

# **Public Health Advisory Procedures**

June 16, 2011

**(Note: This document supersedes the August 11, 1993, and October 10, 1993 procedures)**

**Agency for Toxic Substances and Disease Registry  
US Department of Health and Human Services**

## **Background**

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA); [42 U.S.C. Section 9604(i)], requires the Agency for Toxic Substances and Disease Registry (ATSDR), as the lead public health agency within the US Department of Health and Human Services (HHS), to notify the Administrator of the US Environmental Protection Agency (EPA) of a release or threatened release of a hazardous substance(s) or physical hazard that may pose an immediate and substantial danger to public health and welfare.<sup>1</sup> The ATSDR Public Health Advisory officially provides such notification to EPA Headquarters, EPA Regional Offices, other federal agencies (as appropriate), state and local health/environmental agencies, and the public (as defined in 42 CFR 90.2). Since the creation of ATSDR, Public Health Advisories have only been issued to help resolve situations that may pose an immediate and substantial danger to public health and welfare which cannot be immediately addressed under other existing federal authorities.

This Policy defines when and how ATSDR will issue a Public Health Advisory and provides detailed procedures that ATSDR staff will utilize when considering the issuance of an ATSDR Public Health Advisory.

## **Definition of Public Health Advisory**

A Public Health Advisory is a public statement by ATSDR containing a finding that a release may pose an immediate and substantial danger to public health and welfare and recommending measures to be taken to reduce exposure and eliminate or substantially mitigate the significant risk to human health. (42 C.F.R. Section 90.2) (Release is further defined in 42 U.S.C. Section 9601[22]).

ATSDR Public Health Advisories address the human health risks posed by a substance(s) and/or physical hazards found at a site, facility, or other situation. Specifically, an ATSDR Public Health Advisory will describe the hazardous substance(s) at a site and concentrations in the various environmental media; the fate and transport of those materials as they move through the environment; the size and susceptibility of the population; the likelihood of exposure of the population; and the plausible health outcomes of such an exposure. The Advisory will also describe any physical hazards of concern and the public health impact of the hazard. In addition, Public Health Advisories will indicate what public health actions need to be undertaken.

An ATSDR Public Health Advisory is not used to declare a public health emergency as defined by CERCLA as amended by SARA (42 U.S.C. 9604[i]).

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<sup>1</sup> Although “physical hazards” are not defined within CERCLA, ATSDR as a policy has chosen to address these types of events to be protective of public health. Physical hazards that could be addressed by a Public Health Advisory include hazards (e.g., explosion, fires) that could result in various physical injuries and are uncommon to normal situations.

## **Rationale for Developing Public Health Advisories**

ATSDR may issue a Public Health Advisory based on the findings of: 1) data review conducted by ATSDR staff or any of ATSDR's Cooperative Agreement Partners or contractors in accordance with all applicable federal grants and procurement laws and HHS policies; 2) a public health assessment; 3) a health consultation; 4) an exposure investigation; 5) a health study; or 6) other public health action in which ATSDR is involved. ATSDR may also be requested by EPA, other Federal agencies, states and local authorities, or citizens to evaluate data and information on the significance of a release or physical hazard to determine if a Public Health Advisory is warranted.

A Public Health Advisory spells out the immediate public health actions needed to eliminate immediate and substantial dangers (e.g., provide alternate water source, dissociation of people from exposure) and may also outline less critical public health actions needed to reduce other associated public health hazards (e.g., remedial action to remove contaminants after people have been disassociated from exposure). The actions are often carried out in cooperation with state health departments and other appropriate federal, state, and local organizations.

## **Who Prepares Public Health Advisories**

The preparation of Public Health Advisories is an ATSDR responsibility; which is carried out by any ATSDR division with knowledge and concurrence of the ATSDR Administrator or his/her designee. Preliminary work may be accomplished by any division within ATSDR or any of ATSDR's Cooperative Agreement Partners in accordance with all applicable federal grants and procurement laws and HHS policies. The final preparation of the Public Health Advisory for the ATSDR Administrator's signature is the responsibility of the assigned ATSDR division.

## **Criteria for Developing Public Health Advisories**

A Public Health Advisory may be issued for sites where a release or a threatened release of hazardous substances or a physical hazard may pose an immediate and substantial danger to public health and welfare. The ATSDR criteria for issuing a Public Health Advisory are not intended to limit ATSDR's discretion under CERCLA in issuing Public Health Advisories or in determining other appropriate responses to public health threats at a particular site. Generally the following criteria are used to determine when a Public Health Advisory should be issued:

- ATSDR's evaluation of the situation determines that an Urgent Public Health Hazard exists (as defined on page 9-4 in Public Health Assessment Guidance Manual, HHS, Atlanta, Georgia, January 2005).

**Or**

- ATSDR's evaluation of the situation determines that a Public Health Hazard exists (as defined on page 9-4 in Public Health Assessment Guidance Manual, HHS, Atlanta, Georgia, January 2005); **and**
- No immediate remediation, removal, or other intervention is planned that would reduce or eliminate the exposure or hazard; **and**

- The Public Health Advisory is ATSDR's best option for ensuring a rapid response to safeguard public health.

### **Format of Health Advisories**

The following format is used to ensure that a Public Health Advisory: 1) adequately addresses site conditions, 2) contains a complete discussion of the public health implications of those conditions, and 3) includes conclusions, recommendations, and public health actions for protecting the nearby population:

#### *Introduction (Statement of Purpose)*

This section states the purpose of issuing a Public Health Advisory, provides information on how ATSDR became aware of the site or situation, states the problem, and states the major conclusions, recommendations and public health actions.

#### *Background*

The background section provides a brief site history and actions that have taken place at the site, gives the sources of information used in preparing the Public Health Advisory, and describes the contact(s) made with local, state, and other federal agencies. This section can also include information about the impacted/potentially impacted population and other pertinent information.

#### *Basis for the Public Health Advisory*

This section describes why the Public Health Advisory is being issued. It evaluates the site in terms of the criteria used for issuing a Public Health Advisory. It describes the existence and extent of public health hazards and discusses the potential outcome of continued exposure to those substances or conditions. The presentation is scientific, is supported by appropriately cited references, and focuses on health-based discussions.

#### *Conclusions*

This section provides conclusions based on facts previously discussed in the Public Health Advisory. The conclusions use the most important findings of the advisory to focus attention on the site's most critical health issues.

#### *Recommendations and Proposed Actions*

This section describes actions that ATSDR believes are necessary to protect public health and welfare and prevent exposure to hazardous substance(s) or physical hazard(s) that pose an immediate and substantial danger to public health and welfare. The recommendations follow directly from the conclusions and include commitments from ATSDR and other federal, state and local officials or agencies regarding any health actions that will be conducted.

## *References*

This section lists all data packages and all technical and health information sources cited in the Public Health Advisory.

## *Required Content*

All public health advisories will:

- Identify the data and information reviewed or analyzed in the development of the public health advisory.
- State that the interpretation, advice, and recommendations provided are based on the data and information referenced.
- State that the conclusions, recommendations, and public health actions are site-specific and should not automatically be considered applicable to any other situation.
- Commit to a review of additional data or to respond to additional requests.

## **Administrative Process for Issuing a Public Health Advisory**

Time is critical when preparing a Public Health Advisory. A Public Health Advisory is issued because there are indications of an immediate and significant danger to human health and welfare. Therefore, rapid development, review, and clearance of a Public Health Advisory are paramount but should not be done to the detriment of accurate public health science.

An advisory is initiated upon the recommendation of any ATSDR Division Director with knowledge and concurrence of the ATSDR Administrator or his/her designee. A Site Team Lead will be designated and a site team established; which is typically composed of Division of Health Assessment and Consultation (DHAC) technical staff and ATSDR Division of Regional Operations (DRO), but can also include technical staff from other ATSDR Divisions and Cooperative Agreement partners as appropriate.

Coordination with EPA and other appropriate federal, state, and local environmental and health officials and agencies is critical to the development of an advisory. This coordination should begin prior to obtaining upper management approval to initiate an advisory and should insure that the appropriate governmental organizations are fully informed that a Public Health Advisory is being contemplated. The ATSDR Site Team should clearly define lines of communication with each of the governmental organizations (e.g., who is ATSDR's and that governmental organization's contact for the situation).

Consistent with NCEH/ATSDR review and clearance policies, the initial drafts of the Public Health Advisory are reviewed by the appropriate Site Team Leader(s), Branch Chief(s),

Assistant Director(s) for Science, and Division Director(s). After the Division Director(s) approves the draft Public Health Advisory, it is sent to the NCEH/ATSDR Office of the Director (OD) and NCEH/ATSDR Associate Director for Science, for review. The draft is also sent to the Office of General Counsel (OGC) for review. A courtesy draft is provided to the NCEH/ATSDR Office of Policy, Planning and Evaluation (OPPE) and the NCEH/ATSDR Office of Communications (OC). OPPE is responsible for assuring that the Centers for Disease Control and Prevention (CDC)/ATSDR Washington Office is kept informed about the development of the Public Health Advisory. Comments on the draft are returned to the designated Site Team Lead. It is anticipated that this portion of the advisory clearance process will take less than 4-weeks.

The site team makes appropriate changes and a revised draft is sent to the appropriate ATSDR Regional Representatives to be shared with the EPA Regional Office and Headquarters for comment. The ATSDR Regional Representative also makes copies of the draft available to other federal, state, and local agencies involved with the site. ATSDR, EPA and the other federal, state, and local agencies will jointly agree on the allowable review time for each draft Public Health Advisory when it is written (e.g., ATSDR suggests a five-working day turn around). The designated Site Team Lead receives EPA and other federal, state, and local agencies' review comments through the ATSDR Regional Representative and will make appropriate revisions to the document.

It is anticipated that the final draft of the Public Health Advisory and its accompanying cover letter will be developed by the designated Site Team Lead within one week after receiving comments from the non-ATSDR federal, state and local agencies. The designated Site Team Lead will provide that final draft to NCEH/ATSDR OD, OPPE, OC and DRO. NCEH/ATSDR OD reviews the final draft, makes appropriate changes, in consultation with the DHAC and DRO, and submits the final advisory and cover letter to the ATSDR Administrator for approval and signature. The ATSDR Administrator or designee will immediately send the final Public Health Advisory to the EPA Administrator.

The NCEH/ATSDR Director will immediately sends copies of the final Public Health Advisory to the appropriate EPA Regional Administrator, the principal State Health Official, and the NCEH/ATSDR OPPE, OC, Washington Office, DRO, and DHAC. The lead ATSDR Division will provide copies to other agencies and individuals as appropriate and to the ATSDR Regional Offices involved.

In coordination with EPA and the other appropriate federal, state and local officials and agencies, in most but not in all cases a public meeting will be held shortly after the public release of the final Public Health Advisory.

### **Record Keeping**

Files containing public health advisory documentation are kept by the designated Site Team Lead while the public health advisory is being developed. In accordance with normal ATSDR clearance and data/information collection procedures, the Site Team Lead will assure that the appropriate electronic databases are utilized and populated with required information (e.g.,

Documentum, Sequoia). When the advisory is complete, the file is sent to and maintained by the ATSDR Records Room in accordance with all applicable federal records retention laws and schedules. All confidential medical information is handled in accordance with the Privacy Act of 1974 and ATSDR policy.

### **Quality Assurance**

An ATSDR Public Health Advisory is scientifically and programmatically compatible with other agency documents and policy (e.g., current NCEH/ATSDR clearance policy). The prospective review of the Public Health Advisories includes reviews by the Divisional management with staff involved, Associate Director(s) for Science, and the NCEH/ATSDR Office of Science, to assess consistency, scientific quality, policy implications, and appropriateness. The draft Public Health Advisory is also reviewed by EPA Headquarters and Regional Offices to assure the document is accurate and based upon the best science.

### **External Review of Draft Public Health Advisories**

The contents of a draft Public Health Advisory should be discussed with appropriate federal, state, and local agencies during its development to ensure the completeness of the advisory. At a minimum, EPA Headquarters and Regional Office(s) will be provided an opportunity to review and comment on a draft Public Health Advisory.

### **Public Comment/ Peer Review**

Because of the time-critical nature of ATSDR Public Health Advisories, Public Health Advisories generally are not issued for public comment before final release nor undergo an external peer-review unless directed by the Administrator of ATSDR or his/her designee. As required by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), any Public Health Advisory that is based upon a non-peer reviewed health study will be peer reviewed before it is released.

### **Follow-up on Recommendations**

ATSDR DRO monitors recommendations identified in the Public Health Advisory that require some immediate action on the part of another agency or entity to determine if they have been acted upon. Recommendations requiring immediate follow-up include those that would alleviate an immediate and significant threat to human health or those that request further information to assist ATSDR in characterizing an immediate and significant public health threat at a site or event. ATSDR tracks and evaluates the effectiveness of the advice and recommendations in the Public Health Advisory and other documents. If recommendations are not being followed, then the reasons that recommendations are not being followed will be determined and assessed to determine if other actions are needed to protect public health.