participants should submit materials to the NVPO staff person designated as the contact for additional information. All materials should be submitted to the designated point of contact no later than close of business April 21, 2008. Pre-registration is required for public comment. Any individual who wishes to participate in the public comment session should e-mail *angela.shen@hhs.gov* or call 202–690–5566.

There is limited space available for the public to attend this meeting. However, it is desired that the public participate in the discussions, as well. Registration is required to attend the meeting; registration information can be found at: *https://nvpo.constellagroup.com.* Registration for the meeting will be accepted until April 5, 2008. Registration after that date will be on the basis of space availability. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person.

Dated: March 24, 2008.

Bruce Gellin,

Director, National Vaccine Program Office.

[FR Doc. E8–6433 Filed 3–27–08; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[ATSDR–241]

Public Comments and Revised Final Criteria for Removing Chemicals From Future Editions of CDC's National Report on Human Exposure to Environmental Chemicals

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

SUMMARY: On Tuesday, May 16, 2006, CDC published draft criteria for removing chemicals from future releases of *CDC's National Report on Human Exposure to Environmental Chemicals* (the ''Report'') (See FR, Vol. 71, No. 94, p. 28346–7). This and previous notices related to the ''Report'' are at *http://www.cdc.gov/exposurereport/chemical_nominations.htm.* The proposed criteria provided that a chemical may be removed from the ''Report'' if (1) a new replacement chemical (i.e., a metabolite) is more representative of exposure than is the chemical currently measured; or (2) after three survey periods (or not less than 6 years), detection rates for all chemicals within a methodological and chemically related group are less than 5 percent for all population subgroups (i.e., two sexes, three race/ethnicity groups, and three age groups); or (3) after three survey periods (or not less than 6 years), levels of chemicals within a methodological and chemically related group are unchanged or declining in all the specific subgroups as documented in the ''Report.''

Using these criteria, CDC would have continued to measure the chemical and not remove it from the ''Report'' if it met either of two proposed exceptions to these criteria: (a) It is a chemical for which there is an established biomonitoring threshold (e.g., CDC's level of concern for blood lead levels in children) or any chemical for which there is widespread public health concern (e.g., mercury) or (b) three survey periods (or not less than 6 years) have passed, constituting the minimum time before a chemical could be removed; a longer period may be necessary to account for the half-life of a particular chemical or to account for a recent change (e.g., the removal of a chemical from commerce) that would necessitate monitoring of the population. In that notice, CDC pointed out that the criteria for removing a chemical from the ''Report'' are not corollaries of the criteria for adding chemicals to the ''Report.''

Summary of Public Comments

CDC received 31 public comments on the criteria cited above and describes below the comments received and CDC's responses to those comments. Comments are grouped in the following categories: Removal process, criterion 1, criterion 2, criterion 3, and exceptions ''a'' and ''b.''

General Informational Comments Related to Process and Procedure

CDC received several public comments about how the process of removing chemicals from the ''Report'' would be implemented. These generally pertained to (1) concurrence on the scientific basis for exposure assessment; (2) analytical cost considerations as secondary; (3) description of the policy basis for the process; (4) consideration of and suggestions for alternative approaches to limited sample volumes; and (5) affirmation of decision procedures, transparency, and public notification.

CDC responses to general informational comments:

Understanding exposures through biomonitoring can help scientists focus research on those chemicals found in people's bodies and target the appropriate levels of exposure. The ''Report'' provides unique exposure assessment information and not assessment of health risk. However, the biomonitoring data in the ''Report'' can facilitate and complement the risk-assessment process. For some chemicals, such as lead and mercury, risks have become better characterized when biomonitoring levels have become the benchmark to which the risks are tied. CDC considers the public health utility and quality of biomonitoring information to be the primary consideration, with cost of analysis as an important, but secondary, consideration (See **Federal Register** Vol. 67, No. 34 March 20, 2002, pages 12996–7).

The policy basis for the development of criteria for removing chemicals from the ''Report'' was developed in consideration of sound science and resource utilization. With guidance from a Work Group that was convened at the direction of the Board of Scientific Counselors of the National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), the proposed criteria were established, and comments from the public were solicited through the **Federal Register** notice published in May 2006 (Vol. 71, No. 94, p. 28346–7).

As currently described, only one of the three criteria needs to apply to delist a chemical. That is, the three criteria apply independently—no combinations of criteria are necessary to qualify a chemical for removal from the ''Report.'' When chemicals published in the ''Report'' meet a criterion for removal, they will be deleted from future reports. The Division of Laboratory Sciences (DLS) at NCEH will make these decisions using the finalized criteria only and will post the names of the removed chemicals on its Web site: *http://www.cdc.gov/exposurereport.*

Two commenters provided helpful suggestions for maintaining flexibility in applying the removal process and suggested alternative plans for optimal use of samples. For those chemicals requiring large amounts of sample volume to detect the chemicals, alternatives such as less frequent sampling or pooled analyses are appropriate alternatives. CDC has actively researched these alternatives and will continue to weigh the relative cost-benefit of other approaches in addressing the issue of limited sample volume. Such approaches could include less frequent sampling, pooling of samples, and development of more sensitive analytical methods. For difficult decisions, the NCEH/ATSDR

Board of Scientific Counselors will be consulted for advice on the use of alternative approaches.

This process of announcing draft criteria and requesting comment on the criteria was the first step in ensuring transparency. Commenters' involvement in this process is evidence of CDC's efforts to involve multiple groups with varied viewpoints. CDC will announce the process for both nominating and removing chemicals from the ''Report'' in a future **Federal Register** notice. When chemicals are removed through this process, announcements will be made on CDC's Web site (*http://www.cdc.gov/exposurereport*). Descriptions of ongoing activities related to the ''Report'' have been provided in public meetings with advisory groups, in regional and national conferences, through publication of introductory material in the ''Report'' itself, in previous **Federal Register** announcements, and in postings of these materials on the CDC Web site.

Specific comments related to Criterion 1: If a new replacement chemical (i.e., a metabolite) is more representative of exposure than the chemical currently being measured.

Two specific comments and one general comment were received.

CDC Responses related to Criterion 1:

The first comment recommends a phased overlap in the analysis of the previously measured chemical with the replacement chemical. CDC agrees with this recommendation, which would occur naturally in the course of the scientific accrual of knowledge and measurements about the new replacement chemical. Both old and replacement chemicals may exist in the ''*Report*'' simultaneously until such knowledge and experience are accrued.

The second comment requested a wording change in criterion 1 from ''(i.e., a metabolite)'' to ''(i.e., a metabolite or other chemical).'' The wording change is accepted.

A general comment was made that the meaning of the phrase ''is more representative of exposure'' can be inferred. CDC notes that a replacement chemical is more representative of exposure when the measured concentration of the replacement chemical accounts for a greater fraction of the dose or has pharmacokinetic characteristics that decrease the variability in exposure estimation (such as longer persistence in the body).

Revised draft Criterion 1: If a new replacement chemical (i.e., a metabolite or other chemical) is more representative of exposure than the chemical currently being measured.

Specific comments related to Criterion 2: If after three survey periods (or not less than 6 years), detection rates for all chemicals within a methodologically and chemically related group are less than 5 percent for all population subgroups (e.g., two sexes, three race/ethnicity groups, and three age groups).

CDC received six overlapping comments from different commenters on the description or discussion of the following: (1) The requirement of a 5% detection rate for all population subgroups to meet the criterion; (2) the adequate number of survey periods applicable to the criterion; (3) the definition of ''methodological and chemically related group''; and (4) the application of the criterion to the entire group versus individual chemicals in the group to achieve cost savings.

CDC Responses Related to Criterion 2

(1) *The requirement of a 5% detection rate.* Not removing a chemical from the ''Report'' until all reported subgroups have fallen below the 5% detection rate is a conservative approach, allowing continued population monitoring even though some subgroups would no longer meet that criterion. A 5% detection rate allows an estimate of the 95th percentile for a population group. The 95th percentile is extremely useful for characterizing levels of unusual exposure in a population. If removal of a chemical from the ''Report'' resulted by meeting this criterion, but there were known exposures to special groups that are of public health interest, targeted monitoring studies could be recommended. CDC may be able to assist some states or other agencies in biomonitoring of special groups with unusual potential for exposure or who potentially may be at more risk for adverse health effects.

(2) *The adequate number of survey periods applicable to the criterion.* No absolute guide governs the number of survey periods necessary for inclusion in this criterion. CDC considered three survey periods because this number was the minimum number of survey point estimates from which trends might be calculated. Still, environmental conditions and releases of chemicals may change human exposures over time, and for some persistent chemicals—that is, persistent either in the body or in the environment—the 6-year period would be too short to measure a meaningful change. Thus, to accommodate these situations, CDC added exemption ''b.'' CDC has also rephrased the following statement to address reassessment of a chemical removed from the ''Report'' under either criterion 2 or 3: ''For a chemical that meets criterion 2 or 3, the chemical would be removed from the 'Report' for two future survey periods (4 years) and then measured again in the following survey period (2 years). If either criterion 2 or 3 is still satisfied for this 12-year period (i.e., three initial 2-year survey periods, two intervening 2-year survey periods, final 2-year survey period), then the chemical would be removed from the 'Report' and not reinstated unless the chemical once again met the criteria for inclusion in the 'Report.' ''

(3) *The definition of ''methodologically and chemically related group.''* Often, many similar chemicals are measured together in the same analytical procedure on a single preparation of an individual specimen. This is possible because the chemicals share similar physical/chemical properties and because of recent advances in separation and detection technologies (e.g., chromatography followed by mass spectrometry). Such chemicals were previously referred to as belonging to a ''methodologically and chemically related group.'' Because of issues in the following discussion, the terminology and definition have been changed to the following: A ''method-related group'' is defined as a group of chemicals that are (1) measured together using a single analytical method; (2) structurally similar; (3) typically generated together from exposure sources (e.g., dioxin congeners, furan congeners, polyaromatic hydrocarbons); and (4) typically assessed for health risk together as a group.

Commenters asked whether a chemical satisfying this criterion should be measured in subsequent reports (as CDC intends) only because other chemicals in the ''methodologically and chemically related group'' were being reported. CDC seeks to balance both the scientific importance and cost of measuring specific chemicals. In regard to scientific importance, scientists who consider the aggregate effect of certain chemical groups (e.g., molar sums or toxic equivalents [TEQs]) may need to know whether a component chemical of a group was not detected and noncontributory as opposed to not measured. CDC would continue to measure a chemical in a method-related group that met this criterion for removal where it would be helpful for risk assessment of the entire group of chemicals (e.g., dioxins).

(4) *The application of the criterion to the entire group versus individual chemicals in the group to achieve cost savings.*

Commenters asked whether there would not be some cost savings by not

measuring a chemical that met a criterion for removal among the multiple chemicals measured in such an assay. Removing one of a group of related chemicals (e.g., PCBs) from the ''Report'' although it alone meets a criterion, would generate little additional savings. The relative cost savings are in direct proportion to the number of chemicals in a multichemical analysis. Removing 1 of 26 chemicals (e.g., PCB congeners) would save only about 4% of the post-instrumental analysis labor and cost of standards but would result in little or no savings in all other costs such as labor, supplies, sample preparation, and instrument analysis. Thus, if cost impact were minimal, CDC would continue to measure a chemical in a method-related group that met this removal criterion.

A commenter requested the addition of ''mode of action'' to the definition of a chemically and methodologically related group. Because ''mode of action'' may involve chemicals of different structural classes and different analytical methods, CDC chose not to add this descriptor to the current definition of a method-related group.

Revised draft Criterion 2: If, after three survey periods (a period of not less than 6 years), detection rates for all chemicals within a method-related group are less than 5 percent for all population subgroups (e.g., two sexes, three race/ethnicity groups, and the age groups used in the ''Report'').

Specific comments related to Criterion 3: If, after three survey periods (or not less than 6 years), levels of chemicals within a methodologically and chemically related group are unchanged or declining in all the specific subgroups as documented in the ''Report.''

Comments addressed the following: (1) No change or declining levels over three survey periods is not synonymous with lessened health concerns, (2) the criterion does not address unforeseen increases in chemicals after their removal from the ''Report,'' (3) whether new demographic groups might be added in the future and whether criterion 3 would also apply to these new demographic groups (e.g., people aged 60 years and older), and (4) further definition of unchanged or declining levels is required.

CDC Responses related to Criterion 3:

(1) *No change or declining levels over three survey periods is not synonymous with lessened health concerns.* CDC agrees that the phrase ''no change over a 6-year period'' is not synonymous with a lessened concern for certain chemicals with possible heath risks. If, however, there is public health concern about a particular chemical, exception ''a'' would apply. If 6 years or three survey periods is not long enough to evaluate a persistent chemical, exception ''b'' would apply. In addition, a chemical previously removed from the ''Report'' could reappear in the ''Report'' if that chemical again met the inclusion criteria for selecting chemicals for the ''Report.'' (see **Federal Register**, Vol. 71, No. 94, May 16, 2006, pages 28346–7).

(2) *The criterion does not address unforeseen increases in levels of chemicals after their removal from the ''Report.''* CDC agrees that criterion 3 would not address situations involving an unforeseen rise in the level of a chemical after its removal from future monitoring by the ''Report.'' As it did for criterion 2 (stated above), CDC will include the following language: ''For a chemical that meets criterion 2 or 3, the chemical would be removed from the 'Report' for two future survey periods (4 years) and then measured again in the following survey period (2 years). If either criterion 2 or 3 is still satisfied for this 12-year period (i.e., three initial 2-year survey periods, two intervening 2-year survey periods, final 2-year survey period), then the chemical would be removed from the 'Report' and not reinstated unless the chemical once again met the criteria for inclusion in the 'Report.'''

(3) *Whether new demographic groups might be added in the future and whether criterion 3 would also apply to these new demographic groups (e.g., people aged 60 years and older).* As is also stated above for Criterion 2, Criterion 3 would apply to all subgroups—listed age groups, both sexes, and three race/ethnicities-for which statistically sufficient data are reported. In other words, if all but one subgroup satisfied the criterion, it would be important to continue measuring the chemical. In answer to the possibility of additional subgroups in a future ''Report,'' CDC does intend to divide the 20 and older age group into two groups: 20–59 years and 60 years and older. If past and additional (new) demographic groups all satisfy the criterion, the chemical could be removed. Other than this older age group, NHANES sampling design and statistical considerations make it unlikely that demographic groups will be added.

(4) *Further definition of unchanged or declining levels is required*. CDC agrees that the phrase ''unchanged or declining'' needs further definition. CDC has revised the wording of this criterion by adding the following: ''Evidence that chemical levels are unchanged or declining would be the absence of a statistically significant ($p < 0.05$) positive slope of mean (or geometric mean) levels of the chemical over the time period.''

Revised draft Criterion 3: If after three survey periods (a period of not less than 6 years), levels of chemicals within a method-related group are unchanged or declining in all the demographic subgroups documented in the ''Report.'' Evidence that chemical levels are unchanged or declining would be the absence of a statistically significant ($p < 0.05$) positive slope of mean (or geometric mean) levels of the chemical over the time period.

Specific comments related to Exceptions ''a'' and ''b'': (a) It is a chemical for which there is an established biomonitoring health threshold (e.g., CDC's level of concern for blood lead levels in children) or any chemical for which there is widespread public health concern (e.g., mercury), or (b) three survey periods (or not less than 6 years) have passed, which constitute the minimum time before a chemical could be removed; a longer period may be necessary to account for the half-life of a particular chemical or to account for a recent change (e.g., the removal of a chemical from commerce) that would necessitate monitoring of the population.

Comments addressed the following: (1) the meaning of the phrase ''widespread public health concern'' in exception ''a,'' and (2) the rationale for exception ''b.''

CDC Responses related to Exceptions ''a'' and ''b'':

(1) *The meaning of the phrase ''widespread public health concern'':* A commenter stated that ''widespread health concern'' was broad and vague and wished to know what constituted ''widespread concern'' as well as the process used to determine ''widespread concern.'' CDC will change the sentence in exception ''a'' that contains the phrase ''widespread public health concern'' to ''The chemical has an established federal biomonitoring health threshold (e.g., CDC's level of concern for blood lead levels in children) or after consultation with relevant federal agencies, CDC learns that a federal agency considers the chemical of sufficient priority to warrant continued monitoring.''

(2) *The rationale for exception ''b.'' A commenter stated that* ''* * * this exception appears to provide the CDC with a sensible amount of flexibility; the commenter urges CDC to provide the rationale for applying this exception.'' To better explain exception ''b,'' CDC will use the following wording: ''The chemical has a long half-life (e.g., DDE),

which would require additional time to track changes reliably in population levels, or recent changes in exposure sources indicate that future levels are likely to increase.'' Chemicals with long half-lives in the body or persistence in the environment may not decline appreciably within shorter time frames such as 6 years, and longer periods of monitoring may be necessary to assess whether exposure levels are changing.

Revised draft exceptions: (a) The chemical has an established federal biomonitoring health threshold (e.g., CDC's level of concern for blood lead levels in children) or after consultation with relevant federal agencies, CDC learns that a federal agency considers the chemical of sufficient priority to warrant continued monitoring; or (b) the chemical has a long half-life (e.g., DDE), which would require additional time to track changes reliably in population levels, or recent changes in exposure sources indicate that future levels are likely to increase.

Summary of Revised Draft Criteria

As stated, CDC now publicly announces the final criteria for removing chemicals from future releases of the ''Report.'' These criteria will become part of a combined process for nominating candidate chemicals for inclusion in or removal from the ''Report.'' The process will include (a) nominations from the public of candidate chemicals to include in or remove from the ''Report,'' (b) an external scoring of nominations in accordance with the published nomination and removal criteria, and (c) assistance from the Board of Scientific Counselors of CDC's National Center for Environmental Health/Agency for Toxic Substances and Disease Registry in reviewing plans for including or removing chemicals and identifying alternatives for monitoring specific at-risk population subgroups. This combined process will occur periodically (e.g., every 6 years). Note that the criteria for selecting and removing chemicals apply only to chemicals published in the ''Report''—not to those merely nominated.

The final removal criteria are as follows: A chemical will be removed from the ''Report'' if it meets any one of the following three criteria and does not meet either of the exceptions to those criteria. Accordingly, a chemical will be removed if (1) a new replacement chemical (i.e., a metabolite or other chemical) is more representative of exposure than the chemical currently measured; or (2) if after three survey periods (a period of not less than 6 years), detection rates for all chemicals within a method-related group are less than 5 percent for all population subgroups (i.e., two sexes, three race/ethnicity groups, and the age groups used in the ''Report'') or; (3) if after three survey periods (a period of not less than 6 years), levels of chemicals within a method-related group are unchanged or declining in all the demographic subgroups documented in the ''Report.'' Evidence that chemical levels are unchanged or declining would be the absence of a statistically significant ($p < 0.05$) positive slope of mean (or geometric mean) levels of the chemical over the time period.

For a chemical that meets criterion 1, the chemical would be removed from future reports and would be replaced with the new chemical that better reflects exposure.

For a chemical that meets criterion 2 or 3, the chemical would be removed from the ''Report'' for two future survey periods (4 years) then measured again in the following survey period (2 years). If either criterion 2 or 3 is still satisfied for this 12-year period (three initial 2-year survey periods, two intervening 2-year survey periods, final 2-year survey period), then the chemical would be removed from the ''Report'' and not reinstated unless the chemical once again met the criteria for inclusion in the ''Report.''

A chemical would continue to be measured and not be removed from the ''Report'' if it met either of two exceptions to the above-cited revised draft criteria: (a) The chemical has an established federal biomonitoring health threshold (e.g., CDC's level of concern for blood lead levels in children) or after consultation with relevant federal agencies CDC learns that a federal agency considers the chemical of sufficient priority to warrant continued monitoring; or (b) the chemical has a long half-life (e.g., DDE), which would require additional time to track changes reliably in population levels, or recent changes in exposure sources indicate that future levels are likely to increase.

FOR FURTHER INFORMATION CONTACT: Dorothy Sussman, Telephone 770–488–7950.

SUPPLEMENTARY INFORMATION: CDC publishes the ''Report'' under authorities 42 U.S.C. 241 and 42 U.S.C. 242k. The ''Report'' provides ongoing assessment using biomonitoring of the exposure of the noninstitutionalized, civilian population to environmental chemicals. Biomonitoring assesses human exposure to chemicals by measuring the chemicals or their metabolites in human specimens such as blood or urine. For the ''Report,'' the term *environmental chemical* means a chemical compound or chemical element present in air, water, soil, dust, food, or other environmental medium. The ''Report'' provides exposure information about participants in an ongoing national survey known as the National Health and Nutrition Examination Survey (NHANES). This survey is conducted by CDC's National Center for Health Statistics; measurements are conducted by CDC's National Center for Environmental Health. The first ''Report,'' published in March 2001, gave information about levels of 27 chemicals found in the U.S. population; the second ''Report'' was published in January 2003, and it contained exposure information on 116 chemicals, including the 27 chemicals in the first ''Report.'' The third ''Report'' was published in July 2005, and it contained exposure information on 148 chemicals, including data on the chemicals published in the second ''Report.'' Copies of the third ''Report'' can be obtained in the following ways: Access *http://www.cdc.gov/exposurereport*, send an e-mail to *cdcinfo@cdc.gov*, or telephone 1–800–CDC–INFO.

Dated: March 25, 2008.

Kenneth Rose,

Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. E8–6350 Filed 3–27–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2276–FN]

Medicare and Medicaid Programs; Approval of the Community Health Accreditation Program for Continued Deeming Authority for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final Notice.

SUMMARY: This final notice announces our decision to approve the Community Health Accreditation Program (CHAP) for recognition as a national accreditation program for home health agencies (HHAs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective March 31, 2008 through March 31, 2012.

FOR FURTHER INFORMATION CONTACT: