Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 23, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–237 Filed 1–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health service

National Institute of Environmental Health Sciences, NIH; National Toxicology Program; Solicitation of Comments on Proposed Peer Review of Low-Dose Issues for Endocrine Disruptors

SUMMARY: NTP is soliciting comments on the planned scope and process for a proposed peer review of studies bearing on the question of whether endocrine disruptors may cause effects at doses lower than are tested using standard toxicological testing procedures. Nominations for peer reviewers, as well as nominations for studies to be reviewed, are also being solicited. Results from the peer review will help the U.S. Environmental Protection Agency (a member agency of the NTP) and, in particular the EPA's Endocrine Disruptor Screening Program, determine how to address low-dose questions in endocrine disruptor screening, testing, and hazard assessment.

Background

The U.S. Environmental Protection Agency (EPA) is implementing an Endocrine Disruptor Screening Program as required by the Food Quality Protection Act of 1996 (See 63 FR 71542–71568, Dec. 28, 1998). The EPA is in the process of choosing appropriate assays to use in this screening program and is also developing standardized, validated protocols for these assays. A critical aspect of protocol development is dose-setting. In recent years, there have been suggestions that hormonally active agents may cause effects at doses lower than those normally selected for toxicological testing. A review of the issue can be found in the National Academy of Science's recently-released report Hormonally Active Agents in the Environment (NRC [National Research Council]. 1999. Washington, DC: National Academy Press, pp. 103–111).

The EPA has asked the National Toxicology Program to establish an independent panel of scientists to review the evidence related to low-dose effects and consider their implications for the development, validation, and interpretation of test protocols. If this Panel concludes that significant effects at low doses occur and that the standard dose-setting paradigm is inadequate to detect such effects, the EPA intends to pursue in a separate forum the question of how to test for such effects, including endpoints to be tested, dose-setting protocols and appropriate test methods. If the Panel believes the current data to be inconclusive, it will be asked to describe specific research that would resolve the ambiguities.

Proposed Scope and Process for the review

A. Scope of the Review

Analysis will focus on interpretation of the major data sets showing or refuting effects at low doses. ''Low doses'' are defined for the purposes of discussion as ''doses below the currently accepted No Observed Adverse Effect Level for that substance''. The intent is to evaluate the presence or absence of low-dose effects in specific studies, then evaluate the likelihood and significance of these and/or other potential low-dose effects to humans.

The main topic to be addressed is evidence for defining the shape of the dose/response curves for endocrine-active substances in the low-dos region.

The review is expected to examine all evidence, including such things as relevant pharmacokinetic and mechanistic information, which may have a bearing on the low-dose issue. In order to come to disclosure on the central issue of whether there are sufficient grounds to change the traditional dose-setting paradigm for endocrine-active substances, it will not be possible to go into the details of non-central issues. Issues which may enter the discussion but which are not the central forcus and will not get exhaustive review include:

—existence of inverted U-shaped dose/response curves as a general phenomenon in toxicology;
—completeness of the list of endpoints examined in two-generation toxicity tests;
—definition of ''adversity''.

B. Selection of Studies for Review

Given the breadth of the scope, many studies are likely to be considered relevant to the discussion. NTP proposes to divide studies into two categories: those which provide background information and those which hare critical to the resolution of the issue. Hard copies of both the background information and critical studies will be provided to the Panel in advance of the Peer Review Meeting. For the critical studies, principal investigators will be invited for in-depth discussions with the Panel, and the data sets from these critical studies will be subjected to independent analyses by the panel. NTP anticipates that approximately 10 to 12 studies might be designated critical.

C. Criteria for Selection of Studies for Review

Studies which provide direct evidence for the presence of effects related to the endocrine system at doses below the No Observed Adverse Effect Level will generally be considered critical. Studies which provide direct evidence against such effects at similar doses for the same chemical will also generally be considered critical. Studies which provide direct evidence for endocrine-related effects for chemicals for which NOAELs have not been established will generally be considered critical if there is reason to believe that normal procedures for establishing a NOAEL would set NOAELs at a higher level than those indicated by the study in question, as long as the difference in putative NOAELs would be due to dose/response considerations rather than to definitions of adversity or selection of endpoints for observation. Studies which provide direct evidence against effects at similar doses from chemicals for which such claims have been made will also generally be considered critical.

Pharmacokinetic and mechanistic studies which provide insight into the plausibility or relevance of effects established in the direct studies may be either critical or background information depending on how closely they address low-dose issues.

Studies of other endocrine effects caused by a substance for which a low-dose endocrine effect is established will be considered background information unless mechanistic information establishes a relevant relationship to the low-dose effect.

In general, potency per se, is not a central issue. Studies which show effects at low doses but whose central issue in setting a NOAEL is either the definition of adversity or the completeness of the list of endpoints for which observations are made will not be considered relevant to the dose/response issues that this peer review will address.

For background information, well-written reviews will be preferred over individual studies. Only studies or reviews which have been published in standard, peer-reviewed scientific journals or books will be considered.

Critical studies must be accepted for publication in a standard, peer-reviewed scientific journal or book by April 1, 2000. Studies presented at scientific meetings but not formally accepted for publication in a peer-reviewed journal will not be accepted.

Raw data for critical studies must be available for the Panel to review and analyze. ''Raw data'' includes data on individual laboratory animals, prior to aggregation by statistical or other methods. Data reported under Good Laboratory Practices, for example, will generally be considered ''raw data''.

D. Selection Procedure

An NTP interagency workshop organizing committee will choose the studies to be considered by the Panel.

NTP recognizes that the date of acceptance for publication cannot be predicted with accuracy. Similarly, co-operation by principal investigators to include a study in this review cannot be guaranteed. For planning purposes, it may become necessary to designate certain studies as ''likely to be critical'' before April 1 and to treat them as if they will be examined at the Panel meeting. However, the criteria will be applied on April 1.

E. Preliminary List of Published Studies To Be Considered by the Low-Dose Peer Review Panel

The NTP has compiled the attached preliminary list of relevant studies and invites public comment on the list.

F. Peer Review Panel Members

A panel of 16 to 20 members is anticipated. NTP is soliciting nominations for the Panel from the public. (See Guidelines for Submission of Comments below). Kinds of expertise that are likely to be relevant include reproductive biology (male and female, whole animal and cellular), endocrinology, pharmacology, statistical data analysis, and dose/response modeling. Expertise need not be limited to these areas, nor will these areas necessarily all be included on the Panel. NTP will try to ensure an appropriate breadth of expertise across the Panel. If there are particular kinds of expertise that you feel the Panel should include, please provide a justification in your comments, especially if the expertise is not covered in the list above.

Nominations should be accompanied by complete contact information, including name, address, institutional affiliation, telephone number, and e-mail address. Where possible, a Web page address for research interests and/or curriculum vitae should be included. To avoid the potential for candidates being contacted by a large number of nominators, candidates need not be contacted prior to nomination. NTP will solicit curricula vitae and interest in participation at an appropriate time.

G. Criteria for Selection of Panel Members

Expertise in a scientific field relevant to the low-dose issue is required.

Investigators associated with critical studies will not be considered for the Panel. Principal investigators (or their designated co-authors) for critical studies will be asked to present their data and be available for discussion at the Peer Review Panel meeting, but will not be asked to be part of the Panel itself.

H. Selection Procedure

Panelists will be chosen after critical studies have been selected. An NTP interagency organizing committee will select panel members considering all nominations received from the public as well as nominations developed internally. All nominees will be contacted for interest and availability, and curricula vitae will be solicited from the nominees. Selection will be based on the CVs and accompanying information such as statements of research interest. Official invitations to participate will be sent out in approximately April of 2000. The final list of Peer Review panel members will be available to the public through the Endocrine Disruptor Screening Program's Interent Web site (http://www.epa.gov/scinpoly/oscpendo/index.htm). Panel members will be paid as consultants, and candidates will be required to disclose potential conflicts of interest.

I. Subcommittee Structure

NTP proposes to have Subcommittees of the Peer Review Panel examine specific aspects of the low-dose issue. Subcommittee topics will be determined after studies for review have been selected. Topics that may be appropriate for Subcommittees include:

- Data Analysis and Statistics
- Pharmacokinetics, Receptor Binding, and Modeling
- Effects on Males
- Effects on Females

Comments on the appropriateness of having Subcommittees, and of the specific topics suggested, are welcome.

Approximate Schedule for the Review

A meeting of the Peer Review Panel is tentatively planned for late July 2000 in the Research Triangle Park, NC area. The entire peer review panel meeting will be open to the public, limited only by space available. Details of the meeting location, dates, and times will be announced at a later time.

In order to meet this deadline, designation of critical studies will take place in March, with Panel selection to begin in the March/April time frame.

Between May and late June, the data analysis subcommittee will be asked to review the data on critical studies. Investigators may be asked to run analyses of their own data according to the specifications of the Data Analysis Subcommittee. Approximately four weeks before the Peer Review, this Subcommittee will have the opportunity to meet with the investigators by conference call (or, if necessary, at a central location) to ask questions and obtain additional data that might be needed in preparation for the Panel meeting. The findings of the Data Analysis Subcommittee will be made available to the full Peer Review Panel for discussion at the meeting.

On the first day of the Peer Review Meeting, presentation from principal investigators for the critical studies will be heard by the entire Panel. Also, the Data Analysis and Statistics Subcommittee will present its analysis of the data to the remainder of the Low-Dose Panel. Principal investigators of the critical studies will be available for comment.

On the second day, the remaining Subcommittee will meet separately for discussion. Members of the Data Analysis and Statistics Subcommittee will be asked to split up between the remaining subcommittees.

On the third day, the entire Panel will reconvene as a group to discuss the deliberations of each of the Panels and to integrate the separate aspects into a report.

Each of the Subcommittees, as well as the full Panel, will produce a written Report following the meeting, documenting the discussions and explaining reasons for the scientific judgments made. These reports will be submitted for publication in an appropriate peer-reviewed scientific journal. Reports will also be made on the NTP and EPA (Endocrine Disruptor Screening Program) Web sites.

Public Input Solicited

As described above, the NTP solicits comments on the scope and process for the review; comments on the NTP preliminary list of studies for review; the nomination of studies to be considered for review; and the nomination of peer review panel members. Comments, identified by docket control number OPPTS–42208A,

must be received on or before February 22, 2000.

Guidelines for Submission of Public Comments

EPA will manage the record-keeping aspects of the Peer Review as part of the Endocrine Disruptor Screening Program.

You man obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''Federal Register—Environmental Documents.'' You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/.

For general information about the Endrocrine Disruptor Screening Program go to http://www.epa.gov/scipoly/oscpendo/index.htm.

The EPA has established an official record for this action under docket control number OPPTS–42208A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action. This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW, Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–42208A in the subject line on the first page of your response.

1. By mail. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460.

2. In person or by courier. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G–099, Waterside Mall, 401 M St. SW, Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260–7093.

3. Electronically. You may submit your comments electronically by e-mail to: ''oppt.ncic@epa.gov,'' or mail your computer disk to the address identified above. Do not submit any information that you consider to be CBI. Electronic comments may be submitted in WordPerfect 6.1/8.0 or as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–42208A. Electronic comments may also be filed online at many Federal Depository Libraries.

Do not submit any information that you consider to be Confidential Business Information. If you believe that relevant information will be overlooked because of this restriction, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: James P. Kariya, Office of Science Coordination and Policy (7203), Office of Prevention, Pesticides, and Toxic Substances, Environmental Protection Agency, 401 M St. SW, Washington, DC 20460; telephone number: (202) 260–2916; e-mail address: kariya.jim@epa.gov.

Dated: December 28, 1999.

Kenneth Olden, Director, National Toxicology Program, Department of Health and Human Services.

Attachment—Preliminary List of Published Studies to Be Considered by the Low-dose Peer Review Panel

The NTP has compiled a preliminary list of relevant studies. The public is invited to comment on this list; suggestions for additions, deletions, and substitutions may be submitted. (See Section of this FR announcement on Guidelines for Submission of Public comments.) Submission of a complete copy of the journal article in which the study and its results are described is preferred, but a complete reference (authors' names, name of journal, volume, issue, pages, title, date) will be sufficient if the complete article cannot be submitted. Include a brief narrative explaining the reason for each addition, deletion, or substitution. Raw data need not be submitted at this stage.

Studies which are as yet unpublished but which are expected to be accepted for publication before April 1, 2000 may be nominated. An abstract of the study describing highlights of the study (including species and strain, dosing regimen, duration of study, number of animals per dose, endpoints evaluated and, if available, results) must be submitted in order for the Selection Committee to be able to evaluate the likelihood that the study will be a critical study. As with published studies, a brief narrative explaining the significance of as yet unpublished studies should be included.

Studies which are completed but not published are not included here. This list is being provided as an example of the kinds of studies that may be appropriate for the Panel to consider. Final selection of studies has not been made.

Ashby J, Elliott BM. 1997. Reproducibility of endocrine disruption data. Reg Toxicol Pharmacol 26:94–95.

Ashby J, Tinwell H, Lefevre PA *et al.* 1997. Normal sexual development of rats exposed to butyl benzyl phthalate from conception to weaning. Reg Toxicol Pharmacol 26:102–118.

Boettger-Tong H, Murthy L, Chiapetta C, *et al.* 1998. A case of a laboratory animal feed with high estrogenic activity and its impact on *in vivo* responses to exogenously administered estrogens. Environ Health Perspect 106(7):369–373.

Cagen SZ, Waechter JM Jr, Dimond SS, *et al.* 1999. Normal reproductive organ development in CF–1 mice following prenatal exposure to bisphenol A. Toxicol Sci 50:36–44.

Colerangle JB, Roy D. 1997. Profound effects of the weak environmental estrogen-like chemical bisphenol A on the growth of the mammary gland of Noble rats. J Steroid Biochem.Molec Biol 60(1–2), 153–160.

Makela SI, Pylkkanen LH, Santti RSS, Adlercreutz H. 1995. Dietary soybean may be antiestrogenic in male mice. J Nutr 125:437–445.

Nagel SC, vom Saal FS, Thayer KA, *et al.* 1997. Relative binding affinity-serum modified access (RBA–SMA) assay predicts the relative *in vivo* bioactivity of the xenoestrogens bisphenol A and octylphenol. Environ Health Perspect 105:70–76.

Odum J. Pyrah ITG, Foster JR, *et al.* 1999. Comparative activities of p-nonylphenol and diethylstilbestrol in Noble rat mammary gland and uterotrophic assays. Reg Toxicol Pharmacol 29:184–195.

Portier C, Tritscher A, Kohl M. *et al.* 1993. Ligand/receptor binding for 2,3,7,8-TCDD: implications for risk assessment. Fundamental and Applied Toxicol 20:48–56.

Sharpe RM, Fisher JS, Millar MM, *et al.* 1995. Gestational and lactational exposure of rats to xenoestrogens results in reduced testicular size and sperm production. Environ Health Perspect 103(12): 1136–1143.

Sharp R, Turner KJ, Sumpter JP. 1998. Endocrine disruptors and testis development [letter]. Environ Health Perspect 106(5): A220–A221.

Sheehan DM, Willingham E, Gaylor D, *et al.* 1999. No threshold dose for estradiol-induced sex reversal of turtle embryos: how little is too much? Environ Health Perspect 107:155–159.

Spearow J, Doemeny P, Sera R, *et al.* 1999. Genetic variation is susceptibility to endocrine disruption by estrogen in mice. Science 285:1259–1261.

vom Saal FS, Quadagno DM, Even MD, *et al.* 1990. Biology of Reproduction 43:751–761.

vom Saal FS, Timms BG, Montano MM, *et al.* 1997. Prostate enlargement in mice due to

fetal exposure to low doses of estradiol or diethylstilbestrol and opposite effects at high doses. Proc Natl Acad Sci USA 94:2056–2061.

vom Saal FS, Cooke PS, Buchanan DL, *et al.* 1998. A physiologically based approach to the study of bisphenol A and other estrogenic chemicals on the size of reproductive organs, daily sperm production, and behavior. Toxicol Indust Hlth 14(__):239–260.

Welshons WV, Nagel SC, Thayer KA, *et al.* 1999. Low-dose bioactivity of xenoestrogens in animals: fetal exposure to low doses of methoxychlor and other xenoestrogens increases adult prostate size in mice. Toxicol Indust Health 15:12–25.

[FR Doc. 00–228 Filed 1–5–00; 8:45 am]

BILLING CODE 4140–01–M

U.S. DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–020848

Applicant: Frank H. Cooley, Jasper, TX 75951.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

The public is invited to comment on the following application for a permit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

PRT–021018

Applicant: Thomas J. Hammond, Bloomfield Hills, MI.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Western Hudson Bay polar bear population, Northwest Territories, Canada for personal use.

PRT–014704

Applicant: Toledo Zoological Gardens,Toledo, OH.
Permit Type: Import permit.
Name and Number of Animals: Polar bear (*Ursus maritimus*) 0.1.
Summary of Activity To Be Authorized: The applicant requests an amendment to their permit number MA014704–0 issued 09/10/1999 for the import of a captive born female polar bear from Germany. The applicant wishes to substitute a female captive born polar bear from Monde Sauvage Safari Park, Aywaille, Belgium, for this permit.
Source of Marine Mammals: Born in captivity on 11/10/1998, Aywaille, Belgium.
Period of Activity: Up to 5 years, if issued.

Concurrent with the publication of this notice in the **Federal Register**, the Office of Management Authority is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Written data or comments, requests for copies of the complete application, or requests for a public hearing on this application should be sent to the U.S. Fish and Wildlife Service, Office of Management Authority, 4401 N. Fairfax Drive, Room 700, Arlington, VA 22203, telephone 703/358–2104 or fax 703/358–2281 and must be received within 30 days of the date of publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Dated: December 27, 1999.

Kristen Nelson,

Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 00–224 Filed 1–5–00; 8:45 am]

BILLING CODE 4310–55–U

DEPARTMENT OF THE INTERIOR

Geological Survey

Application Notice Describing the Areas of Interest and Establishing the Closing Date for Receipt of Applications Under the Biological Resource Division Brucellosis Program for Fiscal Year (FY) 2000

AGENCY: Department of the Interior, U.S. Geological Survey.

ACTION: Notice.

SUMMARY: Applications are invited for a research projected on the improvements in ballistic delivery systems for brucellosis vaccination of free-ranging elk and bison of the Greater Yellowstone Area.

The purpose of this project is to develop methods of ballistic delivery that improve the distance, reliability, ease, and/or rapidity of Brucella vaccine parenteral delivery. Such methods will need to take into account vaccine composition and the targeted age and sex of bison and/or elk.

Applications may be submitted by educational institutions, private firms, private foundations, individuals, and agencies of state and local governments.

ADDRESSES: The project announcement is expected to be available on or about January 11, 2000. You may obtain a copy of Announcement No. 00CRPA0001 from the USGS contracts and Grants Information Site at *http://www.usgs.gov/contracts/nehrp/* or by writing Grace Oakeley, U.S. Geological Survey, Branch of Acquisition and Federal Assistance, P.O. Box 25046, MS 204B, Denver, Colorado 80225, or by fax (303–236–1710).

DATES: The closing date for receipt of applications will be on or about February 12, 2000. The actual closing date will be specified in Announcement No. 00CRPA0001.

FOR FURTHER INFORMATION CONTACT: Thomas Roffe, Associate Regional Chief Biologist, U.S. Geological Survey, BRD, FWP Bldg., Montana State University, 1400 S. 19th St., Bozeman, Montana 59717.

SUPPLEMENTARY INFORMATION: Authority for this program is contained in the Fish and Wildlife Act of 1956 (16 U.S.C. 742(a)–742d, 742e–742j–2) and the Fish and Wildlife Improvement Act of 1978, Public Law 95–616 (16 U.S.C. 753a). The Office of Management and Budget Catalog of Federal Domestic Assistance number is 15.808.

Carol Aten,

Acting Chief Biologist.

[FR Doc 00–240 Filed 1–5–00; 8:45 am]

BILLING CODE 4310–31–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submission to OMB for Reinstatement Under Paperwork Reduction Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*), this notice announces that an information collection request was submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs for review and extension under 5 CFR 1320.10. The first notice requesting comments about OMB Control Number 1076–0135, ''Public Law 102–477 Reporting,'' was published in the **Federal Register** on October 1, 1999 (64 FR 53403–53404).