2 grams/day)] are somewhat more stringent than those recommended in the United States (<6 grams/day (<2.4 grams/day)) for the U.S. food label reference values and the sodium chloride (sodium) goals of *The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC VI). However, the more stringent goals as suggested by the WHO guidelines might be more appropriate to lower blood pressure in the intended populations. They are not significantly different than the sodium goals contained within JNC VI, and might be more appropriate from a global perspective.

Page 56, Table 6, footnote e; also page 90, Paragraph 2, last sentence - The note about adjusting the iodine level of salt does not take into consideration that some people are iodine-sensitive and unable to consume this product.

Page 56, next to last paragraph, last sentence - "Highly active groups...may, however, sustain a total fat intake of up to 35 percent without the risk of unhealthy weight gain." Also found on **Page 70, Paragraph 2, last sentence**; and on **Page 89, Paragraph 4, last sentence**. This statement can be misinterpreted. Weight gain results from an imbalance of caloric intake and expenditure. The percent of calories from fat will not result in weight gain unless the total caloric intake exceeds the expenditure.

Page 57, Paragraph 2 ("Free sugars") - It would have been helpful if the term "free sugars" (although defined in footnote "c," in Table 6; page 56) had been defined at the beginning of this Section.

Page 58, Paragraph 3, Sentence 1 - "The benefit of fruits and vegetables cannot be ascribed to a single or mix of nutrients and bioactive substances." Much has been learned about the protective effects of nutrients and bioactive substances in fruits and vegetables. Thus, it would have been better to word this sentence, "The benefits of fruits and vegetables cannot, at present, be ascribed to specific nutrients or bioactive substances."

Page 58, Paragraph 3, last sentence - This states that tubers were excluded from fruits and vegetables, but does not explain why, nor does it indicate which vegetables were included in the tuber grouping. Some tubers, e.g., sweet potatoes, are good sources of nutrients. The *Report* should have noted whether or not legumes were included in the vegetable category.

Page 58, Paragraph 5, Sentence 2; also on Page 70, Paragraph 1, sentence 1 - This sentence says that walking is "moderate-intensity activity," yet this is only true if the rate of walking is about three to four miles per hour.

5.2 Recommendations for the prevention of excess weight gain and obesity

Page 61, Paragraph 1, sentence on lines 1 through 4 - The meaning of this sentence is not clear. It needs to be revised to indicate which facts are positively related to overweight and obesity, and which are negatively related.

Pages 62-63 - No clear prospective data are available to recommend the 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, data are not conclusive to support the recommendation proposed in the *Report* for 60 minutes of physical activity to prevent obesity.

An IOM report recently supported this recommendation, which based its conclusion on the assumption that one hour of moderate physical activity is the dose of daily physical activity needed to move a sedentary person to a moderate level of physical activity. However, as shown in the IOM report, obese people already have physical activity levels in the moderate

range, and prospective studies, largely of children, have failed to demonstrate that reduced energy expenditure at baseline is a risk factor for subsequent obesity. Therefore, the science base for this recommendation is weak. It seems more likely that the recommended daily dose of physical activity will be closer to 30 minutes than to 60 minutes of moderate physical activity. Furthermore, the way in which this recommendation is promoted is crucial, insofar as those who have difficulty achieving even the 30 minutes of moderate physical activity per day met the release of the IOM report with dismay.

Page 63, Table 7 - The biggest 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. 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 we agree, the *Report* still contains many of the inconsistencies upon which the United States commented on the earlier draft (see U.S. submission to the WHO and FAO in July 2002).

The most important problems are found in Table 7, although some of these points are incorporated into earlier sections of the text. We disagreed with the strength of evidence for the recommendations shown in Table 7 in the earlier draft. Because these have not been substantially altered in this draft, our disagreement remains. For example, the *Report* cites the marketing of energy-dense foods and fast-food outlets and high intake of sugar sweetened soft drinks and fruit juices as “probable” causes of obesity.

“Probable” evidence is based on “fairly consistent associations” with shortcomings such as insufficient trials. “Heavy marketing of energy-dense foods and fast-food outlets” and “High intake of sugars-sweetened soft drinks and fruit juices” are listed as “probable” evidence for promoting weight gain and obesity, but because of a lack of hard scientific evidence, the *Report* should list them as “possible” or “insufficient” evidence.

The assertion that heavy marketing of energy-dense foods 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.

With respect to fast food, there are two prospective studies, two cross-sectional studies, and one ecologic study, and the results are inconsistent. Therefore, HHS would consider this linkage as insufficient to possible, based on the *Report*’s own rules of evidence. There is only one study of the relationship of soft drinks and juice to obesity in children, and this is a prospective observational study. No such studies exist in adults. Therefore, although there is a logical mechanism to support a potential relationship between these behaviors and weight gain, the data do not provide sufficient support to be labeled “probable.”

A similar problem is found related to high glycemic foods. Only the most marginal of data suggest that these are associated with obesity, although a clearer relationship exists between these foods and diabetes control.

The word "might" in the table heading may raise questions of validity about the evidence terms ("convincing, probable, possible, insufficient"). Footnote "c" is not accurate, as it says that whole grain cereals are high in water.

Page 69, Paragraph 2, last sentence - "There is an increased risk of metabolic complications for men with a waist circumference..." It would have been more accurate to refer to increased waist circumference as a predictor for chronic disease and metabolic complications (like hyperlipidemia, hyperinsulinemia, etc.)

Page 70, Paragraph 1 - The amount of physical activity necessary to prevent obesity has not yet been established.

5.3 Recommendations for preventing diabetes

Page 72, Paragraph 1 - The mechanism for the cause of type 2 diabetes is not clearly explained. The fourth sentence refers to "process insulin," which is not defined.

Page 72, Paragraph 1, Sentence 3 - "The early stages of type 2 diabetes are characterized by overproduction of insulin." "Overproduction of insulin" should be "higher levels of insulin"; the levels are higher, but not necessarily from overproduction.

Page 73, Paragraph 2, last sentence - "The diets concerned are typically energy-dense, high in saturated fatty acids and depleted in non-starch polysaccharides (NSP)." References are needed for this statement.

Page 73, Section 5.3.3, 2nd paragraph, line 13 - "Evidence that saturated fatty acids increase risk of type 2 diabetes and that NSP are protective is more convincing than the evidence for several other nutrients which have been implicated." The word "implicated" should have been "studied." Also, the evidence needs to be assessed to determine if the risk is a function of these dietary components or related to energy balance.

Page 77, Bullet 5 - The statement is made that high-risk groups should not exceed seven percent of their calories for saturated fat, while others may consume <10 percent of calories. The *Report* should have clearly defined "high-risk groups."

5.4 Recommendations for preventing cardiovascular diseases

Page 81, Section 5.4.1, Lines 1 through 5 - Sentence unclear, dropped line or phrase?

Page 81, Section 5.4.1, Line 5 - "emerging" → "established" consistent with comments on Page 6 above.

Page 81, Section 5.4.1, Paragraph 2, Line 5: "...unbalanced diets, obesity and physical inactivity..." → "unbalanced diets, physical inactivity, and obesity" for logical sequence in that obesity is a joint consequence of unbalanced diets and physical inactivity.

Page 81, Paragraph 4, last sentence - The unhealthy practices associated with CVD should also include excess calorie intake.

Pages 82-83 - The discussion on "Fatty acids and dietary cholesterol" should include high consumption of cholesterol among the unhealthy dietary practices.

Page 83, Paragraph 3, Line 6 - "... evidence for an association of dietary cholesterol intake with CVD ..." – Shekelle et. al., Chicago Western Electric Study, should be considered and cited, with revision of text as judged appropriate.

Page 83, last paragraph - This paragraph should have included dietary cholesterol among the nutrients for which there is convincing evidence of increased risk.

Page 84, Paragraph 2 heading; also page 90, Paragraph 4 – There is no consistency in the terms used. In the heading, "NSP" appears to be used as a synonym for "dietary fiber," yet by definition NSP is a subset of dietary fiber. NSP is not mentioned in this paragraph although fiber is, and yet in the heading, the term "dietary fiber" is in parentheses after "NSP." Additionally, Page 100, Table 11 lists "fiber" rather than "NSP."

Page 85, Paragraph 4 – The *Report* should include and cite evidence from the INTERSALT Study, and should consider quantitative estimates of impact of reduced salt intake from that study, with revision of text as judged appropriate (those estimates might or might not differ from the ones presently cited).

Page 87-89, Disease specific recommendations, Fats - The *Report* should identify the high-risk groups that consume <seven percent of their calories from saturated fatty acids (rather than <10 percent) should be identified.

Page 88, Table 10. Summary of strength of evidence on lifestyle factors and risk of developing cardiovascular diseases – The *Report* should have considered dietary cholesterol in the "convincing" (not "probable") category.

Page 88, Paragraph after Table, last sentence - "Specific sources of saturated fat, such as coconut and palm oil, provide low-cost energy and may be an important source of energy for the poor." It is not clear if this means that it is acceptable for some populations to consume saturated fat. Perhaps the *Report* should have included some cautionary notes.

Page 89, Paragraph 2, Sentence 2 and Paragraph 3 - There is a recommendation for less than one percent of energy intake from trans fatty acids, six to 10 percent of energy from polyunsaturated fatty acids (PUFAs), five to eight percent of energy from n-6 PUFAs, and one to two percent of energy from n-3 PUFAs. However, the *Report* does not include any references as well as specific explanations or rationales for these recommendations.

Page 89, Paragraph 5, last sentence - The suggestion to "employ non-frying methods" should have been more specific, for example "cook without adding fat."

Page 90, Paragraph 1, line 3 - There is mention of "both forms of stroke," but the *Report* does not define them here or mention them elsewhere.

Page 90, Paragraph 5 - The second sentence says that a serving of fish should contain 200-500 mg of eicosapentaenoic and docosahexaenoic acid, but provides no indication of the amount of fish that would contain these amounts of fatty acids. The last sentence recommends consumption of plant sources of alpha-linolenic acid for vegetarians, but does not indicate what the plant sources might be. Some examples would have been helpful.

Page 90, Potassium - The intent of the recommended sodium/potassium ratio needs clarification. Is the ratio based on the goal or is it based on current intake? Based on the text in this section, we are unclear as to the significance of not listing potassium in Table 6 on page 56.

5.5 Recommendations for preventing cancer

Page 95, Paragraph 1, sentence 3 - The risk factors should have been separated with semicolons so that the sentence would read properly (i.e., diet, alcohol, and physical activity; infections; hormonal factors; and radiation).

Page 96, Paragraph 1, Cancers of the oral cavity, pharynx and oesophagus - The prevalence of oral cavity cancers, pharynx and esophagus is not only the result of "micronutrient deficiencies related to a restricted diet that is low in fruits and vegetables and animal products." There is also a high use of tobacco/betel nut products in developing countries, which also contribute to the prevalence of these cancers.

To make a statement of "consistent evidence" that consuming drinks and foods at a very high temperature increases the risk for such cancers with support of only one reference is troubling. There is no similar evidence about heat in the U.S. literature.

5.6 Recommendations for preventing dental diseases

The review of the literature is quite complete, and its recommendations reflect conclusions that one can logically draw from the literature. Of greatest interest is the discussion of the role of diet and caries. Given the significant variation among countries in exposure to fluoride in water and dental products, the conservative approach of these recommendations is probably warranted. The *Report* notes that the evidence is not particularly clear on the interaction of frequency and amount of sugar in the presence of good exposure to fluorides. As more research is conducted, these recommendations might be altered. They are reasonable for the present, however. The summary tables on caries and other oral health conditions are acceptable. See note below regarding recommendations.

Page 109, Paragraph 2 - The definitions for "sugars" (all monosaccharides and disaccharides) versus "sugar" (sucrose) seem odd. The *Report* could have used the term "sucrose" rather than "sugar" to avoid confusion.

Page 115, Dental caries - The discussion of dental caries does not include any discussion of baby bottle caries (early childhood caries), yet this is a major source of dental caries in infants and young children. At a minimum, the section on "Breastfeeding and dental caries" on page 115 should include specific advice not to put an infant to bed with a bottle containing formula, fruit juice, soft drinks, etc.

Page 116, Dental erosion - Ironically, it seems that the people with the most conscientious oral hygiene habits are facilitating erosion by brushing their teeth immediately after consuming acidic foods or beverages. The acid environment leads to demineralization of the enamel, and the toothbrush is actually removing a few microns of the outer layer of this softer enamel. This combination of diet and oral hygiene practices is a contributor to dental erosion (Moss *SI. Dental erosion. International Dental Journal* 1998;48(6):529-539). Another factor in dental erosion mentioned in the literature is gastric acid reaching the oral cavity and the teeth as a result of vomiting or gastroesophageal reflux. These conditions might or might not be related to diet/nutritional factors.

Page 119, Disease-specific recommendations - While it is important to stress that the risk of dental caries is multi-factorial and that exposure to fluoride (by diet or hygiene practices) is also very important, the *Report* does not provide any basis for the specific recommendation for maximum level of free sugar intake in the presence or absence of fluoride.

5.7 Recommendations for preventing osteoporosis

Pages 129-133 - The discussion of osteoporosis seems too brief (five pages), considering its impact on the health of older people, especially older women. Other discussions for chronic diseases ranged from six pages for cancer to 14 pages for dental diseases.

Pages 129-130 - As the consultancy decided to use osteoporotic fracture instead of bone density as the health outcome for the nutritional recommendations, it would have been more appropriate to title the chapter "Nutritional recommendations for the prevention of osteoporotic fracture" rather than "Nutritional recommendations for the prevention of osteoporosis." The WHO definition for osteoporosis is based on bone mineral density (BMD) or bone mineral content (BMC), and a review that focused on BMD or BMC (and thus osteoporosis) as the outcome might have reached different conclusions or recommendations.

Page 131, Table 18 - The table indicates a possible link between high sodium intake and increased risk of osteoporotic fractures, but there appears to be no discussion in the text of this relationship.

Page 131, Paragraph 1, Sentence 1 - It is not clear if the recommendation is for older adults to consume at least 400 mg of calcium per day. In the United States and Canada, the recommended intake for persons over age 50 years is 1,200 mg per day, which is considerably higher. An explanation could have been added as to why some countries, such as the United States, have much higher recommendations for calcium intake than Europe, particularly since change in BMD or BMC was one of the criteria used to make the U.S. recommendations (Institute of Medicine. *Dietary Reference Intakes for Calcium phosphorus, Magnesium, Vitamin D, and Fluoride*. Washington, D.C. National Academy Press, 1997).

Page 131, Paragraph 2 and Table 18 - Some studies have shown that increasing protein intake (which includes protein from animal sources) has a positive effect on BMD in the elderly (*Am. J. Clin. Nut.* 2002, 75, pp. 773-779, is one recent example), and although there is no firm consensus to date, some studies indicate that low calcium intakes adversely influence the effect of dietary protein on fracture risk. This information appears to be covered in the Table, but is not discussed in the text.

Section 6: Strategic directions and recommendations for policy and research

In general, this section is comprehensive and well-done. HHS would encourage the WHO to add more language on the role of industry and/or industry trade groups in addressing diet and nutrition, especially those representing the food and beverage industries. These groups have clear incentives in some areas (such as increasing levels of physical activity because of its association with higher energy requirements) and possible disincentives in other areas (such as promoting weight loss, because of its association with lower energy requirements, i.e., decreased food consumption). Because the food and beverage industries are likely to be affected by particular policy and programmatic directions, their concerns need to be addressed proactively. They are likely to be important factors in the success or failure of these efforts.

Page 135, - The *Report* does not discuss its policy recommendations at length. More details and support for the rationale and efficacy of these recommendations could encourage their adoption. In numerous instances, there is not sufficient scientific evidence to support the policy recommendations of the document, which underscores the need for a rigorous research agenda and well-conducted studies with varied populations.

Page 137, top of page, lines 1 through 4 - For appropriate emphasis and consistency with statements elsewhere in the *Report*, the sentence "However, ... pressing." could have been better stated by: "However, the growing problems of nutritional imbalance, physical inactivity, overweight and obesity, together with their implications for the development of cardiovascular diseases, diabetes, and other diet-related noncommunicable diseases, are now at least as pressing."

Page 139, Paragraph 1- Although there was a specific section in the text devoted to fish consumption (Section 3.5), there is no mention of fish here in the recommendations to support the availability and selection of nutrient-dense foods.

Page 139, Paragraph 5, Sentence 1 - This refers to this *Report* as “these guidelines,” yet the *Report* does not provide any specific set of guidelines.

Page 143, last sentence to Page 144 - There is no mention of the other chronic diseases discussed in the *Report*, for example osteoporosis and dental diseases.

Page 144, next to last sentence “Beyond the rhetoric, this epidemic can be halted – the demand for action must come from those affected.” The intended meaning here is not clear as one could suggest that all persons are affected.

Annex 1 – Summary of the strength of evidence for obesity, type 2 diabetes, cardiovascular disease (CVD), cancer, dental disease and osteoporosis

Page 147, Annex 1 - This table rates the evidence linking dietary cholesterol to an increased risk for CVD as “P” for probable. The evidence is actually quite strong, and the rating should have been “C” for conclusive. Metabolic ward studies have clearly demonstrated that increased dietary cholesterol intake results in increased levels of LDL cholesterol, which raises CHD risk. There is also substantial epidemiological evidence that higher cholesterol intakes are associated with higher serum cholesterol levels. The decline in average serum cholesterol levels in the United States over the past decades is entirely consistent with what would be predicted from the Keys and Hegsted formulae, which relate serum cholesterol levels to the dietary intake of both saturated fat and cholesterol. Some of the epidemiological studies have not had the power to detect the relationship between dietary cholesterol intake and rates of CHD/CVD per se, but the rise in LDL cholesterol seen with increased cholesterol intakes is itself indicative of a higher CHD risk.

Recent studies of the use of sterols/stanol esters, which block the absorption of cholesterol from the gut, have demonstrated a ten to 15 percent decline in LDL levels. This degree of change in LDL from reduced cholesterol absorption reinforces the evidence that dietary cholesterol is related to increased CVD risk.

ANNEX A

**Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of
Information Disseminated by Federal Agencies
Office of Management and Budget, United States Government**

Excerpts from Department of Health and Human Services Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated to the Public (<http://www.hhs.gov/infoquality/part1.html>)

OMB Guidelines

On September 28, 2001, and as amended on February 22, 2002, OMB issued final Guidelines to implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). The statute directs OMB to "issue government wide guidelines that provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." By October 1, 2002, agencies must issue their own implementing guidelines. The guidelines only apply to information that is disseminated on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

In general, the OMB Guidelines require agencies to adopt a basic standard of quality as a performance goal and take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated, and specific standards may be adopted that are appropriate to the various categories of information that is disseminated. Agencies are to develop a process for reviewing the quality of information before it is disseminated. Further, information quality is to be treated as an integral step in every aspect of the information development process.

In issuing the Guidelines, OMB outlined several guiding principles. First, OMB designed the Guidelines to apply to a wide variety of government dissemination activities that may range in importance and scope. OMB also designed the Guidelines to be generic enough to fit all media, whether printed or electronic. OMB specifically sought to avoid the problems inherent in developing detailed, prescriptive, "one size fits all" guidelines that would artificially require all types of dissemination activities to be treated in the same manner. Second, OMB designed the Guidelines so that agencies will meet basic information quality standards. The Guidelines recognize that some government information may need to meet higher or more specific standards than others, depending on their purpose and scope. The more important the information, the higher the quality standards to which it might be held, for example, "influential scientific, financial or statistical information" described below. At the same time, OMB recognizes that information quality comes at a cost. Accordingly, agencies are encouraged to weigh the costs and benefits of higher information quality in the development of information, and the level of quality to which it will be held.

Third, OMB designed the Guidelines so that agencies can apply them in a common sense, workable manner. OMB expects agencies to use existing processes rather than create new and potentially duplicative or contradictory processes. Finally, OMB recognizes that the Guidelines cannot be implemented in the same way by all agencies. While the implementation may differ, the essence of the Guidelines will apply. The agencies must make their methods transparent by providing

documentation, ensure quality by reviewing the underlying methods used, by consulting as needed with both experts and users, and by keeping users notified about corrections and revisions. These underlying principles apply equally well across the diversity of HHS agencies and information dissemination activities, and they have been adopted in the approach to the HHS Guidelines described below.

HHS Responsibilities

In accordance with the OMB Guidelines, agencies subject to the Paperwork Reduction Act (44USC 3502(1)) are required to:

- Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency not later than one year after the issuance of the OMB Guidelines;
- Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines. Agencies also are to specify appropriate time periods for agency decisions on whether and how to correct the information, and are to notify the affected persons of the action taken. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), that person may file for reconsideration within the agency. The agency is to establish an administrative appeal process to review the initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.
- Report periodically to the OMB Director on the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and how such complaints were resolved by the agency.

The HHS guidelines described in this plan incorporate the underlying principles that OMB used in designing their government-wide guidelines. First, the HHS guidelines apply to a wide range of government information dissemination activities across HHS and are generic enough to fit all types of media, including print, electronic, and other forms within HHS. Second, the HHS guidelines are intended to assure that all the information that is disseminated meets a basic level of quality and that more important information meets a more rigorous quality standard. Third, the HHS guidelines explicitly recognize the very different types of information that various HHS agencies disseminate depending on their missions, including the need for flexibility in implementation and avoidance of a "one size fits all" approach. Fourth, the statement of HHS information quality policies and procedures are issued in the form of guidelines and not a regulation.

HHS itself encompasses a broad and diverse range of health and human services programs which, while unified in their pursuit of broad goals, are themselves very diverse, encompassing the nation's largest health insurance plan, the nation's preeminent biomedical research agency, as well as most of the nation's federal capacity for public health protection and preparedness and income assistance to needy families. Accordingly, the HHS approach to implementation of the OMB Guidelines is designed to allow HHS agencies and offices to use existing agency quality assurance mechanisms, and apply the guidelines in a flexible manner that recognizes the mission of the agency, the wide range of data that is disseminated and the frequent reliance on third party sources.

Framework for HHS Guidelines

Purpose

These Guidelines describe the policies and procedures that HHS agencies employ to ensure the quality of the information they disseminate and the administrative complaint mechanisms that HHS agencies make available to the public. The Guidelines provide policy and procedural guidance to HHS staff and are intended to inform the public about agency quality assurance policies and procedures.

HHS views the guidelines as an evolving document and process. HHS will continually review the performance of the guidelines in the context of agency statutes and missions and will make revisions to the guidelines as necessary.

Definitions

- a) "Quality" is an encompassing term comprising utility, objectivity, and Integrity. Therefore, the Guidelines sometimes refer to these four statutory terms, collectively, as "quality."
- b) "Utility" refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.
- c) "Objectivity" involves two distinct elements, presentation and substance. "Objectivity" includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.

(1) If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the

objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01) (www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."

(2) If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about the data and methods to facilitate the reproducibility of such information by qualified third parties.

Original and supporting data must be subject to commonly accepted scientific, financial, and statistical standards related thereto. However, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.

With regard to analytic results, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.

Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. However, agency guidelines, in all cases, shall require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. Each agency is authorized to define the type of robustness checks, and level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent

situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

- d) "Integrity" refers to the security of information – protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.
- e) "Information" means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.
- f) "Government information" means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.
- g) "Information dissemination product" means any book, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.
- h) "Dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor"). Dissemination does not include distribution intended to be limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to request for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, archival records, public filings, subpoenas or adjudicative processes.
- i) "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define "influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.
- j) "Reproducibility" means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, "capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

ANNEX B**EVIDENCE-BASED GUIDELINES**

These guidelines are examples of those HHS technical agencies use to evaluate published information and to determine the most appropriate treatment strategies that would constitute evidence-based clinical guidelines.

Category A

Sources of Evidence: Randomized controlled trials (rich body of data)

Definition: Evidence is from endpoints of well-defined randomized controlled trials (RCT) (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendations is made. Category A therefore requires substantial number of studies involving substantial number of participants.

Category B

Sources of Evidence: Randomized controlled trials (limited body of data)

Definition: Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post hoc or subgroup analysis of RCTs, or mega-analysis of RCTs. In general, pertains when few randomized trials exists, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.

Category C

Sources of Evidence: Nonrandomized trials, Observation studies

Definition: Evidence is from outcomes of uncontrolled or nonrandomized trials from observational studies.

Category D

Sources of Evidence: Panel Consensus Judgment

Definition: Expert judgment is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provision of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C).

Source: *Clinical Guidelines of the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report* (NIH Publication No.98-4083, September 1998, National Institutes of Health/National Heart Lung and Blood Institute, U.S. Department of Health and Human Services, page xiii).

ANNEX C

These comments reflect contributions by a range of U.S. Government scientific and technical experts who participated in the review of the *Report 916*, including:

U.S. Department of Health and Human Services**Office of the Secretary**

Office of Global Health Affairs

Office of Public Health and Science

Office of Disease Prevention and Health Promotion

National Institutes of Health

Division of Nutrition and Research Coordination
Fogarty International Center
Office of Prevention Research and International Programs
National Institute of Child Health and Human Development
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute of Dental and Craniofacial Research
NIH Nutrition Coordinating Committee
Trans-NIH Sub-Committee on International Nutrition Research

Food and Drug Administration

Office of the Commissioner
Center for Food Safety and Applied Nutrition

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion

- Division of Nutrition and Physical Activity
- Division of Adult and Community Health
- Division of Cancer Prevention and Control
- Division of Reproductive Health
- Division of Oral Health

U.S. Department of Agriculture

Selected Offices, Branches, and Divisions