
Washington, DC Report

Continued from Page 28

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

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.

Continued on Page 30

Transgenic Tobacco

Continued from Page 29

Human Serum Albumin (HSA); HSA is a major product of the blood processing industry and is used primarily to replace blood loss from surgery, burns, shock, and other types of physical trauma. The current market for HSA, valued at \$1.4 billion, requires about 100 metric tons of the serum annually. HSA is now obtained from blood donors and, for that reason, periodic shortages occur. In addition, serious safety concerns related to contamination issues are raised regarding a blood product obtained from human donors. CropTech has planted, harvested, and assessed HSA production levels from multiple field sites this year. We have also initiated scale-up of processing and purification of this product.

Vaccine Product Candidates

The recent worldwide upsurge in the occurrence of serious infectious disease has renewed concern over the adequacy of currently available methods to deliver protection to at-risk human populations through immunizations. While many vaccines are effective, problems associated with their cost, distribution, and safety suggest the need for new approaches.

The World Health Organization estimates that over 12 million children under the age of five die each year from infectious diseases. Vaccines already on the market could have saved at least two million of these children. The goal of CropTech's vaccine research program is to develop transgenic plants for the cost-effective production of new recombinant vaccines for both oral (food-based) and traditional delivery systems. These vaccines will be based on isolated DNA sequences coding for highly immunogenic protective antigens. One of the first candidates will use plant-based expression of a viral coat protein antigen for HIV, the pathogen for AIDS. AIDS infection has reached pandemic proportions in the world. A safe, cost-effective vaccine will provide for worldwide relief from this disease.

[CropTech is a technology-intensive company committed to applying plant transgenics for the manufacture of commercially significant recombinant protein products. CropTech is dedicated to producing proteins that are cost-effective and efficacious using plant-based production systems. <http://www.croptech.com>]

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ISB News Report 9/00