

## II. Background

### A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

### B. Public Meeting

EPA has made many recent advances in high throughput bioactivity testing. However, concurrent advances in rapid, quantitative prediction of human and ecological exposures have been lacking, despite the clear importance of both measures for a risk-based approach to prioritizing and screening chemicals. A recent report by the National Research Council of the National Academies, *Exposure Science in the 21st Century: A Vision and a Strategy* (NRC 2012) laid out a number of applications in chemical evaluation of both toxicity and risk in critical need of quantitative exposure predictions, including screening and prioritization of chemicals for targeted toxicity testing, focused exposure assessments or monitoring studies, and quantification of population vulnerability. Despite these significant needs, for the majority of chemicals (e.g. non-pesticide environmental compounds) there are no or limited estimates of exposure. For example, exposure estimates exist for only 7% of the ToxCast Phase II chemical list. In addition, the data required for generating exposure

estimates for large numbers of chemicals is severely lacking (Egeghy *et al.* 2012).

This SAP will review the use of EPA's ExpoCast model to rapidly estimate potential chemical exposures for prioritization and screening purposes. The focus will be on bounded chemical exposure values for people and the environment for the Endocrine Disruptor Screening Program (EDSP) Universe of Chemicals. In addition to exposure, the SAP will review methods to extrapolate an *in vivo* dose from *in vitro* dose data. This will involve presenting pharmacokinetic (PK) data for chemicals that have been run through a battery of high throughput endocrine screening assays and the methodology to use that PK information to estimate an *in vivo* dose. This exposure and RTK information along with high throughput *in vitro* bioactivity data will allow the EPA to assign a risk ranking to chemicals and prioritize them accordingly.

ExpoCast is an EPA initiative to develop the necessary approaches and tools for rapidly prioritizing and screening thousands of chemicals based on the potential for human exposure. This focus for ExpoCast is distinct from many existing exposure tools that support regulatory risk assessment. Traditional exposure tools are lower throughput, requiring considerable data to make predictions of sufficient precision for a full risk assessment. ExpoCast efforts have focused on empirically assessing the uncertainty in forecasts made with limited available data, finding that in some cases even highly uncertain forecasts may be useful for prioritization and screening.

In order to relate high throughput bioactivity data and rapid exposure predictions, an *in vitro-in vivo* extrapolation (IVIVE) via PK is needed. This IVIVE relates the *in vitro* compound concentrations ( $\mu\text{M}$ ) found to be bioactive to the *in vivo* doses needed to produce serum concentrations equal to the *in vitro* concentrations. Without the time and resources necessary to generate *in vivo* PK data for the thousands of chemicals in the EDSP universe, high throughput pharmacokinetics (HTPK) can serve as a useful surrogate. HTPK methods were developed for pharmaceuticals to estimate therapeutic doses for clinical studies. HTPK technologies have been effective for pharmaceutical compounds and predicted concentrations are typically on the order of the measured *in vivo* concentrations. For non-therapeutic compounds in humans, PK data is not available and so it is essential to carefully characterize the

predictive ability of the HTPK models and define the domain of applicability.

High throughput exposure prediction and high throughput PK, when taken together with *in vitro* bioactivity profiling as a surrogate for hazard, will allow for a risk-based, rapid prioritization and screening of chemicals in the EDSP universe and beyond.

### C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available by approximately July 9, 2014. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at <http://www.regulations.gov> and the FIFRA SAP homepage at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP Web site or may be obtained from the OPP Docket or at <http://www.regulations.gov>.

### List of Subjects

Environmental protection, Pesticides and pests, Environmental justice.

Dated: May 20, 2014.

**David J. Dix,**

*Director, Office of Science Coordination and Policy.*

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**BILLING CODE 6560-50-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors.

Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 16, 2014.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Mary Lou Spanier, individually and as trustee of the Jesse L. Thomas Testamentary Trust*, both of Sublette, Kansas; to acquire voting shares of Santa Fe Trail Banc Shares, Inc., and thereby indirectly acquire voting shares of Centera Bank, both in Sublette, Kansas.

Board of Governors of the Federal Reserve System, May 27, 2014.

**Margaret McCloskey Shanks,**  
*Deputy Secretary of the Board.*

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## FEDERAL RESERVE SYSTEM

### Federal Open Market Committee; Domestic Policy Directive of April 29– 30, 2014

In accordance with Section 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on April 29–30, 2014.<sup>1</sup>

Consistent with its statutory mandate, the Federal Open Market Committee seeks monetary and financial conditions that will foster maximum employment and price stability. In particular, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to undertake open market operations as necessary to maintain such conditions. Beginning in May, the Desk is directed to purchase longer-term Treasury securities at a pace of about \$25 billion per month and to purchase agency mortgage-backed securities at a pace of about \$20 billion per month. The Committee also directs the Desk to engage in dollar roll and coupon swap transactions as necessary to facilitate settlement of the Federal Reserve's agency mortgage-backed securities transactions. The Committee directs the

Desk to maintain its policy of rolling over maturing Treasury securities into new issues and its policy of reinvesting principal payments on all agency debt and agency mortgage-backed securities in agency mortgage-backed securities. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.

By order of the Federal Open Market Committee, May 22, 2014.

**William B. English,**  
*Secretary, Federal Open Market Committee.*  
[FR Doc. 2014-12517 Filed 5-29-14; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[60Day-14-14AEH]

### Proposed Data Collections Submitted for Public Comment and Recommendations

The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

### Proposed Project

Assessment of Chemical Exposures (ACE) Investigations—New—Agency for Toxic Substances and Disease Registry (ATSDR)

#### Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year generic clearance for the Assessment of Chemical Exposures (ACE) Investigations to assist state and local health departments after toxic substance spills or chemical incidents. ACE investigations are a component of the National Toxic Substance Incidents Program (NTSIP). NTSIP was introduced in 2010 as a comprehensive agency approach to toxic substance incident surveillance, prevention, and response. This three-part program includes a proposal for state-based surveillance for toxic substance releases, a national database of toxic substance incidents combining data from many sources, and the ACE investigations.

The ACE Investigations focus on performing rapid epidemiological assessments to assist state, regional, local, or tribal health departments (the requesting agencies) to respond to or prepare for acute chemical releases. The main objectives for performing these rapid assessments are to:

1. Characterize exposure and acute health effects of respondents exposed to toxic substances from discrete, chemical releases and determine their health statuses;
2. Identify needs (i.e. medical and basic) of those exposed during the releases to aid in planning interventions in the community;

<sup>1</sup> Copies of the Minutes of the Federal Open Market Committee at its meeting held on April 29–30, 2014, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's Annual Report.