

substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible

addition to the profiles now or in the future.

The draft toxicological profile was made available to the public on January 22, 1999.

Document	Hazardous substance	CAS No.
1 .....	POLYCHLORINATED BIPHENYLS .....	001336-36-3
	AROCLOR 1016 .....	012674-11-2
	AROCLOR 1221 .....	011104-28-2
	AROCLOR 1232 .....	011141-16-5
	AROCLOR 1242 .....	053469-21-9
	AROCLOR 1248 .....	012672-29-6
	AROCLOR 1254 .....	011097-69-1
	AROCLOR 1260 .....	011096-82-5
	AROCLOR 1262 .....	037324-23-5
	AROCLOR 1268 .....	011100-14-4

All profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: February 4, 1999.

**Georgi Jones,**

*Director, Office of Policy and External Affairs,  
Agency for Toxic Substances and Disease  
Registry.*

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BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 99039]

### Community Partners for Healthy Farming Intervention; Notice of Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for Community Partners for Healthy Farming. This program addresses the "Healthy People 2000" priority areas of Community-Based Programs and Occupational Safety and Health. The purpose of this cooperative agreement is to utilize the special resources of researchers, workers, farm managers, local agricultural communities, and other stakeholders to

evaluate farm safety and health interventions.

#### B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

**Note:** Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

#### C. Availability of Funds

Approximately \$850,000 is available in FY 1999 to fund five to seven awards. It is expected that the average award will be \$145,000, ranging from \$45,000 to \$180,000. It is expected that the awards will begin on or about August 1, 1999, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

#### Funding Preferences

Funding preferences may be given to applications from specific locations to achieve geographic distribution.

#### D. Cooperative Activities

In conducting activities to achieve the purpose of this program, the recipient

will be responsible for activities under 1. (Recipient Activities), and CDC/NIOSH will be responsible for the activities listed under 2. (CDC/NIOSH Activities).

#### 1. Recipient Activities

a. Develop an intervention with a clear prevention effect, evidence of community support, and strategies or adoption by the community, and for sustainability.

b. Develop a research proposal which is predicated upon an active partnership between experienced researchers, communities, agricultural workers, management and other stakeholders in the planning, implementation, and evaluation of intervention known agricultural injuries, illness, or hazards. The evaluation component shall include both process and outcome evaluation. The study population and recruitment procedures should be described. A time line which includes post intervention analyses should be developed.

c. Implement, collect and analyze the evaluation data.

d. Identify and implement measures to maintain and extend the intervention.

#### 2. CDC/NIOSH Activities

a. Provide technical assistance, through site visits and other communication, in all phases of the development, implementation and maintenance of these cooperative agreements.

b. Facilitate communication/coordination between recipients and other groups, organizations and agencies involved in agricultural research and outreach.

c. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

#### E. Application Content

Use the information in the Cooperative Activities, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 50 double-spaced pages. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8½" by 11" paper, with at least 1" margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets. Appendices should have indexes and include (1) support letters (2) information on key personnel (3) other supporting documentation.

#### F. Submission and Deadline

##### *Letter of Intent (LOI)*

The letter of intent must be submitted on or before March 23, 1999, to: Sheryl L. Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99039, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E-13, Atlanta, Georgia 30341.

##### *Application*

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before April 23, 1999, submit the application to: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99039, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E-13, Atlanta, Georgia 30341.

**Deadline:** Applications shall be considered as meeting the deadline if they are either:

A. Received on or before the deadline date; or

B. Sent on or before the deadline date and received in time for orderly processing. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

**Late Applications:** Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

#### G. Evaluation Criteria

Applications which are complete and responsive will be reviewed and evaluated by an Independent Special Emphasis Panel in accordance with the following criteria.

##### *1. Background and Need (20 points total)*

a. The extent to which the applicant understands the purpose and provides a comprehensive statement of the specific problem to be addressed. (2 points)

b. The extent to which the applicant presents data justifying the need for the intervention in terms of magnitude of the problem, and the intervention is theoretically justified and supported with epidemiologic, methodological, or behavior research. (9 points)

c. The extent to which the intervention is feasible and can be expected to produce the expected results in the target group. Efficacy of adoption and sustainability of the intervention acknowledging potential strengths and barriers to adoption and sustainability, e.g. the impact of trends in agriculture, support by partners and stakeholders, costs of implementation, effects on production, and community norms. Identified participant population, including extension agents, farmers, farm workers, and farm safety and community organizations that have expressed an interest in supporting and extending the intervention beyond the current agreement. (9 points)

##### *2. Goals and Objectives (20 points)*

The extent to which specific research questions and/or hypotheses are described. The extent to which the applicant has included goals which are relevant to the purpose of reducing injuries, illnesses, and/or hazard exposure to agricultural workers and the specific problem addressed by the applicant.

The extent to which the applicant has included goals and objectives that are specific, measurable, time-phased, feasible to be accomplished during the budget period, and which address all activities necessary to accomplish the purpose of the proposal.

The extent to which objectives include involving agricultural workers, communities, and other stakeholders in the planning, implementation and evaluation of the intervention.

##### *3. Methods (25 points)*

The extent to which the applicant provides a detailed description of overall design and methods selected for the intervention(s) including the designation of responsibility for each action undertaken.

The extent to which the target population and setting in which the intervention is to be implemented are clearly described and shown to be adequate for achieving the desired objectives.

The extent to which it is demonstrated that the participation of the target group will be sufficient to evaluate the intervention in an unbiased fashion.

The extent to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (b) The proposed justification when representation is limited or absent; (c) A statement as to whether the design of the study is adequate to measure differences when warranted; (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits will be documented.

##### *4. Staffing, Facilities and Resources (15 points total)*

a. The extent to which organizational structure, job descriptions, proposed staffing, staff qualifications and experience, identified training needs or plan, and curricula vitae for both the proposed and current staff indicate the applicant's ability to carry out the objectives of the program. The extent to which the management staff and their working partners are clearly described, appropriately assigned and have pertinent skills and experiences, e.g. previous accomplishments in agricultural safety and health interventions. Time allocation of the professional staff to be assigned to this project. (8 points)

b. The extent to which concurrence with the applicant's plans by all other involved parties is specific and documented, e.g. support for proposed activities as well as commitment to participate from proposed partners (e.g. letters of support and/or memoranda of understanding). The extent to which the participants are clearly described and their qualifications for their component of the proposed work are explicitly

stated. The extent to which the applicant provides proof of the involvement of partners/stakeholders (e.g., agricultural workers, agricultural organizations, agribusiness) in the development of this proposal. (7 points)

#### 5. Evaluation (20 points)

The extent to which the proposed evaluation system is detailed and will document program process, effectiveness, impact, and outcome. The extent to which an evaluation plan has been developed to determine both the success of the pilot intervention or demonstration project(s) and to determine its utility as a public health prevention strategy with broader application in other communities. The extent to which the applicant demonstrates potential data sources for evaluation purposes, and documents staff availability, expertise, and capacity to perform the evaluation. The extent to which a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions is included.

#### 6. Budget and Justification (not scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

#### 7. Human Subjects Review (not scored)

The applicant must clearly state what precautions exist to protect human subjects.

### H. Other Requirements

#### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E13, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970, [29 U.S.C. 669(a) and 671(e)(7)]. The Catalog of Federal Domestic Assistance number is 93.283.

### J. Where To Obtain Additional Information

Please refer to Program Announcement 99039 when you request information. To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

See also the CDC home page on the Internet:

<http://www.cdc.gov>

If you have questions after reviewing the contents of all the documents, please contact: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99039, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E-13, Atlanta, GA 30341, telephone (404) 842-6814, Email address SLH3@cdc.gov

For program technical assistance, contact Janet Ehlers, R.N., M.S.N., Occupational Health Nurse, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Division of Surveillance, Hazard Evaluations and Field Studies, 4676 Columbia Parkway, R-21, Cincinnati, OH 45226, Telephone (513) 841-4208, fax (513) 841-4489, e-mail: [jje0@cdc.gov](mailto:jje0@cdc.gov); or Teri Palermo R.N., Public Health Advisor, NIOSH/CDC, Division of Respiratory Disease Studies, Office of the Director, 1095 Willowdale Road, Mailstop 127 Morgantown, WV 26505-2888, telephone (304) 285-5836, fax (304) 285-5861, e-mail: [bt00@cdc.gov](mailto:bt00@cdc.gov).

Dated: February 4, 1999.

**Diane D. Porter,**

*Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97D-0383]

### Guidance for Industry on Population Pharmacokinetics; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Population Pharmacokinetics." This guidance provides recommendations to pharmaceutical industry scientists, who have long been interested in the application of population pharmacokinetics, during the new drug development, safety and efficacy evaluation, and approval processes.

**DATES:** Written comments on the guidance may be submitted at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this guidance for industry are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or "<http://www.fda.gov/cber/guidelines.htm>". Submit written requests for single copies of "Population Pharmacokinetics" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Copies of this guidance may also be obtained by fax from 1-888-CBERFAX or 301-827-3844 or by mail from the Voice Information System at 800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

He Sun, Center for Drug Evaluation and Research (HFD-880), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2205, or

Martin D. Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville