



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.

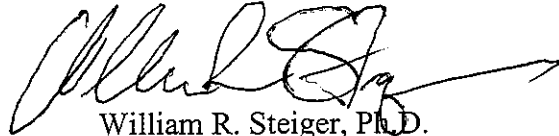
The comments in the enclosed document are an indication of the U.S. Government's continued commitment, under the leadership of Secretaries Tommy G. Thompson and Ann Veneman, to work with the WHO, FAO, and the international community to address the growing challenges of obesity and chronic diseases through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

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, 2<sup>nd</sup> 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.

