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# Washington, DC Report

## Committee to Advise on Reassessment and Transition (CARAT)

The following description is an introduction to CARAT the successor to TRAC (Tolerance Reassessment Advisory Committee). TRAC was created in April, 1998 and had its first meeting on May 27-29, 1998. It was a committee composed of some 45-50 individuals representing growers, food processors, pesticide registrants, environmental groups, farm workers, land-grant university scientists, public health personnel, state governments, etc. and was designed to be a forum for stakeholder input to USEPA and USDA. TRAC held nine meetings with the last one in October, 1999. TRAC addressed a variety of issues related to the implementation of the Food Quality Protection Act but focused on two main topics: risk assessment and risk management related to the reassessment of organophosphate tolerances.

The USEPA and USDA wanted to retain the stakeholder input and thus, established CARAT on June 6, 2000. The first meeting was held June 22-23, 2000 and the second on October 11-12. Meeting agendas and much more information may be found at the CARAT web site <http://www.epa.gov/pesticides/carat/>. The following background and descriptions are taken from the EPA web site with minor editing.

### Background

The EPA-USDA CARAT was established in accordance with the Federal Advisory Committee Act, as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology (NACEPT). CARAT provides a forum for a diverse group of individuals representing a broad range of interests and backgrounds from across the country to consult with and make recommendations to the Administrator of EPA and the Secretary of Agriculture regarding strategic approaches for pest management planning and tolerance reassessment for pesticides as required by the Food Quality Protection Act.

A notice requesting nominations for appointment was published in the Federal Register on May 12, 2000. Nominations were accepted by EPA until May 26. A list of CARAT members is attached as referenced above.

All Committee meetings will be called, announced, and held in accordance with the Federal Advisory Committee Act and NACEPT, which requires open meetings, and an opportunity for interested persons to file comments before or after meetings, or to make statements during the public meetings to the extent time permits.

## Purpose and Authority

This Mission Statement establishes CARAT in accordance with the Federal Advisory Committee Act, 5 U.S.C., App. 2 Section 9(c). The CARAT is being established as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology. The purpose of CARAT is to provide advice and counsel to the Administrator of EPA and the Secretary of Agriculture regarding strategic approaches for pest management planning and tolerance reassessment for pesticides as required by the Food Quality Protection Act of 1996. CARAT is preceded by the Tolerance Reassessment Advisory Committee and will be guided by the principles set forth by the Vice President for EPA and USDA to work together to ensure smooth implementation of FQPA through use of sound science, consultation with stakeholders, increased transparency and reasonable transition for agriculture. It is determined that CARAT is in the public interest in connection with the performance of duties imposed on the Agency by law.

## Objectives

CARAT provides independent advice and counsel to the Administrator of EPA and the Secretary of Agriculture on issues such as: identifying opportunities for reasonable transition and strategic pest management planning for agriculture and public health uses of pesticides; providing advice to promote sound science and transparency in the scientific risk assessments necessary to implement the Food Quality Protection Act, including tolerance reassessment and pesticide reregistration; assuring appropriate priority is given to risk management strategies for the pesticides that are most likely to lead to exposures to children; ensuring acceptable pesticide safety while developing strategic approaches for critical pest control needs; recommending ways to increase the availability of safer pest management strategies, including chemical and non-chemical alternatives, for growers and other users; developing ways to increase the pace of registration decisions for new and safer pesticides; and fostering transparency and public participation in decision making.

## Objective and Scope of the Activity

The Committee will analyze issues, review and compile information, make recommendations, compile reports, and undertake other activities necessary to meet its responsibilities.

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## Composition

CARAT shall be composed of 25 members approved by the Administrator of EPA and the Secretary of the Department of Agriculture. Members shall be selected based on their relevant experience and diversity of perspectives on pesticide/food safety issues and will be appointed for two years. Committee members shall be appointed with balanced representation from the following sectors: environmental/public interest groups; pesticide industry and trade associations; pesticide user, grower, processor and commodity organizations; public health organizations, including children's health representatives; Federal agencies; State, local and tribal governments; academia; consumers and the public. The Deputy Administrator of EPA and the Deputy Secretary of Agriculture will serve as Co-Chairs.

## Meetings

The Committee will hold two or three meetings per year. A regular employee of EPA will act as the Designated Federal Officer who will be present or represented at all meetings and is authorized to adjourn any such meetings whenever the official determines it to be in the public interest. Each meeting shall be conducted in accordance with an agenda approved in advance by the Designated Federal Officer. Budgetary support for CARAT is provided by EPA's Office of Prevention, Pesticides and Toxic Substances. The estimated operating costs for two to three meetings per year totals approximately \$200,000 and 2.0 work years of staff support.

### EPA- USDA Committee to Advise on Reassessment & Transition Members List

#### Chairpersons

Richard Rominger	Michael McCabe
Deputy Secretary, USDA	Deputy Administrator, EPA

## Environmental/Consumer/Farmworker Representatives

Carolyn Brickley, National Campaign for Pesticide Policy Reform (AZ)  
Sarah Lynch, World Wildlife Fund (DC)  
Adam Goldberg, Consumers Union (DC)  
Shelley Davis, Farmworker Justice Fund (DC)  
Erik Olson, NRDC (DC)  
Olga Lydia Moya, Professor & Farmworker Advocate (TX)

## Academia/Public Health

Dr. Jose Amador, Texas A&M (TX)  
Dr. Rob Hedberg, Weed Science Society (DC)  
Dr. Mark Miller, American Academy of Pediatrics (CA)  
Dr. Eldon Ortman, Purdue University (IN)  
Dr. Mark Whalon, Michigan State University (MI)  
Patricia Widder, Poison Control Center of Children's Hospital of Philadelphia (PA)  
Pediatrician Invited

## Agriculture/Farmer Representatives

Dan Botts, Florida Fruit & Vegetable Association (FL)  
Dr. Hugh (Wally) Ewart, Northwest Horticulture Council (WA)  
Jack Laurie, President, Michigan Farm Bureau (MI)  
William Lovelady, Chairman, National Cotton Council (TX)  
Dr. Cliff Ohmart, Lodi-Woodbridge Winegrape Commission (CA)  
Jean-Mari Peltier, California Citrus Quality Council (CA)  
John Wallendal, Owner-Operator, Wallendal Supply (WI)

## Pest Consultants

Dr. Lori Berger, California Minor Crops Council (CA)  
Dr. Robin Spitko, New England Fruit Consultants (MA)

## Pesticide Companies/Trade Associations

Cindy Baker, Gowan Company (AZ)  
Tanya Bobo, Makhteshim-Agan of North America, Inc. (NY)  
Robert Kiefer, Chemical Specialties Manufacturers Association (DC)  
Jay Vroom, President, ACPA (DC)  
Dr. Dave Whitacre, Novartis (NC)

## NACEPT Representative

Dr. Valerie Petit Wilson, Tulane University (LA)

## Tribal/State/Local Government

Jamie Clover-Adams, Secretary, Kansas Department of Agriculture (KS)  
Steven Rutz, Florida Department of Ag and Consumer Affairs and represents AAPCO (FL)  
Paul Helliker, Director of Pesticide Regulation, California EPA (CA)  
Ed Snetsinger, Pesticide Coordinator, White Earth Band of Minnesota Chippewa (MN)  
George Wichterman, Lee County Mosquito Control District (FL)

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### Food Processors/Distributors

Dr. Steve Balling, Del Monte Foods (CA)  
Margaret Wittenberg, Whole Foods Market, Inc. (TX)

### Structural Pest Control

Robert Rosenberg, National Pest Management Association (VA)

### Ex-Officio

Dr. Terry Troxell, Director, Plants and Dairy Foods and Beverages, FDA  
Dr. Richard Jackson, Director, National Center for Environmental Health, CDC

### Observers

Ramona Trovato, Office of Children's Health Protection, EPA  
George Pavlou, Director, Enforcement and Compliance Assistance, Region II-EPA

### International Observers

Claire Franklin, Executive Director, Health Canada  
Gustavo Olaiz Fernandez, Director General, de Salud Ambiental, Mexico

Article by Willis Wheeler

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## Transgenic Tobacco

CropTech was established in 1992 with a mission to develop and commercialize genetically engineered plants for production of high-valued proteins and biochemicals. CropTech has demonstrated that plants have surprising promise to provide large-scale, cost-effective production of complex bioactive recombinant proteins. In fact, plants may offer the only effective means to manufacture proteins and biochemicals at the scale and cost that will be required for many biopharmaceutical applications, such as anti-cancer drug treatments. We currently have seven sites in Virginia where tobacco with human genes encoding pharmaceutically useful proteins are being grown. CropTech has approximately 40 employees and is located in Blacksburg, VA.

The biopharmaceutical product candidates that CropTech has initially chosen to pursue were selected because the market demand for them is large, the products address significant medical needs, or because they are relatively expensive to manufacture using current techniques. Cost is a special concern in vaccine therapy; CropTech's technologies could feasibly put the vaccine products in the hands of the Third World countries where many effective vaccines cannot be employed due to the expense associated with their production, storage, and distribution. All of the Company's product candidates are in various stages of pre-clinical evaluation.

### Biopharmaceutical Product Candidates

**Urokinase:** Urokinase-type plasminogen activator is a thrombolytic enzyme used to lyse acute thrombi obstructing coronary arteries; these occlusions are associated with evolving myocardial infarction. CropTech has cloned and expressed active urokinase at high levels in transgenic tobacco. The company estimates that production using tobacco will cost much less than current methods. Cost estimates for the currently used animal-cell production systems are above \$1,000 per gram. At this time, urokinase therapy is not available in the United States because of concerns with the safety of the production method.

**Glucocerebrosidase:** This molecule is a lysosomal enzyme used in replacement therapy for Gaucher's disease, a rare genetic disorder. Current treatment requires extensive processing of cells isolated from human placenta or Chinese hamster ovary tissues. Between 400 and 2000 placentas are required to supply a standard dose, which is a major factor in the extreme cost to patients, \$100,000 to \$400,000 annually. CropTech has successfully cloned and expressed active glucocerebrosidase in tobacco. More importantly, the synthesized protein is enzymatically active. Further testing is required before pre-clinical trials can begin.

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