

The Center for Regulatory Effectiveness

REQUEST FOR CORRECTION OF INFORMATION CONTAINED IN A WORLD HEALTH ORGANIZATION REPORT

Filed by: The Center for Regulatory Effectiveness and Jim J. Tozzi
11 Dupont Circle, N.W.
Washington, D.C. 20036
(202) 265-2383

September 8, 2003

The Center for Regulatory Effectiveness and Jim J. Tozzi (Petitioners) file this Request for Correction pursuant to the Data Quality Act,¹ as implemented by the Office of Management and Budget s [OMB s] Government-wide Data Quality Act Guidelines² and by the Data Quality Act Guidelines of the Department of Agriculture [USDA]³ and the Department of Health & Human Services [HHS].⁴

ISSUE: USDA and HHS have established a Dietary Guidelines Advisory Committee to review and update the most recent scientific literature in preparation for the release of the 2005 version of Dietary Guidelines for Americans. Both USDA and HHS have stated an intent to base what they would include in the 2005 Dietary Guidelines in part on a World Health Organization (WHO) Report that does not meet the U.S. Government s data quality standards. Before USDA and HHS are legally able to rely on any of the facts and analyses supporting the scientific recommendations stated in WHO Technical Report 916 (WHO Report), USDA and HHS will have to carry out a pre dissemination review (that needs to include the public involvement of all stakeholders) to identify specifically in what ways this WHO Report fails to meet the U.S. Government s data quality standards. After that review, either USDA and HHS or WHO will have to supplement this WHO Report with corrections before USDA and HHS will be able to base any dietary or nutrition policy guidance on any scientific recommendations and associated facts and analyses stated in the WHO Report.

¹ The Data Quality Act amendments to the Paperwork Reduction Act, 44 U.S.C. 3516 statutory and historical notes, P.L. 106-554 Appendix C, §515; 114 Stat. 2763A-153; (Data Quality Act or Act).

² 67 FR 8452 (February 22, 2002) (OMB Guidelines). Guidelines refers to the OMB, USDA, and HHS guidelines collectively.

³ http://www.ocio.usda.gov/irm/qi_guide/index.html (USDA Guidelines).

⁴ <http://www.hhs.gov/infoquality/part1.html> (HHS Guidelines). We also refer to the Guidelines issued by the HHS Office of Public Health and Science, <http://www.hhs.gov/infoquality/os.html> (OPHS/HHS Guidelines).

I. THE SECRETARIES OF USDA AND HHS HAVE STATED AN INTENT TO ADOPT POLICY GUIDANCE BASED ON SCIENTIFIC RECOMMENDATIONS SUPPORTED BY FACTS AND ANALYSES IN A WORLD HEALTH ORGANIZATION REPORT THAT FAIL TO MEET U.S. GOVERNMENT DATA QUALITY STANDARDS.

In April 2003, the World Health Organization published Technical Report 916, entitled, Diet, Nutrition and the Prevention of Chronic Diseases.⁵

On August 11, 2003, the USDA and HHS Secretaries issued identical press releases. The primary purpose of this press release was to identify the academic experts that had been appointed to the Dietary Guidelines 2005 Advisory Committee. The press release stated:

The [Advisory] Committee designees will meet in the early fall [of 2003] to review and update the most recent scientific literature in preparation for the release of the 2005 version of Dietary Guidelines for Americans. ...

The Dietary Guidelines for Americans is the cornerstone of nationwide nutritional and dietary programs and policies, and will become increasingly significant as we continue to wage battles against obesity, diabetes, cardiovascular disease and other chronic illnesses, Secretary Thompson said. ...

This committee will consider the latest science as they develop a report that will offer Americans information that is critical to their health and welfare. Our goal is to provide clear information for consumers through the Dietary Guidelines for Americans, Secretary Veneman said. ...

First published in 1980, the Guidelines are reviewed, updated and released by HHS and USDA every five years, and contain nutritional and dietary information and guidance for the general public.

Near the end of the press release, USDA and HHS both stated an intent that the Advisory Committee rely in part upon scientific facts and analyses contained in the WHO Report in making its recommendations.

In order to prepare the [Dietary] Guidelines [for Americans] for release in 2005 the sixth edition the **designees** [to the Dietary Guidelines Advisory Committee] **will examine** the new Dietary Reference Intakes by the Institute of Medicine; **the World Health Organization report on Diet, Nutrition and the Prevention of Chronic**

⁵ Technical Report 916, Diet, Nutrition and the Prevention of Chronic Diseases, World Health Organization (Geneva, 2003), a Report of a Joint WHO/FAO Expert Consultation (WHO Report). See, <http://www.who.int/hpr/gs.who.fao.report.shtml> .

Diseases: and other recent scientific research. ... The designees, selected expressly for the purpose of reviewing and revising the Guidelines, will recommend guideline revisions to the HHS and USDA Secretaries in a formal report, if warranted.⁶

However, in July 2002, the United States Government, writing through the Office of International Affairs in the Department of Health & Human Services, had already expressed serious concerns to WHO concerning the quality of the facts and analyses supporting the scientific recommendations stated in the WHO Report, e.g:

Science should drive policy, ... In finalizing the report, the WHO and the FAO must adopt a comprehensive, evidence-based approach, in which qualified experts rigorously and objectively evaluate the science in a transparent manner and clearly articulate the basis for conclusions and recommendations, reflecting internal consistency and scientific rigor. ...

[T]he WHO/FAO report makes it clear that it is premature to use available data to develop national food and nutrition policy without further evidence. The lack of clear links between the evidence provided, either in the report or its accompanying annexes, and the proposed recommendations delineated in Sections 5 and 6 of the report are of particular concern.⁷

As explained below, the WHO Report fails to resolve the concerns itemized by the U.S. Government and also fails to comply with the U.S. Government's data quality standards for objectivity and utility.

II. CORRECTIONS REQUESTED.

1. Predissemination Review. As facts and analyses supporting scientific recommendations in the WHO Report fail to meet the concerns already stated by the U.S. Government, and do not meet the U.S. Government's data quality standards for objectivity and utility, USDA and HHS are required by the U.S. Government's data quality standards to conduct a predissemination review of the WHO Report to identify which scientific facts and analyses need to be corrected.

⁶ <http://www.usda.gov/news/releases/2003/08/0283.htm>;
<http://www.hhs.gov/news/press/2003pres/20030811.html>

⁷ July 2, 2002, letter from William R. Steiger, Special Assistant to the Secretary for International Affairs, Office of the Secretary, Department of Health & Human Services, to the Honorable Gro Harlem Brundtland, Director-General, World Health Organization, page 2 (U.S. Letter). Attached to the U.S. Letter were the 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). See, <http://www.who.int/hpr/CommentsOrganizations.shtml> .

The Center for Regulatory Effectiveness -4-

This predissemination review should include active outreach to all private stakeholders through notice and request for public comment in the *Federal Register*.

Once this predissemination review identifies specifically in what ways the facts and analyses supporting scientific recommendations in the WHO Report fail to meet the U.S. Government's data quality standards, then USDA and HHS will need to supplement the WHO Report to make the needed corrections to the scientific facts and analyses, and to the ways in which they are presented in the WHO Report. As an alternative, once USDA and HHS have identified the scientific facts and analyses that need correction, USDA and HHS could contact WHO to work with WHO so that WHO supplements the WHO Report to make the corrections needed to ensure that the WHO Report meets the U.S. Government's data quality standards.

Given the apparent importance and uses intended for this WHO Report, USDA and HHS need to assure the overall quality—the objectivity and utility—of the facts and analyses supporting the scientific recommendations made in the WHO Report now, before the Advisory Committee begins to rely upon the WHO Report in any way in making policy recommendations to USDA and HHS. Otherwise, the USDA and HHS will not be able to rely on any recommendations from the Advisory Committee based on the scientific recommendations that the designated experts read in the WHO Report.

2. Retract USDA/HHS Press Release. The Secretaries of USDA and HHS should publicly retract their statement in their press release that appears to commit the Dietary Guidelines Advisory Committee to relying on scientific recommendations in the WHO Report in making their recommendations for adoption by USDA and HHS in the 2005 version of the Dietary Guidelines for Americans. USDA and HHS cannot make such a public commitment until after they have conducted a predissemination review of the facts and analyses supporting the scientific recommendations in the WHO Report and have supplemented the WHO Report in ways necessary to assure that the facts and analyses supporting the scientific recommendations in the corrected WHO Report meet the U.S. Government's data quality standards.

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

III. THE WHO REPORT CONTAINS INFLUENTIAL SCIENTIFIC INFORMATION THAT USDA AND HHS WILL DISSEMINATE, MAKING THE WHO REPORT SUBJECT TO THE U.S. GOVERNMENT'S DATA QUALITY STANDARDS.

A. The WHO Report contains influential scientific information.

The OMB Guidelines specifically define what is meant by influential scientific information:

Influential , when used in the phrase influential scientific, financial, or statistical information , means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.⁸

Both USDA and HHS follow the OMB definition of influential.

The WHO Report itself describes the broad, international policy-development use that WHO intends for this WHO Report.

The Consultation provided an opportune moment for FAO and WHO to draw on the latest scientific evidence available and to update recommendations for action to governments, international agencies and concerned partners in the public and private sectors. The overall aim of these recommendations is to implement more effective and sustainable policies and strategies to deal with the increasing public health challenges related to diet and health. ...

Nutrition is coming to the fore as a major modifiable determinant of chronic disease, with scientific evidence increasingly supporting the view that alterations in diet have strong effects, both positive and negative, on health throughout life. ...

This report calls for a shift in the conceptual framework for developing strategies for action, placing nutrition together with the other principal risk factors for chronic disease, namely, tobacco use and alcohol consumption at the forefront of public health policies and programmes. ...

During the preparation of this report, by resolution WHA55.23 in May 2002, the World Health Assembly called upon the Director-General to develop a global strategy on diet, physical activity and health (WHA55.23). The process for developing the WHO global strategy will involve formal consultation with Member States, United Nations agencies, civil society, and the private sector over a period of a year, prior to drafting a proposed

⁸ Paragraph V.9, p. 8460/3.

global strategy for presentation to the Fifty-seventh World Health Assembly in 2004.⁹

Based on both the intended use that USDA and HHS have already stated for the WHO Report, as well as the intended international use stated by WHO itself, it is clear that the WHO Report contains influential information.

B. As stated in the press release, both USDA and HHS plan to disseminate the WHO Report.

OMB, in issuing its guidelines, stated:

[I]f an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines.¹⁰

USDA adopted this principle in its Guidelines:

These [USDA] guidelines apply not only to information that USDA generates, but also to information that USDA disseminates that was provided by or obtained from outside parties and which USDA adopts, endorses, or uses to formulate or support a regulation, guidance, or other agency decision or position.

So did HHS:

The Guidelines apply to substantive information disseminated by OPHS offices and representing OPHS/HHS views.¹¹

While USDA and HHS are not obligated to follow the recommendations of the Dietary Guidelines Advisory Committee in drafting the 2005 Dietary Guidelines for Americans, the press release strongly implies that USDA and HHS plan to do so.

The [Dietary Guidelines Advisory] Committee designees will meet in the early fall to review and update the most recent scientific literature in preparation for the release [by USDA and HHS] of the 2005 version of Dietary Guidelines for Americans. ... In order to prepare the [Dietary] Guidelines [for Americans] for release in 2005 the sixth edition the designees [to the Dietary Guidelines Advisory Committee] will examine ... the

⁹ WHO Report, pp. 2, 3 & 135 at footnote 1.

¹⁰ OMB Guidelines, Supplementary Information, p. 8454/1.

¹¹ OPHS/HHS Guidelines, p. 14.

The Center for Regulatory Effectiveness -7-

World Health Organization report on Diet, Nutrition and the Prevention of Chronic Diseases

And, if USDA and HHS do so, then under the U.S. Government's data quality standards, USDA and HHS will have had to have already reviewed the WHO Report and determined that the WHO Report had been supplemented as necessary to comply with the U.S. Government's data quality standards.

Moreover, as indicated above, this WHO Report contains the update[d] recommendations for action to governments, international agencies and concerned partners in the public and private sectors¹² to be considered in drafting a proposed global strategy [on diet, physical activity and health] for presentation to the Fifty-seventh World Health Assembly in 2004.¹³

Again, it is speculative to anticipate what the Fifty-seventh World Health Assembly will decide in 2004. But, to the extent that WHO member countries agree to a global strategy on diet, physical activity and health in 2004, the Dietary Guidelines Advisory Committee, USDA, and HHS will be under strong pressure to harmonize the 2005 version of Dietary Guidelines for Americans to the policies embodied in the WHO global strategy.

In summary, WHO clearly intends the international community to rely upon the scientific recommendations stated in the WHO Report.¹⁴ Those who drafted the WHO Report will certainly work to have it relied upon by national delegations in helping to formulate the WHO global strategy to be agreed to by the WHO member countries (of which the United States is one). It would be irresponsible for the Dietary Guidelines Advisory Committee, USDA, and HHS not to give the WHO global strategy great weight in deciding what kind of guidance to include in the 2005 Dietary Guidelines for Americans.¹⁵ All of these factors make it even more important for USDA and HHS to review the WHO Report and supplement it now to have it comply with the U.S. Government's data quality standards.

¹² WHO Report, p. 2.

¹³ WHO Report, p.135, footnote 1.

¹⁴ As WHO states on its web site: The Joint WHO/FAO Expert Report, Diet, Nutrition and the Prevention of Chronic Diseases (WHO TRS 916), was formally launched in Rome on April 23, 2003, by WHO Director General Dr Gro Harlem Brundtland, and FAO Director General Jacques Diouf.

¹⁵ As OMB recently stated, in a different context, Information is relevant to regulatory policy if it might be used by local, state, regional, federal and/or international regulatory bodies. (OMB Proposes Draft Peer Review Standards for Regulatory Science, OMB Press Release 2003-34, August 29, 2003 (<http://www.whitehouse.gov/omb/pubpress/index.html>).)

IV. GIVEN THE INTENDED USE FOR THIS WHO REPORT, THE U.S. GOVERNMENT S DATA QUALITY STANDARDS REQUIRE USDA AND HHS TO CONDUCT A PREDISSEMINATION REVIEW (THAT NEEDS TO INCLUDE THE PUBLIC INVOLVEMENT OF ALL STAKEHOLDERS) OF THE WHO REPORT TO IDENTIFY SPECIFICALLY IN WHAT WAYS THE WHO REPORT FAILS TO MEET THE U.S. GOVERNMENT S DATA QUALITY STANDARDS.

Based on what USDA, HHS, and WHO have already been stated, there is a strong likelihood (1) that both the United States and many other governments will be relying upon the facts and analyses cited in support of the scientific recommendations in the WHO Report in developing a global strategy on diet, physical activity and health, and (2) that the USDA and HHS (through their policy acceptance of recommendations from the Dietary Guidelines Advisory Committee) will be relying on the facts and analyses supporting the scientific recommendations in the WHO Report in deciding what guidance to include in the 2005 version of the Dietary Guidelines for Americans. On that basis, the U.S. Government s data quality standards require a predissemination review of the WHO Report now.

The OMB Guidelines require:

As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency s development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information its has disseminated through documentation or other means appropriate to the information.¹⁶

This requirement is reflected in both the USDA and HHS Guidelines:

USDA agencies and offices will review the quality (including objectivity, utility, and integrity) of information before it is disseminated to ensure that it complies with the standards set forth in these Guidelines.

We [HHS] are committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. * * * OPHS [The Office of Public Health and Science] reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination.

We strongly recommend that, in carrying out the required predissemination review, USDA

¹⁶ Paragraph III.2, p. 8459/1.

and HHS include active outreach to all private stakeholders through notice and request for public comment in the *Federal Register*.

In July 2002, the U.S. Government recommended that WHO allow additional opportunity for input from interested stakeholders:

We strongly encourage WHO and FAO to allow sufficient time for review and input from a range of stakeholders, including the scientific research community, industry, non-governmental organizations, and professional health societies. Specifically, we suggest that Member States and other stakeholders be given an additional opportunity for review and comment on the next draft report prior to final publication.¹⁷

As WHO did not provide the additional opportunity for stakeholder input that the U.S. Government requested, USDA and HHS should provide that opportunity now.

Such additional opportunity for stakeholder input would be consistent with both USDA and HHS policy concerning important scientific studies, e.g:

To ensure the objectivity of scientific research ... disseminated by USDA, its agencies and offices will: ... [w]here appropriate, subject the information to formal, independent, external peer review to ensure its objectivity.

Research and scientific studies disseminated by HHS are subject to an external, objective peer review process at both the inception stage and the pre-dissemination stage as part of the publication process in peer reviewed journals.

We are strongly recommending that USDA and HHS include, as part of their predissemination review of the WHO Report, an active outreach to all private stakeholders through notice and request for public comment in the *Federal Register*. As the U.S. Government already indicated, there are many potential stakeholders involved probably too many to be included in a more formally structured peer review. If USDA and HHS were to decide to undertake formal, independent external peer review as would be consistent with their data quality guidelines they could conduct the peer review at the same time as the more general notice and request for public comment in the *Federal Register* were taking place.

We would further note that OMB recently proposed Draft Peer Review Standards for Regulatory Science.¹⁸ On the assumption that this Proposed OMB Bulletin takes effect (more or less in its present form) on its target date of January 1, 2004, it would appear that USDA and

¹⁷ U.S. Letter, p. 2.

¹⁸ OMB Press Release 2003-34, August 29, 2003 (<http://www.whitehouse.gov/omb/pubpress/index.html>).

HHS would have to conduct a scientifically-rigorous peer review of this WHO Report, consistent with the Bulletin's peer-review standards and procedures, before USDA or HHS would be able to rely on any of the facts and analyses supporting the scientific recommendations in the WHO Report.

V. THE WHO REPORT FAILS TO MEET THE U.S. GOVERNMENT'S DATA QUALITY STANDARDS FOR OBJECTIVITY AND UTILITY.

A. The Objectivity and Utility Standards Include TRANSPARENCY and REPRODUCIBILITY.

OMB Guidelines include objectivity standards for influential scientific information involving transparency and reproducibility:

If an agency is responsible for disseminating influential scientific ... information, agency guidelines **shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.** ... With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public.¹⁹

OMB explains this requirement for transparency and reproducibility as follows:

The purpose of the reproducibility standards is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the **capable of being substantially reproduced** standard. ...

The more important benefit of transparency is that the public will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency. Concreteness about analytic choices allows, for example, the implications of alternative technical choices to be readily assessed.²⁰

Both USDA and HHS Guidelines require this transparency and reproducibility:

With regard to original and supporting data related to *influential* scientific information, USDA agencies and offices will ensure reproducibility With regard to analytic results

¹⁹ Paragraphs V.3.b.ii and V.3.b.ii.B, p. 8460/1.

²⁰ Supplementary Information, p. 8456/2&3.

The Center for Regulatory Effectiveness -11-

related to *influential* scientific information, USDA agencies and offices will ensure sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. ...

[When HHS agencies disseminate influential scientific information,] care is taken to ensure that the information is substantially reproducible and replicable. The goal is accomplished by using reliable data sources and sound analytical techniques, and by employing a high degree of transparency about the data, sources, methods, measures, assumptions and limitations used to develop the information in order to facilitate reproducibility by qualified third parties.

The utility standard in the OMB Guidelines also calls for transparency.

Utility refers to the usefulness of the information to its intended users, including the public. ... [W]hen transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.²¹

To ensure the utility of scientific research information ... disseminated by USDA, its agencies and offices will ... take care to ensure that transparency has been addressed in its review of the information before it is disseminated.

Utility involves the usefulness of the information to its intended users. ... Based on internal analyses of information requirements, ... working with ... stakeholders, ... and where appropriate, testing publications with targeted audiences to ensure relevance, clarity, and comprehensiveness, HHS agencies keep abreast of information needs.

B. The WHO Report fails to meet the applicable standards of TRANSPARENCY and REPRODUCIBILITY.

The U.S. Government has already pointed out that the WHO Report, in a draft form, did not meet these standards of transparency and reproducibility:

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....

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. ...

²¹ Paragraph V.2., p. 8459/2-3.

The Center for Regulatory Effectiveness -12-

Care must be taken to ensure recommendations are grounded in sound scientific evidence. ... [I]t is unclear what process was used to reach the conclusions and how specific recommendations were derived.

The Strength of evidence: criteria used section (page 22) is one of the most, if not the most, critical components of this Report. Yet as currently formulated, it is not always clear and is unlikely to enjoy scientific consensus.²²

Additionally, the U.S. Government advised the WHO that:

The current WHO/FAO Report returns to the concepts of the 1990 #797 report of recommending population nutrient intake goals. The 1990 recommendations were rejected by the 1992 International Conference on Nutrition for several reasons. The recommendations were not considered to be science-based. ...

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.²³

and further counseled that:

Of even greater concern & is the concern for the lack of science behind the solutions offered. The recommendations & 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.²⁴

These concerns of the U.S. Government were presented to the WHO before the October 1, 2002, effective date for the USDA and HHS data quality standards. These U.S. Government concerns, however, articulate strongly the failure of the WHO Report to meet what are now, for all Federal agencies (including USDA and HHS), the U.S. Government's data quality standards for transparency and reproducibility.

In the required predissemination review, USDA and HHS need to verify that these concerns, previously stated by the U.S. Government, have been examined. The following three examples suggest that these previously stated concerns have not been taken into consideration and that the facts and analyses supporting these three scientific recommendations do not comply with the U.S. Government's data quality standards.

²² U.S. Comments, p. 2.

²³ U.S. Comments, p. 3

²⁴ U.S. Comments, p. 4.

1. Percent of Total Energy Goal Total Carbohydrates: 55-75%.

On page 56, the WHO Report sets forth, in Table 6, Ranges of Population Nutrient Intake Goals. For carbohydrates, it states a goal of 55-75% of total energy. According to footnote b on page 56, this recommendation is simply a mathematical calculation, unsupported by any independent scientific reference.

As the U.S. Government already stated to the WHO, quantitative carbohydrate recommendations must be supported by the body of scientific literature.

The discussion of carbohydrate recommendations is particularly problematic for its lack of a more current review of the extant literature.²⁵

Inconsistent with the data quality standards for transparency and reproducibility, the WHO Report fails to provide the factual nor analytic basis supporting this 55-75% goal. Lack of the factual and analytic basis for this quantitatively specific scientific recommendation also prevents consideration of alternative approaches, a basic purpose of these transparency and reproducibility standards.

In addition, the U.S. Government commented that:

[T]he discussion does not mention metabolic syndrome X or glycemic index. Both topics have been widely explored in the recent research literature.²⁶

For example, one reason the WHO Report contains nutrient intake goals is to support recommendations to fight increased obesity. However, such high levels of carbohydrates appear to be inconsistent with the low-carbohydrate diets many have found successful in the United States.²⁷

The existing medical literature is positive concerning the health effects of low-carbohydrate diets, but more studies need to be done:

The results of our systematic review [of over 100 articles] suggest that if participants without diabetes tolerate a lower-carbohydrate diet better than a higher-carbohydrate alternative, this diet may be an effective means of achieving short-term weight loss without significant adverse effects on serum lipid levels, glycemic control, or blood

²⁵ U.S. Comments, p. 5.

²⁶ U.S. Comments, p. 5.

²⁷ See, for example, *The South Beach Diet*, Dr. Arthur Agatston (Rodale, 2003), pp. 62-65, 79-80.

pressure. However, there is insufficient evidence to recommend or condemn the use of these diets among participants with diabetes for long-term use. ...

Despite the abundance of lay literature on the topic of low-carbohydrate diets, to date our study is the first published synthesis of the evidence from the English-language literature. Our results demonstrated the marked discordance between the knowledge needed to guide dietary choices and the information that is available in the medical literature.

Investigations that will examine the long-term effects and consequences of low-carbohydrate diets among both older and younger participants with and without diabetes, hyperlipidemia, and hyperkalemia are in urgent need.²⁸

The U.S. Government's comment is still valid; the WHO Report needs to be supplemented to include a more thorough, transparent review of the extant literature. In addition, to be consistent with the U.S. Government's data quality standards, the WHO Report needs to be supplemented to articulate explicitly the factual and analytic basis supporting this quantitatively specific total carbohydrate recommendation advocated in the WHO Report.

2. Percent of Total Energy Goal Free Sugars: <10%.

The WHO Report sets forth, also in Table 6, Ranges of Population Nutrient Intake Goals, a percent of total energy goal for free sugars of <10% .

The eleven studies (pages 57-58) cited in support of the free sugars recommendation appear to be generalized aggregations of material; it appears that these eleven citations provide no detailed factual and analytic support for the quantitatively specific free sugars recommendation included in Table 6, and are not presented in a way that would meet the transparency and capable of being substantially reproduced standards in the OMB, USDA, and HHS guidelines.

The brief dialogue at the bottom of page 57 discusses more what is not known than what is; this discussion also does not meet the transparency and capable of being reproduced standards of the U.S. Government's data quality standards.

Inconsistent with the data quality standards for transparency and reproducibility, the WHO Report does not provide the factual nor analytic basis for this <10% guideline. Unless the WHO Report can articulate explicitly the factual and analytic basis supporting this quantitatively specific scientific recommendation, the WHO Report should be supplemented to note that this quantitatively specific scientific recommendation has no factual or analytic support and should be withdrawn from the WHO Report.

²⁸ "Efficacy and Safety of Low-Carbohydrate Diets: Systematic Review," Bravata, Sanders, Huang, Krumholz, Olkin, Gardner, and Bravata, *JAMA*, Volume 289, No. 14, p. 1837, 1848 (April 2003).

The Center for Regulatory Effectiveness -15-

Moreover, to paraphrase the earlier comment from the U.S. Government:

The discussion of the free sugars issue is particularly problematic for its lack of a more comprehensive review of the extant literature.²⁹

For example, the other report that USDA and HHS specifically cited in the press release as important for consideration by the Dietary Guidelines Advisory Committee the new Dietary Reference Intakes by the Institute of Medicine suggests a maximal intake level of 25 percent or less of energy from added sugars.³⁰ Specifically, the Institute of Medicine report states:

Although a UL is not set for sugars, a maximal intake level of 25 percent or less of energy from added sugars is suggested based on the decreased intake of some micronutrients of American subpopulations exceeding this level (see Chapter 11).³¹

Another study does not recommend establishing a quantitatively specific intake limit for sugars, but does advise to limit excessive intake.³²

In summary, the WHO Report lacks data and analytic support for the quantitatively specific guideline for <10% of daily energy as free sugars. The other Dietary Reference Intakes report fully documents its quantitatively specific, science-based suggestion of <25% of daily energy as added sugars. As required by the U.S. Government's data quality standards, this inconsistency in guidance highlights the need to supplement the WHO Report to provide the transparency and reproducibility in the presentation of the facts and analyses supporting the WHO Report's quantitatively specific scientific guideline to limit free sugars to <10% of daily energy.

²⁹ A thorough, transparent review of the extant scientific literature is particularly important here, as the statute directing the Secretaries of USDA and HHS to issue the Dietary Guidelines for Americans requires that: The information and guidelines contained in each report [entitled Dietary Guidelines for Americans] shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared. (Title III, Section 301, P.L. 101-445, National Nutrition Monitoring and Related Research Act of 1990.)

³⁰ Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Food and Nutrition Board, Institute of Medicine (2002), p. 6-42.

³¹ p. 6-42.

³² Current Knowledge of the Health Effects of Sugar Intake, Mardis, *Family Economics and Nutrition Review*, Vol 13, No. 1 (2001), p. 87, 89.

3. Recommendation to Reduce Dental Caries [Cavities] by Reducing Intake of Free Sugars.

At page 119, the WHO Report asserts [i]t is important to set a recommended maximum level for the consumption of free sugars; a low free sugars consumption by a population will translate into a low level of dental caries [cavities]. ... For countries with high consumption levels it is recommended that national health authorities and decision-makers formulate country-specific and community-specific goals for reduction in the amount of free sugars, aiming towards the recommended maximum of no more than 10% of energy intake.

The U.S. Government has already commented that:

The association between free sugars and chronic diseases is limited to increased risk for dental disease. ... 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. ...

In fact, there is no real correlation between per capita sugar consumption and dental caries [cavities] rates in a population. Current research is leading to a greater emphasis on frequency and duration of fermentable carbohydrate intake, rather than total consumption.³³

The WHO Report did not appear to respond to the comments from the U.S. Government.

To the extent that this recommendation to reduce dental caries [cavities] relates to the <10% total energy goal for free sugars, discussed in Example 2, above, our concerns described there also apply here. The eleven studies cited in support of the free sugars recommendation appear to be generalized aggregations of material; it appears that these eleven citations provide no detailed factual and analytic support for the quantitatively specific free sugars recommendation included in Table 6, and are not presented in a way that would meet the transparency and capable of being substantially reproduced standards in the OMB, USDA, and HHS guidelines.

In summary, the WHO Report needs to be supplemented to provide the transparency and reproducibility in the presentation of the scientific facts and supporting analyses required by the U.S. Government's data quality standards.

VI. PETITIONERS ARE AFFECTED PERSONS.

The Center for Regulatory Effectiveness (CRE) has been a proponent of the Data Quality Act from the Act's drafting to its implementation by OMB and other agencies, including USDA and HHS. CRE commented extensively on OMB's, USDA's, and HHS's proposed Data Quality

³³ U.S. Comments, pp. 15 and 22.

The Center for Regulatory Effectiveness -17-

Act Guidelines. CRE's website, <http://www.TheCRE.com>, has several sections devoted to Data Quality Act issues.

The global strategy on diet, physical activity and health to be adopted at WHO's Fifty-seventh World Health Assembly in 2004 and guidelines to be set forth in the 2005 Dietary Guidelines for Americans will affect the food choices available to and made by all Americans, including CRE employees, and Mr. Tozzi, both personally and in his role as a member of CRE's Board of Advisors. To the extent that future U.S. dietary guidance is affected by recommendations in the WHO Report presently based on scientific facts and analyses that fail to meet the U.S. Government's data quality standards, Americans run the risk of being less healthy than if these recommendations were based on impartial scientific facts and analyses that met the U.S. Government's data quality standards.

The real possibility for harm is best summarized by quoting from the U.S. Government comments to the WHO.

Efforts should be focused on improving the data attesting to the relative burden of major chronic diseases, including the relative impact across different 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 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.

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.³⁴

³⁴ U.S. Comments, p. 4.