DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of International Affairs
Washington, D.C. 20201

JUL -2 2002

The Honorable Gro Harlem Brundtland, M.D.
Director-General
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27
Switzerland

Dear Madam Director-General:

The United States Government is pleased the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) are examining the growing public health challenges of diet, physical activity and health for the prevention and control of chronic diseases, especially as the WHO moves to develop a larger global health strategy. We appreciate the opportunity to comment on the April 26, 2002, draft report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases.

The United States shares your concern about the increase in chronic diseases throughout the world. Many developing countries are grappling with health problems caused by under-nutrition, chronic vitamin and mineral deficiencies, and preventable deaths, especially of mothers and children, who are the most vulnerable. At the same time, changing demographics are leaving many middle-income and wealthier countries with steadily older populations, and chronic diseases related to dietary excesses and imbalances are increasing in both developed and developing countries.

The United States supports a robust disease prevention and health promotion framework. As you know, Secretary Thompson has made preventive health and healthy behaviors a cornerstone of U.S. public health policy. This year, the Department of Health and Human Services (HHS) will spend more than $15.3 billion on prevention activities, including child immunization, health education, food safety, and disease prevention. President Bush's budget for fiscal year 2003 requests a $950 million increase in prevention spending. Secretary Thompson remains committed to expanding the global dialogue on preventive health practices and the promotion of healthier lifestyles.

As you can see from the depth and breadth of our comments, the United States is most interested in the draft joint report from the WHO/FAO expert consultation. To maximize technical input to our response to the draft report, the United States initiated an interagency process, engaging scientific and policy experts from such agencies as the U.S. Departments of Commerce, Agriculture and State, the U.S. Agency for International Development, the Office of the U.S. Trade Representative, and our own staff here at HHS. We hope our expert technical and scientific commentary will contribute in a meaningful way to the next draft of this report.

We look forward to continued collaboration with WHO and FAO in this important area.

Sincerely,

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

U.S. Comments on the
Draft Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases

(Version April 26, 2002)

U.S. Comments on the Draft Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases

General Comments:

Scientific Evidence

- The quality and quantity of the available data are insufficient at this time to support many of the conclusions and recommendations offered in the Draft Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases. While it is important to try to rationalize information and provide key insights to the general population about diet and nutrition, there is a deep concern that the introductory section contains misleading information and certainly many statements that are unsubstantiated opinions. It is exceedingly important that points are documented.

- Some of the recommendations in the Report appear to be at variance with other recent FAO/WHO expert consultations on diet and human nutrition and the formulation of food based dietary guidelines, especially those regarding aggregate level nutrient data and individual level behaviors. Care must be taken to ensure recommendations are grounded in sound scientific evidence. WHO and FAO are encouraged to focus on the research needs to develop the evidence required to implement strategies at the country level. Moreover, this Report fails to note the mechanisms for evaluating health and making dietary recommendations for a nation, such as the *U.S. Dietary Guidelines for Americans.*

- Although criteria for evaluating the strength of the evidence are described in the Report, it is unclear what process was used to reach the conclusions and how specific recommendations were derived. Information as to what criteria were used to identify literature for review and evaluation and the process for inclusion or exclusion of studies in support of the recommendation would improve the value of the Report. Clarity and transparency of the process used in developing the expert consultation's recommendations would enhance the utility of the Report.

- The "Strength of evidence: criteria used" section (page 22) 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 trial (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 general 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.

- The current WHO/FAO Report returns to the concepts of the l990 #797 report of recommending "population nutrient intake goals." The l990 recommendations were rejected by the l992 International Conference on Nutrition for several reasons. The recommendations were not considered to be science-based. They were also considered impossible to implement and potentially harmful to people living in developing countries.

- Although not made explicit, the Report 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. In numerous places in the text, the Report implies that both these relationships are negative (see pages 10, 11, 12, 19 as examples). Such an implication is, first and foremost, inappropriate, as the literature in these two fields has not been reviewed for this Report. Secondly, these conclusions are largely unsupportable from the evidence in the international trade and agriculture and environment literatures.

- The suggestion on pages 12, 19, and elsewhere for the need to have a broad-based analysis of the sustainability of production is an important one. WHO and FAO could do a valuable service by initiating such a dialogue through a process that is inclusive, transparent, and grounded in evidence. Such a process may result in valid conclusions about some of the issues raised in the current Report, taking into account technological, cultural, economic, and institutional realities. Without such a process, the conclusions expressed in the Report regarding matters of food trade, consumption, and production are of little use.

- The problem statements in the Report are disturbing, for example, the increasing incidence of rising risk factors for chronic disease. The data suggest these trends are persisting and becoming more widespread. However, even in cases where the WHO/FAO Report indicates convincing or probable links between risk factors and disease, the evidence basis is narrow and not representative of most of the populations of concern in the developing world. The World Cancer Research Fund (WCRF) report on cancer and chronic diseases is a poor model on which to base the criteria for strength of evidence. That report used as evidence very few studies from developing countries, contained few studies examining multiple risk factors, and completely disregarded food supply, agricultural, and agroecosystem realities in making its dietary recommendations. The WCRF report is currently

being revised. Further, there is limited longitudinal data on the "tracking" or long-term temporal patterns of risk factors for a number of chronic diseases that would allow for some judgment about the appropriate timing of interventions in infants and children.

- Of even greater concern than the scientific support for the problem statements in the WHO/FAO Report, is the lack of science behind the solutions offered. The recommendations ranging from health education to limitations on advertising to pricing policies should be contextualized for very specific conditions, and its impact evaluated for efficacy, efficiency, and equity. Such analysis is missing from the Report and requires a country, commodity, and population-specific approach.

- Efforts should be focused on improving the data attesting to the relative burden of major chronic diseases, including relative impact across differing risk groups, i.e. by gender, age, demographics so that they may be more useful for prioritizing public health interventions, and on building information about the potential macroeconomic and microeconomic costs of chronic diseases. Careful use of such evidence, along with appropriately designed and targeted public policies, will prompt governments and civil society to address the chronic disease problem. Conclusions such as on page 20 regarding potential cost savings of changing risk behavior with respect to chronic diseases are not supported with data.

- Recommendations in this Report are complementary to existing WHO/FAO reports on energy and nutrient requirements. However, it is likely that the Report's recommendations will be widely circulated and promoted without this notation. Therefore, we highly recommend that comprehensive guidance be provided in the recommendations themselves, to include recommendations for nutrient adequacy. These recommendations could be appended to Table 2 (titled *Ranges of population nutrient intake goals*) with reference to the other reports as the source for these recommendations. By providing guidance in one comprehensive document, the opportunity for misinterpretation of the recommendations is lessened. The public often focuses on a perceived negative attribute of food, and makes choices to avoid this attribute without concern for obtaining essential nutrients. Guidance should counter this with messages that food is essential as a source of energy and nutrients, but that moderation, variety, and proportionality of food choices are vital for lifelong health and prevention of disease.

- The WHO/FAO Report includes no distinctions between high-risk and population-based recommendations. Many of the recommendations made in the Report are generalized and not directed toward age or gender - a particular concern in the context of applicability of such recommendations to infants, children, the elderly, and other potentially high-risk groups.

References/Citations

- Quantitative recommendations must be supported by the cited literature. Some of the quantitative nutrient intake goals presented in Table 2 (page 21) are not supported by the literature that is cited in the related sections of the Report. Additionally, more detail concerning the research, including the actual recommendations, should be presented for any studies that are in press but not yet published. Examples include the citations provided for the quantitative recommendations for physical activity in Annex 2, page 25; Annex 3 page 16; Annex 4 pages 6, 7, and 15; Annex 5 page 7; and Annex 7 page 9; which do not appear to support a population goal of one hour of moderate activity on most days of the week.

- References throughout the document, and especially in the Background section, need to be updated. Many of the references cited are 5-10 years old. In other cases, references are not cited when they are available. For example, in several places (pages 25, 30, and 34), the justification for not providing numeric recommendations for non-starch polysaccharides/dietary fiber is because definitions vary depending on "analytical methodologies used"; yet nowhere in the document is there a discussion of what those methodologies might be or recommendations regarding standardization of approaches to generate universally acceptable data. Moreover, a definition of fiber that has been generated and vetted through a scientifically defensible process should be provided for reference. To address these shortcoming, the Institute of Medicine's process for development of a definition of dietary fiber could be referenced (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, 74 pp.).

- The discussion of carbohydrate recommendations is particularly problematic for its lack of a more current review of the extant literature. For example, the discussion does not mention metabolic syndrome X or glycemic index. Both topics have been widely explored in the recent research literature.

- The Report includes a numerical recommendation for sugars intake. The importance of limiting the consumption of highly sweetened, calorically-dense foods that supply few nutrients other than carbohydrate should be emphasized as such recommendations would be consistent with current public health recommendations (e.g. U.S. Dietary Guidelines Advisory Committee (DGAC), *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2000.* Prepared for the Committee by the Agricultural Research Service, U.S. Department of Agriculture (USDA), 2000, pp. 37-40).

  >> As with dietary fiber, where the recommendation is for increased consumption of vegetables, fruits, legumes and whole grains, the advice

regarding sugars intake would be best given by recommending limited consumption of heavily sweetened foods and beverages, the use of added sugars and excess consumption of fruit juices, which makes an important contribution to the diet but not when it displaces other food.

>> In the United States, consumption of non-diet soft drinks, sugars and sweets (including candies), sweetened grain products, fruit-ades and fruit drinks, and sweetened milk products account for over 75 percent of added sugars intake in the diet (Guthrie, J.F. and Morton, J.F., *J Amer Diet Assoc.* 2000, 100:43-48, 51.) Recommending a limit on consumption of such foods is merited and may be easier for most countries to track than would be a goal for "free sugars" consumption using current methods for measuring food consumption, or for analyzing the sugar content of marketed foods.

>> The Report defines added sugars as "all mono- and disaccharides added to foods by the manufacturer, cook or consumer, plus sugars naturally present in honey, syrups and fruit juices." However, the inclusion of "fruit juices" in this context is confusing and requires further delineation. The focus should be on (1) limiting intake of concentrated fruit juice sweeteners and not on fruit juices from citrus products, and (2) on the excess intake of fruit juice to the extent that it displaces other foods in the diet. The term "added sugars and sweeteners" better fits the intent of the recommendation.

- Given the lack of data available, it is unclear why the Report singles out soft drinks (soda). The Report seems to unduly focus on soft drink ingestion, and advocates for national and international policies aimed at reducing consumption of soft drinks and the use of vending machines in schools.

Policy Issues

- Policy recommendations are not discussed at length. More details and support for the rationale and efficacy of these recommendations could encourage their adoption.

- The *U.S. Dietary Guidelines for Americans* (aka *U.S. Dietary Guidelines* or *U.S. Guidelines*) is an example of a national nutrition policy. Although many of the main recommendations are reasonably similar to *U.S. Dietary Guidelines*, the WHO/FAO Report goes significantly beyond the *U.S. Guidelines* in topics addressed and details given. Some of the recommendations fall outside the usual purview of public health and science, and are not supported by randomized clinical trials or a substantial body of data, especially those recommendations that deal with advertising restrictions and tax levies.

- The recommendations targeted at national governments use language with legal and regulatory implications such as “ensure”, “regulate”, “enforce”, and “policy”. Such language could preclude other methods of achieving nutritional goals that would be more easily implemented by national governments. It may also prevent or inhibit acceptance or support for this Report overall. Future versions of the Report should consider the use of terms such as “encourage” and “promote” in the place of more legal terms.

- All governments are committed to food security, and the United States is no exception. However, establishing food security as a basic human right could have major implications for national and international law. We suggest the Report avoid inferences that could advocate for changes in international and national human rights arenas. These types of references dilute the overall objective of the Report. Such recommendations also most likely fall outside the scientific and technical expertise of most of the experts used in the consultation for this Report and could question the primary intent for publication.

- The WHO/FAO Report advocates for stringent codes of practice on advertising of sugar-rich items, and the introduction of fiscal pricing (taxes) on such items. Such advocacy would seem to fall outside the scope and expertise of the expert consultation and the core competencies of WHO and FAO. Taxation policies, advertising restrictions, and market regulations are the purview of national governments. Rather, international guidelines and national policies should encourage healthy and nutritious diets through increased consumer awareness of the link between diet, health, and physical activity, and implementation of evidence-based strategies to motivate them to make appropriate changes. The WHO/FAO Report should provide evidence-based guidance to national governments in the development and implementation of policies that provide education, information, and motivational messages to consumers so that they have the knowledge, skills, and encouragement needed to make choices for their health from the wide variety of foods available.

- The Report recommends encouraging food production based on small regional food producers to prevent rural migration and the loss of production of diverse and traditional food in favor of cash export oriented production. This type of advocacy would seem to fall outside the scope and competency of the expert consultation of this Report as well as the core competencies of WHO.

  >> National governments may or may not support policies based on this type of intervention. For many governments, consumer demand is a primary determinant of what is produced at domestic market prices.

  >> In order to offset rural migration, a government may choose to implement policies that do not affect price and production of food commodities, yet entice people to stay in the rural areas. A prime approach may be to assist

with the development of off-farm rural employment opportunities. And, exporting products is one way to enhance farm economies.

- The Report promotes the development of sectoral policies that enable adequate production of fruits, vegetables, and whole grain cereals at affordable prices to all segments of the population. Many governments view consumer demand as a primary determinant of what is produced and have developed national policies and programs to encourage fruit and vegetable consumption with the hopes of increasing consumer demand. Improving crop productivity is an essential means of lowering production costs and providing reasonably priced food to the entire population. In order to further accomplish the important objective of providing adequate supplies of fruits and vegetables and whole grain cereals at affordable prices to consumers, the answer is not one of dictating producer prices, but rather one of providing nutrition education and promotion to stimulate consumers to make healthier food choices and offering healthy food choices through food assistance programs.

- The Report advocates the development and implementation of policies that enable an adequate and sustainable supply of fish in domestic markets. Again, to many governments, consumer demand should be a primary determinant of what is produced.

- The Report recommends monitoring of national guidelines for quality and consumption of foods served in schools and other government facilities. The U.S. Government does establish and monitor implementation guidelines for Federally reimbursed meals served in schools and childcare centers. For many countries however, including the United States, establishing national government controls over non-federally reimbursed food service in State and local government facilities would be controversial and undesirable.

- The Report recommends regulating the use of hydrogenated oils in food production. Such regulations would unduly infringe upon consumer choice. Many countries have a variety of available foods, and plenty of low-fat and unsaturated fat alternatives for consumers. The United States and other countries support nutrition policy geared towards changing behavior through public education and motivational messages rather than through restriction of the food supply. Labeling may also be an alternative.

- The Report recommends that national governments provide guidelines to ensure that nutrition education materials be free of industry bias. While the United States agrees that industry should not wield undue influence in the development of national nutrition guidelines, this recommendation could limit or delay the dissemination of valuable nutrition education materials produced by industry sources.

U.S. Dietary Guidelines

- It is important to emphasize a total diet message such as that recommended by the *U.S. Dietary Guidelines for Americans* (low in saturated fat and cholesterol and moderate in total fat, lower in salt, levels of energy intake and physical activity to maintain or lose weight and needed for health, etc.). While consumption of vegetables and fruit, the amount and quality of fat ingested, and the intake of salt are important, other dietary components such as antioxidants, fiber, calcium and potassium may also be beneficial in the prevention of cancer and risk factors for cardiovascular diseases.

  >> Energy balance -- that is to say balancing calories eaten with adequate physical activity -- is also important, and this critical interaction is not adequately addressed in the WHO/FAO Report.

- The 1990 WHO Study Group *Report on Diet, Nutrition, and the Prevention of Chronic Diseases* contained a useful summary of the *U.S. Dietary Guidelines for Americans* in its Table A4.1 entitled "Dietary recommendations in industrialized and developing countries, 1977 to 1989." This table summarized the quantitative recommendations of the *U.S. Dietary Guidelines* along with dietary guidelines recommended by other countries. Revision and inclusion of a similar table in this Report would allow readers to quickly note current recommendations used by many countries. The *U.S. Dietary Guidelines* provide easily understood, science-based guidance to the population for choosing diets that promote good health, which were updated in 2000 and forms the basis for U.S. Federal nutrition policy and programs.

- The *U.S. Dietary Guidelines* provide guidance for a total diet, including guidance for nutrient adequacy, as well as guidance that focus on moderation of certain food components. We encourage that the *U.S. Dietary Guidelines* and guidelines from countries, be reviewed as possible models.

- The *U.S. Dietary Guidelines* were reviewed/updated most recently in 2000, so in some areas newer evidence may be important to consider. Additionally, the National Academy of Sciences (NAS) will issue a new report in the near future, which will address many of the issues in the WHO/FAO Report. It would be useful to WHO, FAO and Members States to be able to compare the WHO/FAO Report with the NAS Report.

Food Labeling

- As for the Codex Alimentarius Commission (CODEX), it is expected that the contents of the WHO/FAO Report will be used by some countries to advocate for significant impacts on both the Codex Committee on Labeling as well as the Codex Committee on Foods for Special Dietary Use. Other CODEX committees

may also be affected. Such a potential underscores the necessity of a science-based WHO/FAO Report and recommendations.

Behavior Change

- Changing behavior to improve health is a complex process and past efforts reflect failures as well as successes. Whether behavior such as dietary habits, food choices and physical activity can be manipulated by mandates of legislative bodies or regulatory impositions is not clear. The involvement of a range of key stakeholders is essential for the development of clear, understandable, and effective messages to consumers to encourage improved dietary habits. These stakeholders include the medical, public health and research communities, the educational sector, the agriculture sector, industry and the media. In addition, there is a need for continued research to identify the essential determinants of food habits, attitudes, and beliefs across different ethnic and demographic settings.

Undernutrition/Developing Countries

- The WHO/FAO Report is more directed towards issues in the developed world. However, the issue of risk for chronic diseases in the developing world is becoming larger as the transition from traditional indigenous diets to diets consistent with patterns in the developed world continues. Donor countries' efforts to prevent hunger and malnutrition and their sequelae are primarily aimed at increasing the use of health interventions that save the lives of people in low-income, developing countries where the food supply, diversity, and choice are severely limited resulting in serious negative effects on a population's health and survival. There is little mention in this Report of the more than 800 million chronically undernourished individuals whose lack of good quality foods prevents them from realizing their physical and cognitive potential and from contributing to their countries' development.

- The relationship of food production to the health, nutritional status and well-being of people in low-income countries is of particular concern. The continuing growth of the world's population will mostly occur in low income, food deficit countries, creating additional demand for food of all types. The importance of a diverse diet and its impact on health and productivity should be recognized, especially for those at risk of nutrient deficiencies.

- The recommendations appear to promote a single style of eating that may not be appropriate to all people every where, especially those whose choices are seriously compromised by lack of education, income and access to health services. Rather than a "one size fits all" approach, there clearly is need for research to develop ethnocentric strategies to address the improvement of diets in all settings.

- In reviewing these recommendations, the unintended consequences of any recommendations should be taken into consideration, especially those that might have a negative effect on the long-term health and well being of at-risk populations in low-income countries. It is suggested that a subset from the least developing countries have scientific representation on the expert panel(s) developing recommendations for the final version of the Report and subsequent global strategy.

Specific Comments

Section 1: Background

Page 5, paragraph 4, and elsewhere in the document: The categorization of risk factors for chronic diseases appear inadequate to cover the factors that deserve attention. The three categories mentioned are: non-modifiable, behavioral, and societal risk factors. To these categories the text adds 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, see page 17, "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 be modified to encompass the lipid risk factors.

Section 2: The current state of the food supply at the global level

General Comment:

A considerable number of concerns expressed in Section 2 on Food Supply are based on extrapolation of current trends (see example on page 11 regarding consumption of various commodities). As has been learned many times in the past (for example, the Club of Rome), projections based on extrapolation are unreliable and misleading. The WHO/FAO Report would have a more credible basis for conclusions and policy recommendations if projections were based on well-known and professional models of future food production and consumption. Two examples are FAO's recent report, Agriculture Towards 2030 (FAO, 2000), and the International Food Policy Research Institute's agricultural trade model (Rosenweig, et. al.).

Page 9, paragraph 3. In discussion of the oils that contain trans fatty acids, no mention is made of the work being done through processing methods and plant breeding to develop oils that are modifying the fatty acid content for a healthier oil. In addition, agricultural production methods for both plant and animal are being developed to ensure

less harmful impact on the environment. USDA's Agricultural Research Service has research programs in both of these areas.

Page 11, paragraph 2. Concern is expressed for depleting fish from ocean sources if fish consumption increases. No mention is made that aquaculture has been substituting for ocean catch and types of fish species are increasing through aquaculture production. Researchers are investigating ways to feed fish on more plant protein through better plant breeding methods. Aquaculture programs are expanding worldwide.

Section 3: Diet, nutrition and chronic diseases in context

General Comment:

This section does not convey the relative strength of various diet-disease links summarized. To improve scientific basis for dietary recommendations, one should consider utilizing true meta-analysis techniques.

Page 14, paragraph 4. Discussion of the "wider social, political and economic environment" is somewhat vague. Consider including an annex paper on these issues.

Pages 14-15: 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. Longitudinal studies are lacking to support a direct link between risk factors that might appear in children and subsequent development of adult disease. More research is needed to assess the temporal relationship between the putative risk factors that have been identified in adults and those that might appear in children. Such data are an essential prerequisite to the determination of the appropriate timing and safety of interventions in infants and children.

Page 15: Fetal development and the maternal environment. High birth weight also relates to an increase in obesity in adulthood.

Page 15, Section 3-2. Interactions between early and later factors. Studies that indicate that rapid growth after intrauterine growth retardation (IUGR) is associated with increase risk of disease are inconclusive and very preliminary. They fail to show an increase risk of disease over and above that caused by low birth weight. Studies do show that high birth weight may be associated with obesity in children.

Suggest replacing the sentences, "Studies have demonstrated an interaction … in increased risk of diseases. Conversely there is also … diabetes with shorter stature." with "Results of studies of the relationship between IUGR, rapid catch-up growth in weight and height suggest a link to subsequent development of chronic diseases. Expanded research is necessary to further explore these potential relationships and thus caution is suggested to avoid over-interpretation of these data at this time."

Page 17, last paragraph. In the sentence that begins "reversing current trends will require…" we suggest the elimination of the suggestion that energy dense nutrient food products should be taxed.

Page 17, Intervening throughout life. The major biological risk factors have been shown to occur in early life and may be associated with adverse health outcomes in adulthood, although longitudinal data demonstrating such a relationship are limited.

Page 18, paragraph 2. Nutritional guidelines, such as the *U.S. Dietary Guidelines for Americans*, is based on a consensus of the most current scientific evidence to date and is given as guidelines for the general population with regard for potential adverse effects. Thus, the recommendations are targeted toward specific age groups or gender or health conditions, where appropriate. The Expert Consultation of 2002 was mentioned in following paragraph, without referral to the *2000 Dietary Guidelines for Americans*.

Page 18, paragraph 5. Increasing the consumption of fruits, vegetables and fish, and decreasing the consumption of certain types of oils and sugars is a valid recommendation, as there is overwhelming scientific evidence of their health benefits. However, there are numerous studies that show the importance of animal protein as part of a healthful diet. Animal protein is a significant source of many micronutrients such as iron and zinc, and certain B vitamins, which are highly bioavailable from this source. Meat and poultry are a part of USDA's Food Guide Pyramid.

Page 19: The evidence that soft drinks are associated with obesity is not compelling and should be deleted or significantly revised to provide a more accurate reflection of the available data.

Section 4: Summary of population nutrient intake goals for preventing chronic diseases

Page 21. There is no literature cited to base a generalized statement of 1 hour for physical activity for the general population. This is also stated several other places in this document. In the *U.S. Dietary Guidelines,* the recommendation for the adult population is for at least 30 minutes most days of the week and 60 minutes for children.

Page 21, Table 2. 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 the population, thereby increasing CHD risk. The lower bound for total fat should be revised upward and the upper bound for carbohydrate should be revised downward.

The goal suggested for saturated fat, <7 percent of energy, appears to be low enough to constitute a goal for therapeutic intake by a patient who is trying to lower an elevated LDL level rather than a goal for average population intake, especially as developing

countries become more affluent. A more realistic goal for the population average intake would be <10 percent, a level that would be compatible with maintaining a low risk for CVD throughout the lifespan and consistent with the *U.S Dietary Guidelines*.

The population nutrient intake goals for sodium chloride (sodium) [<5 grams/day (<2grams/day)] are somewhat more stringent than those recommended in the U.S. [<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 may 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 may be more appropriate from a global perspective.

Page 21, Table 2 - Fat (15-30 percent of energy) and page 33, paragraph (d) of Report. While the upper limit of 30 percent of energy from fat agrees with that set in the *Dietary Guidelines for Americans*, there is no rationale given for the lower limit of 15 percent. The DGAC cautioned that fat intake well below 30 percent of calories has "the potential for adverse metabolic effects," which could "predispose to CHD and type 2 diabetes mellitus." (page 36, DGAC report)

Page 22, Table 2 - Saturated fat (<7 percent of energy), page 32, paragraph (a) and page 19-21 of Report and Annex 3 pages 23-25. This recommendation for <7 percent of energy from saturated fat is lower than that in the *Dietary Guidelines for Americans* of <10 percent. The Report and accompanying annexes provide no rationale for this specific quantitative recommendation.

Page 21, Table 2 – polyunsaturated fatty acids (PUFAs) (6-10 percent of energy) and monounsaturated fatty acids (MUFAs) (by difference), page 33 paragraph (c), and Annex 3 pages 23-25. The DGAC recognized the potential health benefits of unsaturated fats and of substitution of these fats for saturated fats. However, given the available evidence at the time, they did not make a quantitative recommendation for these fatty acids.

Page 21, Table 2 - Trans fats (<1 percent of energy), page 33, paragraph (b), and Annex 3, pages 22-25. While the DGAC recognized the evidence for the association of trans fat intake with blood lipids and CHD, they did not make a quantitative recommendation for its intake.

Page 21, Table 2 – Protein (10-15 percent of energy). The quantitative recommendation for protein does not appear to be linked to its association with any NCDs. While the recommendation itself is justified, it is not clear why protein is listed in Table 2, since recommendations for other nutrients needed for health, such as vitamins and minerals, are not given. If Table 2 were to be expanded to include recommendations for nutrient adequacy as suggested, then a recommendation for protein would be appropriate.

Page 21, Table 2 - Free sugars (<10 percent of energy), page 40, paragraph 1 of Report, and Annex 6, page 33 paragraph 5.1 and page 38 paragraph 6.1.1. The association between free sugars and chronic diseases is limited to increased risk for dental disease. This link is noted to be one for both amount and frequency of consumption. The DGAC also recognized this link, but did not recommend a quantitative limit on consumption of added sugars. Given the evidence that the relationship is to some extent based on frequency of consumption rather than just total amount, a quantitative limit on free sugar consumption does not appear to be warranted.

Page 21, Table 2 - Total carbohydrate (by difference – 55-75 percent): A total carbohydrate intake of 55 to 75 percent of energy is noted in a footnote to Table 2 as "the percentage of total energy available after taking into account that consumed as protein and fat." No documentation related to the health of the general population was given to support this recommendation. Since this intake range is "by difference" and is not related to an association between total carbohydrate and NCD, it should not be presented as a recommendation in Table 2. The *U.S. Dietary Guidelines* do not present quantitative recommendations for total carbohydrate intake, but do recommend specific numbers of servings for grains and fruits and vegetables, the major sources of complex carbohydrates and fiber in the diet.

Fiber intake is identified in the Report as convincingly associated with a decreased risk for obesity and probably associated with a decreased risk for diabetes and CVD. While a recommendation for fruit and vegetables is given (see comment below), no total recommendation is given for intake of whole grains. The *U.S. Guidelines* do not give a quantitative recommendation for whole grain intake, but a specific recommendation for number of servings based on calorie level is given for all grains. The *U.S. Guidelines* also suggest that grain servings "include several servings of whole grain foods."

Page 21, Table 2 - Fruits and vegetables > 400 grams/day (g/d). The Report recommends an intake level for fruits and vegetables of a constant 400 g/d. This corresponds to the range recommended in the 1,600-calorie pattern of the USDA's Food Guide Pyramid, which was included in the *Dietary Guidelines for Americans*. The Pyramid recommends a given number of servings of fruits and vegetables of a defined size each day, based on a person's approximate energy needs, as outlined in the table below:

Group	1,600 calories	2,200 calories	2,800 calories
Fruit	2 servings = 1 cup	3 servings = 1 ½ cups	4 servings = 2 cups
Vegetables	3 serv = 1 ½ c	4 servings = 2 cups	5 servings = 2 ½ cups
Total	2 ½ cups (375-500 g*)	3 ½ cups (525-700 g*)	4 ½ cups (675-900 g*)

*Assuming a rough conversion of 1 cup to approximately 150 to 200 grams

Page 21, Table 2 – Sodium (<2 g/d), page 33, paragraph 3, and Annex 4, page 40 last paragraph: The DGAC and the *Dietary Guidelines for Americans* recommend moderate intake of salt and sodium, and refer to the quantitative amount of 2,400 mg sodium determined as the Daily Value for sodium by the HHS/FDA and used on its "Nutrition Facts Label". A lower recommendation should not be given for the general population without very convincing evidence.

Page 21, Table 2 - Physical Activity (one hour per day on most days of the week of moderate-intensity activity); page 27, last paragraph; page 30, paragraph 2; page 36, paragraph 2, and Annex 2, page 25; Annex 3 page 16; Annex 4 pages 6, 7, and 15; Annex 5 page 7; and Annex 7 page 9. The quantitative recommendation for physical activity is not consistent with findings and recommendations for the general population found in the articles that are cited in Annexes 2, 3, 5 and 7. The scientific basis for recommending 60 minutes of daily moderate-intensity physical activity to maintain healthy weight as stated in the Report is also unclear. The *U.S. Dietary Guidelines for Americans* recommends at least 30 minutes daily for adults and 60 minutes for children to maintain health, and indicates that more may be necessary to lose weight or to maintain weight loss, but does not include a specific amount of time. Additionally, the JNC VI recommended moderate physical activity of at least 30 minutes per day, most days a week.

The sole reference for the Report's recommendation in Annex 2, page 25, paragraph 4.12, is *Increasing Physical Activity: Report on Recommendation of the Task force on Community Preventive Services*, which was published in the HHS/Centers for Disease Control and Prevention (HHS/CDC) *Mortality Morbidity Weekly Report* (MMWR), Volume 50, October 26, 2001. This HHS/CDC report included quantitative physical activity recommendations from the Healthy People 2010 goals. None of the Healthy People 2010 goals target one hour of physical activity on most days of the week. The published references cited for Annex 3, page 16, paragraph 5.2, also do not support the quantitative recommendation for one hour of physical activity most days of the week for the general population.

Page 22. The criteria presented for ranking the strength of evidence are far too liberal for the designated labels. The quality of evidence ranked as "convincing" in the report falls far short of that descriptor. If the ranking of evidence was held to the same standard employed by the various units within the HHS technical agencies, there would be few, if any, recommendations supported by convincing evidence (see **ANNEX A** for HHS evidence categories). It is strongly suggested that the rating of evidence in the Report needs to be reformulated. With that done, approaches delineated in the Report could be investigated in an appropriate manner to establish those that will produce desired outcome(s) and those that will not.

Page 22, Table 2, body mass index (BMI). The *U.S Dietary Guidelines* provide a BMI range for healthy weight of 25-29.9 kg/m². It is not clear what provides the basis for the population mean of 21 suggested in Table 2.

4.1 Nutrient Recommendations for the prevention of excess weight gain and obesity

Page 24, paragraph 2. Direct health care costs of obesity in the United States were 5.7 percent of health care costs in 1995 or $51.6 billion. (A. Wolf.) And, recent literature supports the economic case for treating obesity. (*Obesity Research*, Vol. 6 Suppl., April 1, 1998.) Under the strength of that evidence, data for probable risk are based on evidence showing fairly consistent association between the disease and exposure period.

This is not the case for television advertising and obesity. Although television viewing alone relates to an increase risk of obesity in children, it is not clear whether the obesity risks are mediated by the consumption of foods advertised on television or inactivity associated with television. There are not enough studies cited that allow television advertising to be classified as a probable risk.

Page 24, paragraph 4. Nutrient factors and environmental issues are mentioned as relationships to obesity, but no mention is made of genetic predisposition to this condition. It is well known through many scientific studies that certain populations have a genetic predisposition to obesity and that certain dietary and lifestyle habits can aggravate this. Section 4.1 discussion is really on developed countries without mention of this issue in developing countries as discussed in the introductory section. Surely, this points to disparaging differences in lifestyles and diet. No mention is made of the "Green Revolution" and how this has filled a food insecurity void, while adding to malnutrition in many countries of the developing world due to micronutrient deficiencies.

Page 25, Table 3. There is more evidence that breastfeeding protects against obesity than any of the probable causes listed. For example, there are no data that link heavy marketing of energy dense foods and fast food outlets, although a logical assumption could be made. Similarly, there is one prospective study that demonstrates an association of sugar sweeteners, and soft drinks and fruit juices' association with obesity. Lack of data would suggest that these should be in the insufficient or possible categories. These comments about the possible and probable causal factors apply equally to Annex 1 of the WHO/FAO Report.

Pages 26, 29, 36. Recommendation on physical activity is too vague to be of use to public health officials, to whom this document is targeted. The level of intensity of the recommended activity should be described (for example, see the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2000.* (Prepared for the DGAC by the Agricultural Research Service, USDA, 2000, page 26). Perhaps this information is in the referenced International Agency for Research on Cancer (IARC) Handbook, but it should be included in the Report itself.

Page 26. The National Institute of Hearth Lung and Blood (NIHLB), National Institutes of Health (NIH), HHS, is unaware of the data to support the waist circumferences provided for "increased risk of metabolic complications." NHLBI uses only one category

for high risk; the waist circumferences listed in the report for "substantially increased risk of metabolic complications" is consistent with the NHLBI recommendations.

Page 26. Again, the dose of physical activity necessary to prevent obesity has not been established.

Page 27. The term "free sugars" needs to be better defined. "Free sugars," which is later defined on page 39, would be better stated as added sugars and sweeteners. The *U.S. Dietary Guidelines* does not give a specific recommendation for level of intake of sugars. Rationale is not given for the one stated in this WHO/FAO Report (<10 percent of what? We assume total calories).

Page 27. Footnote reference states that if one consumes a lot of fruits, vegetables, legumes, and whole grains than caloric values from fat can be as high as 35 percent without risking weight gain. This is also noted several other times in the report. No rationale is given to support this statement. The *U.S. Dietary Guidelines* recommends no more than 30 percent of calories from total fat and discusses the types of fats, with guidance given. These recommendations are based on sound scientific evidence.

4.2 Nutrient Recommendations for the prevention of diabetes

Page 28, paragraph 1. In a recent study in *Diabetes Care* where projections to the year 2050 were published, results indicated that approximately one-third of the increased projected prevalence was due to the growth in the population; about one-third associated with aging of the population; and about one-third to behaviors. Thus, the last sentence in the first paragraph could be restated as follows: "Among the mutable factors that can be addressed to control the epidemic of type 2 diabetes, excess weight gain…."

Page 28, paragraph 2. It is a stretch beyond the science to suggest that weight control, reduction, and/or increased physical activity would result in reductions in death and morbidity. Science does show that these interventions can prevent and/or delay the onset of diabetes, but clear links are lacking to death and morbidity at the current time. David Eddy has some early modeling results that suggest the Diabetes Prevention Program (DPP) of the National Institute of Diabetes and Digestive and Kidney Diseases, NIH/HHS, may not have lots of impact on ultimate morbidity and mortality (not published). The phrase "are likely to be" is not a statement of definitive proof. A more cautious word to use would be "may."

Page 28, paragraph 3. The Harvard studies in nurses and physicians find many "associations" and apparently never identify "no association". There has never been a paper from this group, which does not find a positive association. Could this be due to an N=200,000 and only using relative risk and/or first versus fifth quintile? In any case, the other issue is with the "component" theory of the incidence of diabetes – glycemic index, trans-fatty acids, saturated fats, etc. that emerges from an absolute risk perspective especially since these elements are miniscule when compared to over all calorie consumption, weight gain, or physical inactivity (Willet et. al.)

A recent editorial in *Diabetes Care* (March 2002, Vol. 25, p. 620) about dietary fat and the development of type 2 diabetes, presents a better and more balanced view of the constituents of food vs. diabetes incidence, than do other association studies. Given the absolute risk of weight and physical inactivity, focusing on trans-fatty acids, fiber, and glycemic index - unless there is at least one good RCT - is a significant distracter from the main issues. Saturated fats do not deserve a "probable" grade, but definitely a "possible" one. Similarly, the IUGR remains very controversial, at least within the diabetes community, with many now arguing whether it really exists or is just newborn weight gain, etc. Some would say it is selected mortality, for example, differences in fetal death rates. In any case, there are certainly no RCTs that would suggest the validity of IUGR.

Page 29. The statement is made that saturated fat should not exceed 7 percent. What is the source for this recommendation? The *U.S. Dietary Guidelines for Americans* recommends less than 10 percent of calories.

Page 29. In the "convincing" category in Table 5, no RCT has documented that voluntary weight loss in overweight and obese people per se is associated with a decreased incidence of type 2 diabetes. A published or soon to be published study by Da Qing, Pan, X-P et. al., "Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance." *Diabetes Care*, 1997;20:537-44 and a Finnish study: Tuomilehto J, et. al., "Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance" *New England Journal of Medicine*, 2001;344:1343-50, DPP of the HHS/NIH/National Institute of Diabetes and Digestive and Kidney Diseases have or are using only people with impaired glucose tolerance (IGT). For example, in the DPP, the benefits of life-style interventions occurred regardless of weight, even though most were at least overweight. Therefore, the "decreased risk" to date would be in people who are overweight/obese, but only if they also have IGT. There is no study in overweight/obese individuals in the absence of IGT. Since many overweight/obese persons do not have IGT, HHS/CDC suggests that the science has to direct us to some sort of screening effort, perhaps in overweight/obese individuals who do have IGT. Further, Gerry Reaven (1997) would suggest that interventions to change behavior should only be in people with insulin resistance, but this cannot be measured easily. The state of IGT/impaired fasting glycaemia (IFG)/"pre-diabetes" needs to be somehow reflected in the "convincing" category.

4.3 Nutrient recommendations for the prevention of cardiovascular diseases

Page 31, last paragraph. Risk associated with β-carotene supplements is based on one highly publicized study. Clinical studies are still ongoing and the results are inconclusive.

Pages 31-33. The paragraph on "Diet and disease" (page 31) should include high consumption of cholesterol among the unhealthy dietary practices. The evidence is

strong, as stated above, and the last sentence of the paragraph should therefore begin: "Unhealthy dietary practices include the high consumption of saturated fats and cholesterol, salt...."

The paragraph on "Strength of evidence" (page 31) should include dietary cholesterol among the nutrients for which there is convincing evidence of increased risk.

Page 32. Specific fatty acids are mentioned that are to be limited. This type of recommendation would be difficult for the public to discern. There is a lack of food composition data on many foods. This would also assume that the public has access to this data. Food composition data is available on the *Internet* (although not everyone has access to the *Internet*, especially in developing countries). These types of data are also available through hard copies when requested from USDA's Agricultural Research Service Nutrient Data Laboratory, which maintains the National Nutrient Databank.

Page 32, Table 6. Summary of level of evidence on lifestyle factors and risk of developing cardiovascular diseases. Dietary cholesterol should be moved from the "probable" category to the "convincing" category.

Page 32-33, Disease specific recommendations, Fats. (a). The goal for saturated fatty acids should be revised from <7 percent, which is more appropriate for therapeutic lifestyle intervention in individuals who have to lower their elevated cholesterol, to <10 percent, which is more appropriate for a population average intake as previously stated.
(b) There is a recommendation of less than 1 percent of energy intake from trans fatty acids. The *U.S. Dietary Guidelines* recommends cutting back on these, but no specific requirement of total calories is given.
(c) *U.S. Dietary Guidelines* does not give a specific percent of calories for PUFA; no literature is cited. The same criticism can be given for (d).
(d) The lower bound of the goal for total fat intake should be raised from the current 15 percent, which could lead to higher triglyceride and lower HDL levels and raise CVD risk, also as previously stated. The *U.S. Dietary Guidelines* recommends a total fat intake of no more than 30 percent of calories and saturated fat intake of <10 percent of calories.
(f) No recommendation is given for limiting fat intake from diary and meat products by selecting low fat dairy products and lean meat, as is recommended in numerous nutrition education publications distributed by USDA and HHS.

Page 34, Potassium. The intent of the sodium/potassium ratio recommended needs to be clarified. Is the ratio based on the goal or is it based on current intake? Based on the text in this section, what is the significance of not listing potassium in Table 2 on page 21?

Page 34, Fish. No recommendation exists in *U.S. Dietary Guidelines* on eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) intakes.

Page 34, Alcohol. This WHO/FAO Report did not recommend the use of alcohol, even though they state that a low to moderate consumption is protective against CHD. The *U.S. Dietary Guidelines* recommends, "if you drink alcoholic beverages, do so in moderation." Drinking in moderation may lower risk for CHD, mainly among men over

age 45 and women over age 55. Guidance is given as to those that should avoid alcohol consumption. A recent study just published in the *Journal of the American Medical Association* showed that drinking alcohol may reduce diabetes risk in middle-aged women.

Appendix 1, Potassium. This table suggests that increasing potassium would decrease cardiovascular risk and the evidence was considered convincing. This is consistent with statements made by the National High Blood Pressure Educational Program at the National Heart, Lung, and Blood Institute, HHS/NIH.

Appendix 1, Sodium. The review of the literature regarding sodium and populations was quite good.

Appendix 1, Dietary cholesterol. Change "P" to "C" under column "CVD" to reflect changes proposed in the text of the Report.

4.4 Nutrient recommendations for the prevention of cancer

Page 37, item 7. Cancer is multi-factorial and there is no confirmed clinical studies showing that red meat consumption causes cancer. There are many types of cancer, and dietary effects can vary depending on the type. Total diet must be taken into account.

Page 37, item 8. There is a recommendation to not consume thermally hot foods and drinks relative to cancer risk. Is there sufficient evidence to provide some sort of temperature or temperature range here? The definition of "hot" may vary widely from person to person and culture to culture.

4.5 Nutrient recommendations for the prevention of dental diseases

General Comments. For many years, the dental profession has focused only on the dental caries aspect of nutrition, overlooking the growing scientific understanding of the wider range of interactions between nutrition and oral health. It is true that dental caries remains one of the world's most prevalent diseases, but many other oral conditions are impacted by nutrition and diet, and nutrients other than sugars affect oral health.

There is no discussion other than the role of vitamin C in this section of the Report. HHS/CDC suggests that benefit could be realized by some mention of the important role of various vitamins, minerals, trace elements during tooth development and the effects of severe nutritional deficiencies (which are rare in United States but not so in underdeveloped countries) in the pre-eruptive time period. Additionally, while it is stated early on that this Report would not cover diseases of the oral mucosa, many deficiency states that affect the oral mucosa also affect the periodontal tissues. Unless oral mucosa problems will be discussed in a separate report, it seems that, at a minimum, this topic could be covered if only to mention the importance of prenatal nutrition and early childhood nutrition for the proper development of teeth and oral tissues and for a basic balanced nutritional intake for long-term maintenance. It could be included with perhaps

minimal effort if the information was presented as "informational only" and not with in-depth review or evidence-based recommendations.

Some confirmed and potential relationships between deficiency states and oral diseases that could be mentioned include deficiencies in vitamins like riboflavin and angular stomatitis; cleft lip and palate - folic acid deficiency; fetal alcohol syndrome - dental malformations; role of calcium, phosphorus, magnesium etc in tooth and alveolar bone development; role of inorganic and organic trace elements, minerals in the maintenance of healthy tissues; sore tongue - iron deficiency, nicotinic acid and riboflavin; taste alterations, sore tongue, glossitis, stomatitis - zinc; lack of protein - kwashiorkor - stomatitis, angular cheilitis, circumoral pigmentation, retarded growth of teeth and jaws, increased enamel dissolution, periodontal problems; Vitamin A - tooth developmental disturbances - rat studies; Vitamin D - delayed eruption, enamel/dentin changes, periodontal disease in adults with osteomalacia; Vitamin B complex - deficiencies resulting lesion of soft tissues including tongue, lips, gingival and others.

A broader approach in the consideration of nutrition and oral health needs to be taken. Some of the issues that should be considered include:

- **Dental caries.** The etiology of dental caries is multifactorial, and quantity of sugar consumption is not the only factor involved in this disease. In fact, there is no real correlation between per capita sugar consumption and dental caries rates in a population. Current research is leading to a greater emphasis on frequency and duration of fermentable carbohydrate intake, rather than total consumption. Disease rates are also impacted strongly by the availability of the micronutrient fluoride, both dietary and topically applied. Fluoride increases the enamel's resistance to decay, and helps to reverse the carbohydrates' effects in enamel demineralization. The role of nutritional factors in host susceptibility to infectious diseases, such as dental caries is also being explored.

  The discussion of dental caries does not include any discussion of baby bottle caries, yet this is a major source of dental caries in infants and young children. At a minimum, USDA suggests that point #4 on page 40 should include specific advice not to put an infant to bed with a bottle containing formula, fruit juice, soft drinks, etc.

- **Periodontal diseases.** While the Report dismisses periodontal diseases as being unrelated to diet, several papers by Cyril Enwonwu, DSc, PhD, MDS, BDS, a researcher at the University of Maryland School of Dentistry, discuss in great detail the link between nutrition and periodontal diseases. Dr. Enwonwu points out that the progression of periodontal disease is much worse in malnourished children. He cites studies that look at the role of micronutrients in inflammatory response, immune system suppression, and cytokine function, all of which factor into the severity and pathogenesis of periodontal infections. In addition, a Task Force on Sugars of the HHS/FDA also implicated fermentable carbohydrates in the development of plaque and periodontal diseases. (Enwonwu CO. Interface of

malnutrition and periodontal diseases. *American Journal of Clinical Nutrition* 1995;61(Suppl.):430-6S. Department of Health and Human Services, Food and Drug Administration. Evaluation of health aspects of sugars contained in carbohydrate sweeteners, Report of Sugars Task Force, 1986, Executive Summary. DHHS 1986.)

- **Saliva.** Optimal salivary gland function is crucial for maintenance of good oral health, including dental and periodontal health. Many studies in both humans and animals have shown that nutrition, including physical consistency of foods consumed, impact on salivary gland structure as well as the production of adequate saliva with a full complement of the well-characterized bactericidal substances contained therein. In a 1996 paper, Dr. Juan Navia states, "Moderate malnutrition, particularly lack of protein and deficiencies of certain micronutrients such as vitamin, zinc and iron (anaemia), can influence the amount and composition of saliva limiting the protective effects it has in the oral cavity." (Navia JM. Nutrition and dental caries: ten findings to be remembered. *International Dental Journal* 1996;46 (Suppl. 1):381-387.)

- **Craniofacial birth defects.** Maternal nutrition is suspected to have an important role in craniofacial birth defects. While the folate-neural tube defect (NTD) story is well known, scientists are looking at various micronutrients potentially involved in the development of the common birth defect of oral clefting. WHO, led by Dr. Victor Boulyjenkov, is heading up a global project to create an international network for craniofacial birth defects research, and nutritional research is a key component of this project. Clefting is a multifactorial condition, involving a complex interaction between genes and environmental factors, including maternal smoking, alcohol use and nutrition.

- **Oral cancer.** Oral cancer is another multifactorial disease. Tobacco use and excessive alcohol use are considered the primary risk factors, but research suggests that diet and nutritional status could be an important etiologic factor. Dr. Enwonwu has published a paper advancing the idea that alcohol and tobacco abuse have their effects because of their negative impact on nutrition, and the resulting decrease in the competence of the immune system. (Enwonwu CO, Meeks VI. Bionutrition and oral cancer in humans. *Critical Review of Oral Biological Medicine* 1995;6(1):5-17.)

- **Noma.** Noma, or cancrum oris, is a gangrenous lesion found almost exclusively in malnourished children in extremely impoverished communities. Per Dr. Enwonwu, the first stage in the disease process is "a multifactorial staging period resulting in impaired immune status as a consequence of malnutrition and viral and/or other parasitic infections." (Enwonwu CO, Sanders C. Nutrition: impact on oral and systemic health. Compendium 2001;2(3):12-18.)

- **Dental erosion.** One other topic mentioned in the Report is dental erosion. The first line of the abstract of that paper says, "Tooth enamel erosion occurs only in

susceptible individuals regardless of food and beverage consumption patterns; that is, consumption of an acidic drink or food alone is highly unlikely to cause erosion." Other factors play a role in erosion as well. Ironically, it seems that the people with the most conscientious oral hygiene habits are facilitating erosion by rushing to brush their teeth immediately after consuming any acidic food or beverage. 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. It is the combination of diet and oral hygiene practices that looks to be the cause. (Moss SJ. Dental erosion. *International Dental Journal* 1998;48(6):529-539).

Page 38, Background. The WHO/FAO Report states, "the cost of dental caries treatment is unlikely to be reduced in industrialized countries." In the United States, an increasing percentage of gross national dental spending is for diagnostic/preventive care versus restorative care, and similar trends may exist in other industrialized countries.

Page 38, Strength of evidence. The statement made that "systemic and local fluoride is protective" could be modified to emphasize the major role of topical fluoride, and therefore fluoride is protective for all ages.

Page 40, Disease Specific recommendations # 1 and #2. While it is very important to stress that the risk of dental caries is multi-factorial and that exposure to fluoride (by diet or hygiene practices) is very important, the basis is not given for the specific recommendation of free sugar intake in the presence or absence of fluoride. It is likely that frequency of intake of added sugars is as important as total intake, yet no differences are offered in #2. In the presence of adequate fluoride, both recommendations seem unnecessarily restrictive. Furthermore, individual exposure to fluoride fortification varies both within and among countries.

Page 40, Disease Specific recommendations # 3. The recommendation is not supported by the first sentence of the explanation that follows. The explanation should be changed to note that "it should be recognized that, while frequent exposure to fluoride, by water, salt, or fluoride toothpaste is effective, a combination of either water or salt fluoridation and fluoride toothpaste may be the most effective population-based approach. Environmental and social circumstances determine which is likely to be most effective and appropriate for any specific community."

Page 41, Disease Specific recommendations # 5. It would be helpful for WHO/FAO to define what is meant by "excess fluoride." In the United States, the required action level as defined by the U.S. Environmental Protection Agency is 4.0 ppm with a voluntary level of 2.0 ppm.

4.6 Nutrient recommendations for the prevention of osteoporosis

Page 42, paragraph 4. HHS/CDC suggests this paragraph would be strengthened with the inclusion of some definition or examples for "countries with high osteoporotic fracture incidence."

Page 43. Recommendations are given for calcium and vitamin D in older populations, which is valid. However, there is no mention of the importance for adolescents. There is considerable supporting published scientific data on this and yet none was cited. There is no real mention of (1) the importance of vitamin K and bone development; (2) that physical activity should be weight bearing; and (3) that the best bioavailable source of calcium is dairy products.

Page 43. The consultancy decided to use osteoporotic fracture instead of bone density as the health outcome for the nutritional recommendations. Dr. Anne Prentice presents a case for this decision in her review. Given this decision, would it be 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 may have reached different conclusions or recommendations.

WHO and FAO may also wish to consider adding a brief explanation 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 43, last paragraph. Counter to what is stated in the Report, studies have shown that increasing protein intake (which includes protein from animal sources) has a positive effect on bone mineral density in the elderly (*Am. J. Clin. Nutr.* 2002, 75, pp. 773-779, is one recent example). There is no firm consensus to date, but studies do indicate that low calcium intakes adversely influence the effect of dietary protein on fracture risk.

Page 43, Table 12. Given that fracture is the outcome of interest, it is somewhat unclear why high sodium intake is considered a probable risk factor. While the author points out in her review, sodium is linked to urinary calcium excretion and is thought to be a risk factor for poorer bone health, she also indicates, "The evidence that sodium is important in the aetiology of osteoporosis or that sodium restriction may be a beneficial strategy for fracture prevention, however, is inconclusive." Given this statement by the author, and the little evidence in the literature the sodium is related to fracture risk, we would suggest it may be more appropriate to classify high sodium intake as a "possible" risk factor for osteoporosis.

In Table 12, HHS/CDC suggests it would be more appropriate to either place "increased magnesium intake" in the increased risk category or delete "increased" under the "no association" category.

Page 44. We suggest that Item 2 under the recommendations be written as a recommendation (similar to Items 1, 3 and 4). Is the recommendation that older adults get at least 400 mg of calcium? The United States and Canada's recommended intake for person over age 50 is 1,200 mg per day.

We further suggest that Items 2 and 3 in the recommendations be a subset of Item 1, as Items 2 and 3 are the targeted interventions mentioned in Item 1.

Page 44, Item 3. The report should indicate whether the recommended amounts of intakes of calcium and of vitamin D describe what the "average" or the most "vulnerable" person in the population needs. Specifically, can documentation for where the specific recommendation for vitamin D consumption (5 to 10 micrograms) is derived be provided? The reference does not appear to be in the review (page 20) or in the final recommendations. The Report should provide information on how much sunlight exposure provides adequate vitamin D status. Also, does this change with age?

Page 44, Item 4. Are the recommendations listed meant to be for the whole population or just older adults? If the recommendations are meant for older adults only, the listing of "increased physical activity" as one item with "firm evidence lacking" is inconsistent with Table 12, which states there is "convincing evidence" for a relationship between physical activity and osteoporosis. If the recommendations are for the whole population, do recommendations about calcium and vitamin D need to be included for those in the population who are not older? Additionally, the increase in physical activity to prevent osteoporosis should be weight-bearing exercise.

Section 5: Recommended Action

Many comments relevant to this specific section are delineated in the opening section under **General Comments**. The following offers additional, more specific commentary.

Overall, this section proposes a range of recommendations for potential strategies, which are not necessarily linked to either the data provided in the annexed papers or on the earlier sections to the report. For some of the recommendations proposed, there is scant data available to support them. In fact, there is a clear disconnect between some of the recommendations and the data presented, or at a minimum, recommendations are loosely worded and could benefit from a more rigorous scientific phraseology. Many of the recommendations also fall outside of the purview of health and public health, and future revisions of the Report's recommendations could benefit from incorporating a range of experts, in the development of regulations and labeling, agricultural policy, urban planning, etc. Some examples include:

Food and nutrition policies

- **Encourage a food production policy based on small regional food producers as such policy often prevention the movement of people from a rural to urban setting, resulting in a loss of diversity of food production of traditional foodstuffs in favour of wide-scale production of cash crops demanded by export markets;**

NOTE: While the development and promotion of such a food production policy may prevent movement of people, evidence of this is documented in the report, especially in support of the term "often". Similarly, this statement infers that the rural-urban movement is the primary reason of the loss of diversity of traditional foodstuffs, which may or may not be the case.

Regulation of food quality, advertising and labeling

- **Take action to respond to the changing food supply by developing or adjusting food regulations that control food quality and safety, the labeling of foods and the advertising of foods;**

NOTE: This statement infers that food quality and safety, food labeling and food advertising are directly linked to improved nutritional outcomes, which may or may not be the case.

- **Enact and enforce measures for labeling of food products, with respect to their sodium, fatty acid and sugar content, with clear codes, which will enable consumers to readily identify products with high sodium and/or fatty acid content.**

NOTE: In this instance, how is the term "clear codes" being defined?

This bullet should also include dietary cholesterol, in addition to fatty acid content, in its call for appropriate labeling of food products.

Throughout the Report, the Expert Consultation group provides guidance for a few nutrients that is not provided or is more specific than that provided by the NIHLB, NIH/ HHS. For example, trans fatty acids: recommendations to limit intake of trans fatty acids by decreasing total fat (thereby decreasing trans fat) are prudent. However, it is unclear which data were used by the Expert Consultation to recommend limiting intakes to a specific amount (<1 percent of total energy) in this Report. Another example, involves omega-3 and omega-6 fatty acids in fish. It is unclear how specific recommended amounts of omega-3 and omega-6 fatty acids were derived, given the data cited. The Expert Consultation concluded that convincing evidence exists, however they may not have critically evaluated available findings in light of appropriateness of study design. Most data are from observational studies. Four randomized clinical trials have assessed secondary not primary prevention and some were not optimally designed.

Recommendations to international agencies

NOTE: It is assumed that WHO and FAO have conferred with the other multilateral and bilateral agencies identified, including the World Trade Organization and the UN Development Program, among others, in the development of these recommendations.

Recommendations for civil society

- **Use public transport, walking and cycling more often.**

NOTE: Walking or cycling could be achieved with or without a dependence on public transportation. In fact, the recommendations should promote civil society to increase their levels physical activity generally. Delineating a specific type of exercise may infer that this level of activity is superior to other types of activity.

- **At all levels, support advocates who promote health.**

NOTE: How is WHO/FAO defining "support" or "health"? Just because an advocate or advocacy group would promote health, this would not necessarily support a blanket endorsement for advocacy by civil society.

Page 46, bullet 3, **Under Assuring Food Quality, Advertising and Labeling recommendation**. Add 'added sugars' in the last line.

Page 46, bullet 4. Food labeling recommendations were enacted with the U.S. National Labeling and Education Act (NLEA), which requires 14 nutrients be identified. To identify the fatty acid content of every food would be very costly. For some foods, this may require development of new analytical methods.

Page 47. Tailoring of nutrition education to ensure that all messages are appropriate for all minority groups would be a tremendous task in the increasingly diverse United States. The United States supports the creation and use of culturally and linguistically sensitive materials, but could not guarantee tailoring for all groups. We are concerned that a requirement to provide materials appropriate to all minority groups could slow down public release of new, up-to-date materials.

Page 47. The United States has a national food intake survey through the USDA and DHHS, entitled "What We Eat In America." This new integrated national survey is an annual one.

Annex 1: Summary of the strength of evidence for obesity, type 2 diabetes, cardiovascular disease, cancer, dental disease and osteoporosis

Summary of the strength of evidence for obesity, type 2 diabetes, CVD, cancer, dental disease and osteoporosis. 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 be changed to "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 formulas, 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 10-15 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. The evidence rating for dietary cholesterol should be changed to C for conclusive.

The table also rates the evidence linking "high" intake of non-starch polysaccharides (fibre) with decreased risk for obesity as "C" for conclusive. This should be changed to reflect the evidence. For example, on page 15 it states that a high intake is generally, but not always associated with a lower BMI and that "these studies are highly susceptible to measurement errors and confounding factors."

Annex 2: The scientific basis for diet, nutrition, and the prevention of excess weight gain and obesity.

Page 18: Some detail on the obesogenicity of soft drink vending in schools is discussed. This issue is currently a controversial topic in U.S. schools. Issues surrounding other competitive foods and soda manufacturer contracts with schools for exclusive rights to sell in schools are not discussed in the Report.

Section 3.3.2 cites one study that has shown that the consumption of high-sugar soft drinks predict weight gain. We would suggest that this is insufficient evidence to conclude a causal link between soft drinks consumption and weight gain exists. In this same Section, similar references and inferences are made about a link between soft drink vending machines and obesity, where little, if any, scientific evidence exists.

Annex 4: Cardiovascular Disease

Section 1 is familiar ground and is in most respects accurate. HHS/CDC takes exception to the unqualified adoption of the "epidemiologic transition" because it indicates a necessary reduction in communicable disease death rated as a precondition for the circulatory disease epidemic, which is untrue. Incidentally, Column 1, Table 1 should be "circulatory disease mortality." One column appears to have numbers that seem to represent data somewhere between CHD and stroke.

Section 2 on methodology is relevant and generally well written but for non-epidemic readers, it could usefully be made more explicit about the concerns raised. For example, what effects do the cited limitations have and how do they relate to (mis) interpretation of the evidence? The last paragraph (page 18) suggests the need to formulate and test alternative models of the relations among the many determinants, factors and outcomes at issue.

In **Section 6**, the references seem to be missing for **Section 6.4** and may be in error for other topics.

Overall **Section 7**, "Implications for Policy," appears sound and well supported by the material reviewed.

The summary table (**Section 7**) "dietary cholesterol" should be moved from the "probable" row to the "convincing row" to be consistent with previous comments.

The summary table (**Section 8, page 67**) is convenient, but would be difficult to interpret or evaluate outside the context of the full review in Section 3-6.

Annex 5: The scientific basis for diet, nutrition and the prevention of cancer

This section focuses mainly on epidemiological evidence. While epidemiological evidence is important, it is only one of the many sources of information. Many documented cases of observational epidemiological studies do not always hold up to intervention findings. The various modifiers are not always known and thus it is not always possible to determine who is and is not benefiting from specific foods or food components. It is a mistake to imply that to a large extent the relationship of nutrition to cancer rest with obesity and alcohol consumption. While there are links, the overall impact is not compelling. While a focus on fruits and vegetable consumption may be logical from an overall health perspective, it likewise suffers from insufficient information. Overall, the real problem is trying to be proactive in promoting nutrition as a determinant of health and not confuse people with unsubstantiated information. U.S. experts have a real concern with the suggested desire to increase fish consumption and limit production animal usage. While a more vegetarian lifestyle might be better for some, there remains considerable controversy. Unfortunately the controversy does not come out in the annexed document.

The annex is appropriately circumspect regarding the evidence for the involvement of diet in cancer. However, the specific recommendations (for example, avoid obesity and alcohol and maintain exercise) are likely to be more relevant to the other health issues raised in the larger WHO/FAO Report than they are to the incidence of cancer. Estimates going back to the early 1980's that 30 percent of cancers are attributable in some way to diet are likely too high and the annex makes this point. Moreover, there has never been a suggestion that 30 percent of cancers could actually be eliminated even if all of the recommendations made here were adopted universally.

Overall, this annex points out the shortcomings of the data and makes recommendations based only on what is the more convincing links to diet that have been published.

Annex 6: The scientific basis for diet, nutrition and the prevention of dental disease

Page 36 6.1 Recommendation for prevention of dental disease. The recommendation states that it should be recognized that the most effective means of delivering fluoride is by use of fluoride toothpaste. Although this may be true on an individual basis and in given certain circumstances on a community basis, it should also be stated that community water fluoridation may be a more effective way of delivering optimal levels of fluoride on a community level.

Page 38 6.5 Recommendations to civil society. Besides providing dental health and dietary education as recommended, schools should also promote healthy meals and snacks in their cafeterias and vending machines.

Page 38 6.6 Recommendations at the individual level. Although there is a fair amount of discussion in the document on dental erosion, there are no recommendations on limiting the high consumption of acidic soft drinks, high acid candies, or prolonged sucking of citrus fruits.

NOTE: This USG response reflects contributions by a range of scientific, technical, and policy experts who participated in the review of the April 26, 2002 version of the WHO/FAO Report. These experts' affiliated committees, offices, programs, centers and institutes, are located at **ANNEX B.**

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ANNEX A

EVIDENCE-BASED GUIDELINES

Evidence-Based Guidelines: Using the following evidence-based categories, these guidelines are used by the U.S. Department of Health and Human Services' technical agencies to evaluate published information and to determine the most appropriate treatment strategies that would constitute evidence-based clinical guidelines.

Category	Sources of Evidence	Definition
A	Randomized controlled trials (rich body of data)	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.
B	Randomized controlled trials (limited body of data)	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, Category B pertains when few randomized trials exits, 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.
C	Nonrandomized trials Observation studies	Evidence is from outcomes of uncontrolled or nonrandomized trials from observational studies.
D	Panel Consensus Judgment	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 thought 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, page xiii).

ANNEX B

USG comments reflect contributions by a range of scientific, technical, and policy experts who participated in the review of this report. They include experts from:

U.S. Department of Health and Human Services

Office of the Secretary

Office of Global Health Affairs

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

Centers for Disease Control and Prevention
Division of Nutrition and Physical Activity
National Center for Chronic Disease Prevention and Health Promotion

Office of Global Health

Food and Drug Administration
Center for Food Safety and Applied Nutrition

Office of International Affairs, Office of the Commissioner

Agency for International Development

Global Health Bureau

Department of Agriculture

Special Nutrition Staff
Office of Analysis, Nutrition and Evaluation
USDA Food and Nutrition Service

Center for Nutrition Policy and Promotion

National Program - Human Nutrition
Agricultural Research Service

Special Nutrition Staff
Office of Analysis, Nutrition and Evaluation
Food and Nutrition Service

National Program - Human Nutrition
Cooperative State Research, Education and Extension Service

Nutrition and Food Safety Program
Cooperative Research Grants and Awards Management
National Research Initiative
Cooperative State Research, Education and Extension Service

Family, 4-H and Nutrition
Cooperative State Research, Education and Extension Service

Department of Commerce

International Trade Administration
Chemicals, Pharmaceuticals and Biotechnology Division

Office of Consumer Goods

Department of State

Bureau of International Organization Affairs

U.S. Trade Representative

Office for Multilateral Trade and Environment Policy