

## II. Background

### A. What action is the agency taking?

EPA is announcing the availability of a draft guidance document titled, "Weight-of-Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing." This document invites the public to review and comment on the guidance document, which is available electronically at [regulations.gov](http://www.regulations.gov) (<http://www.regulations.gov>) using docket ID number EPA-HQ-OPPT-2010-0877 and the EDSP Web site <http://www.epa.gov/endo>.

This document was prepared to provide a transparent, scientific approach to set forth some general principles, criteria, and considerations EPA generally believes to be relevant using a WoE approach to evaluate data submitted as part of EPA's EDSP involving a battery of validated Tier 1 screening assays as described in a notice published in the **Federal Register** issue of October 21, 2009 (74 FR 54415) (FRL-8432-6). The criteria discussed in this document are based, in part, on EPA's experience in developing and applying risk assessment guidelines involving cancer, reproductive and developmental toxicity, and ecological toxicity. Important considerations include the use of expert judgment formed through the scientific process, current understanding of endocrine mechanisms of toxicity, and knowledge of other fields of toxicology (e.g., developmental, reproductive, neurological and immunological toxicology, and toxicokinetics). Principles articulated in this document are equally applicable to a WoE evaluation of data from individual assays with multiple endpoints, as well as across the whole suite of assays in the EDSP Tier 1 screening battery. In addition, these principles would be generally applicable to the review of other scientifically relevant information (OSRI) submitted in response to test orders that request OSRI to be considered in lieu of designated screening assays in the Tier 1 battery.

In general, the EDSP is a two-tiered paradigm for screening and testing chemicals with the potential to interact with the endocrine system. Tier 1 screening consists of a battery of complementary *in vitro* and short term *in vivo* assays designed to maximize sensitivity for detecting interactions with the E, A, and/or T hormonal systems; whereas, Tier 2 testing consists of a group of individual *in vivo* tests designed to include males and females with an intact hypothalamic-pituitary-

gonadal axis, multiple pathways of exposure and life-stages, and various taxa to further identify and characterize chemical-induced interactions with E, A, and/or T for risk assessment. The diversity in endocrine endpoints within and among the Tier 1 screening assays is expected to provide corroborating information and support a WoE evaluation to yield a decision as to whether or not the chemical identified in Tier 1 requires additional testing in Tier 2.

### B. What is the agency's authority for taking this action?

Section 408(p) of FFDCFA requires EPA to "develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as [EPA] may designate." (21 U.S.C. 346a(p)). The statute generally requires EPA to "provide for the testing of all pesticide chemicals." (21 U.S.C. 346a(p)(3)). "Pesticide chemical" is defined as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and inert ingredients of such pesticide." (21 U.S.C. 321(q)(1)).

### List of Subjects

Environmental protection, Endocrine disruptors, Screening assays, Weight-of-evidence.

Dated: October 27, 2010.

**Stephen A. Owens,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9220-9]

### Announcement of Local Government Advisory Committee Members

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** The U.S. Environmental Protection Agency announces that Administrator Lisa P. Jackson has appointed 29 local, State, and Tribal elected and appointed officials from across the country to serve on the EPA's Local Government Advisory Committee (LGAC). The Committee's purpose will be to give advice and recommendations

on a broad range of environmental issues affecting local governments. These new appointments include:

### Mayors (Large Cities)

Phil Gordon, Mayor, Phoenix, Arizona.

John W. Hickenlooper, Mayor, Denver, Colorado.

### Mayors (Moderate Sized Cities)

Jennifer Hosterman, Mayor, Pleasanton, California.

Terry Bellamy, Mayor, Asheville, North Carolina.

Elizabeth Kautz, Mayor, Burnsville, Minnesota.

Teresa Coons, Mayor, Grand Junction, Colorado.

Dana L. Redd, Mayor, Camden, New Jersey.

### Mayors (Small Cities and Towns)

Bob Dixon, Mayor, Greensburg, Kansas.

Marilyn Murrell, Mayor, Arcadia, Oklahoma.

Ronald K. Davis, Mayor, Prichard, Alabama.

Adam Ortiz, Mayor, Edmonston, Maryland.

Heather McTeer Hudson, Mayor, Greenville, Mississippi.

Carolyn Peterson, Mayor, Ithaca, New York.

Lisa A. Wong, Mayor, Fitchburg, Massachusetts.

David W. Smith, Mayor, Newark, California.

### Tribal (Elected and Appointed)

Steve Ortiz, Chairman Prairie Band Potawatomi Nation, Kansas.

Aaron Miles, Manager at Nez Perce Tribe, Idaho.

### Commonwealth

Evelyn Delereme Camacho, Mayor, Municipality of Vieques, Puerto Rico.

### County Executive

Tom Hickner, County Executive, Bay County, Michigan.

### County Commissioners

\*Dave Somers, Councilor, Snohomish County, Washington.

Robert Cope, Commissioner, Lemhi County, Idaho.

Salud Carbajal, Supervisor, Santa Barbara County, California.

### Conservation Districts

Jeffrey Tiberi, Director of Montana Association of Conservation Districts, Helena, Montana.

### City Councilmember

Jill Duson, Councilor, Portland, Maine.

**State Elected Officials**

Mary Margaret Whipple, State Senator, Commonwealth of Virginia.

Chris Ross, State Representative 158th District, Harrisburg, Pennsylvania.

**County Judge**

Edward M. Emmett, Harris County Judge, Houston, Texas.

**Appointed Officials**

Dr. Hector Gonzalez, Director, Laredo, Texas Health Dept.

Susan Hann, Deputy City Manager, Palm Bay, Florida

(\* Formerly served one term on LGAC).

If you desire further information go to: at <http://www.epa.gov/ocir/scas> or contact the Designated Federal Officer (DFO), [Eargle.Frances@epa.gov](mailto:Eargle.Frances@epa.gov).

Dated: October 29, 2010.

**Frances Eargle,**

*Designated Federal Officer, Local Government Advisory Committee.*

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**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-9220-4]

**Notice of a Project Waiver of Section 1605 (Buy American Requirement) of the American Recovery and Reinvestment Act of 2009 (ARRA) to the Town of Taos, NM**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Regional Administrator of EPA Region 6 is hereby granting a project waiver of the Buy American requirements of ARRA Section 1605 under the authority of Section 1605(b)(2) [manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality] to the Town of Taos ("Taos") for the purchase of 40 lb/yd American Society of Civil Engineers (ASCE) crane railing, which is part of the overhead bridge crane, proposed for the expansion of its existing Wastewater Treatment Plant (WWTP). The 40 lb/yd ASCE crane railing is manufactured by companies located in foreign countries and no United States manufacturer produces an alternative that meets Taos' technical specifications. This is a project specific waiver and only applies to the use of the specified product for the ARRA funded project being proposed. Any other ARRA project that may wish to use the

same product must apply for a separate waiver based on the specific project circumstances. The Regional Administrator is making this determination based on the review and recommendations of the EPA Region 6, Water Quality Protection Division. Taos has provided sufficient documentation to support its request.

The Assistant Administrator of the EPA's Office of Administration and Resources Management has concurred on this decision to make an exception to Section 1605 of ARRA. This action permits the purchase of 40 lb/yd ASCE crane railing not manufactured in America, for the proposed project being implemented by Taos.

**DATES:** *Effective Date:* October 18, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Nasim Jahan, Buy American Coordinator, (214) 665-7522, SRF & Projects Section, Water Quality Protection Division, U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

**SUPPLEMENTARY INFORMATION:** In accordance with ARRA Section 1605(c), EPA hereby provides notice that it is granting a project waiver of the requirements of Section 1605(a) of Public Law 111-5, Buy American requirements, to Taos for the acquisition of 40 lb/yd ASCE crane railing that will be part of the overhead bridge crane for the WWTP.

Section 1605 of the ARRA requires that none of the appropriated funds may be used for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States unless a waiver is provided to the recipient by EPA. A waiver may be provided if EPA determines that (1) applying these requirements would be inconsistent with public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) inclusion of iron, steel, and the relevant manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent.

Taos' waiver request is to allow the purchase of a 40lb/yd ASCE crane railing that will be part of the overhead bridge crane for the WWTP in Taos, New Mexico. Taos has provided information to the EPA demonstrating that there is no 40 lb/yd ASCE crane railing manufactured in the United States in sufficient and reasonable quantity and of a satisfactory quality to

meet the required technical specification. The United States stopped producing 40lb/yd rail at the turn of 20th Century due to increases in weight demand on railroads. The ASCE designed a load limit for railroad tracks that severely limited the quantity of rail less than 80 lb/yd being produced. Taos has also indicated that Steel of West Virginia is a steel mill that produces rails for the mining industry and this manufacturer's product does not meet ASCE standards and therefore cannot be used in this project.

Based on additional research conducted by EPA Region 6, there does not appear to be any domestic crane rail manufacturer that would meet Taos' technical specifications. EPA's national contractor prepared a technical assessment report based on the waiver request submittal. The report confirmed the waiver applicant's claim that there is no American-made 40 lb/yd crane railing available for the overhead bridge crane for use in the proposed WWTP.

EPA has determined that the City's waiver request may be treated as timely even though the request was made after the construction contract was signed. Consistent with the direction of the OMB Guidance at 2 CFR 176.120, EPA has evaluated the City's request to determine if the request constitutes a late request. EPA will generally regard waiver requests with respect to components that were specified in the bid solicitation or in a general/primary construction contract as "late" if submitted after the contract date. However, in this case EPA has determined that the City's request, though made after the contract date, may be treated as timely. This request is submitted after the contract date because the crane rail, according to the project specifications, must be designed by a qualified supplier. The supplier provided this information through contractor submittals. The need for a waiver was not determined until after the supplier of the overhead bridge crane confirmed that there was no domestically made 40 lb/yd crane railing available to meet the project specifications. Accordingly, EPA will evaluate the request as a timely request.

The April 28, 2009 EPA HQ Memorandum, Implementation of Buy American provisions of Public Law 111-5, the "American Recovery and Reinvestment Act of 2009", defines reasonably available quantity as "the quantity of iron, steel, or relevant manufactured good is available or will be available at the time needed and place needed, and in the proper form or specification as specified in the project plans and design." Taos has