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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of a Workshop and a Request for Public Comment on Questions
Regarding Dietary Reference Intakes and Chronic Disease Endpoints

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: The Dietary Reference Intakes (DRI) Committees of the U.S. and Canadian governments will hold a workshop entitled “Options for Consideration of Chronic Disease Endpoints for Dietary Reference Intakes.” The objective of the workshop is to critically evaluate key scientific issues involved in using chronic disease endpoints for setting DRIs and, in this context, to provide information for future decisions as to whether and/or how chronic disease endpoints can be incorporated into the setting of DRI values. In preparation for this meeting, the DRI Committees are asking for public comment on the set of questions that the meeting panelists will discuss.

DATES: This meeting will be held on March 10, 2015 from 8:30 a.m. to 5:00 p.m. E.D.T. and on March 11, 2015 from 8:30 a.m. to 12:30 p.m. E.D.T.

ADDRESSES: The workshop will be held at the Lister Hill Auditorium, National Institutes of Health, in Bethesda, Maryland, USA. The workshop will be open to the public either in-person (seating is limited) or by videocast on the Internet.

FOR FURTHER INFORMATION: Additional information about this workshop and the agenda will be made available on the Internet at <http://www.health.gov/dri/> as the meeting approaches. You may also send e-mails to DRI@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background Information:

The current DRI approaches for selecting indicators of adequacy and toxicity and for estimating dose-response relationships between nutrient intakes and selected outcomes derive from several Food and Nutrition Board committee reports published by the Institute of Medicine (IOM) in 1994¹ and 1998². These committees recommended that DRIs for adequacy be expressed as Estimated Average Requirements (EARs) and Recommended Dietary Allowances (RDAs, representing 97.5% of population requirements). They also recommended that reference values for Tolerable Upper Intake Levels (ULs) be included in future DRI evaluations. Additionally, the 1994 IOM committee concluded that future RDA processes (now called DRIs) should include the concept of chronic disease risk reduction in addition to the classical nutrient deficiency

¹ Food and Nutrition Board, Institute of Medicine. 1994. *How Should the Recommended Dietary Allowances Be Revised?* National Academy Press, Washington, D.C.

² *Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients.* National Academy Press, Washington, D.C.

endpoints. The approaches recommended by the 1994 and 1998 committees were applied, with a few additions (e.g., Adequate Intakes, Acceptable Macronutrient Distribution Ranges), for all seven of the DRI reviews published from 1997 to 2011. These reports can be accessed at the following website: <http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes/dri-reports>.

It has become apparent that a number of unanticipated challenges were encountered when chronic disease endpoints were considered as indicators for setting DRI reference values. Many of these challenges were discussed in a 2007 “lessons learned” workshop conducted by the IOM after the first six DRI reports were published³. Other scientific publications have also discussed the challenges, but approaches for addressing the identified challenges have not yet been adequately explored.

Recently, the DRI Committees of the U.S. and Canadian governments called for nominations for nutrients to be considered for future DRI reviews. Many of the nominated nutrients cited new data on chronic disease relationships as the justification for new DRI reviews, including three of the four nutrients selected by the DRI Committees for further consideration based on the availability of sufficient new and relevant evidence. Given the clear need for more in-depth evaluation of the challenges involved in incorporating chronic disease endpoints into DRI processes prior to initiating a new DRI review, the two government committees announced plans to sponsor a workshop to

³ The Development of DRIs 1994-2004: Lessons Learned and New Challenges, Workshop Summary, November 30, 2007. Available from: <http://www.iom.edu/Reports/2007/The-Development-of-DRIs-1994-2004-Lessons-Learned-and-New-Challenges-Workshop-Summary.aspx>.

be held in 2015 to address whether, and how, chronic disease outcomes can be incorporated into the process of setting DRI values.

The limited time available for the workshop may preclude consideration of all issues relevant to the incorporation of chronic disease endpoints into DRI processes. As warranted, subsequent activities will address issues that arise in the workshop or that have been identified in other activities but not covered in workshop discussions.

WRITTEN PUBLIC COMMENTS:

The key questions for the workshop, on which the committees would like public comments, are derived from prior discussions of the major challenges in incorporating chronic disease endpoints into DRI considerations:

1. What dose-response models can be considered for future DRI reviews when chronic disease endpoints are used?
 - a. What are the scientific issues?
 - b. What are the options for addressing these issues?
 - c. What are the advantages and disadvantages of the various options?

2. What are the evidentiary challenges important in selecting and using chronic disease endpoints in future DRI reviews?
 - a. What are the scientific issues?
 - b. What are the options for addressing these issues?
 - c. What are the advantages and disadvantages of the various options?

3. What arguments can be made for and against continuing to include chronic disease endpoints in future DRI reviews?
 - a. What are the scientific issues?
 - b. What are the options for addressing these issues?
 - c. What are the advantages and disadvantages of the various options?

Public comments are to be submitted via e-mail to DRI@hhs.gov. Provide a brief summary (approx. 250 words) of the points or issues. If providing literature or other resources, one of the following forms is preferred:

- Complete citation, as in a bibliographic entry
- Abstract
- Electronic link to full article or report

Please provide comments as early as possible in order to increase the likelihood of having a meaningful impact, as the workshop panelists will be considering them prior to the workshop. The deadline for comment submission is Friday, January 30, 2015. Comments received later than January 30, 2015 will not be considered.

Meeting Registration: The meeting will be publicly accessible both in-person and by videocast on the Internet. Due to limited seating capacity, registration will be required for in-person attendance. Notice of registration will be available on

<http://www.health.gov/dri/> prior to the workshop; registration is expected to open on or about February 15, 2015.

Dated: December 16, 2014.

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