COMMERCIAL FISH & SHELLFISH TECHNOLOGIES
Virginia Polytechnic Institute and State University

FOR IMMEDIATE RELEASE

Date: November 25, 2002
Contact: Angela I. Correa, Commercial Fish and Shellfish Technologies (CFAST)
Virginia Sea Grant Communications (540) 231-2075, or cfast@vt.edu

Medical Industry Adopts Seafood HACCP as a Model of Quality Assurance

Blacksburg, VA -- Five years ago, the U.S. medical device industry set an important goal. Their products were already the most reliable in the world, but they wanted to take the extra steps necessary to implement a risk analysis and risk management tool that would further increase the safety of their products. Their goal was not only to find a regulatory paradigm that would increase accountability but also to reduce waste, curtail the production of defective or substandard devices or products, and implement an efficient and effective quality assurance program at each manufacturing facility. The challenge was anything but simple, and industry leaders began to canvass recent regulatory history for programs that had handled similar challenges with a great deal of success.

Their search led them to the Seafood HACCP (Hazard Analysis and Critical Control Points) Alliance, and Dr. George Flick, a member of Virginia Sea Grant's Marine Advisory Service. Dr. Flick has been an integral participant in the highly lauded efforts of the Seafood HACCP Alliance, which was responsible for promulgating compliance with the HACCP regulations imposed on the seafood industry a decade ago.

Dr. Flick, a University Distinguished Professor of Food Science and Technology was initially surprised by the request to provide guidance for the medical industry, because the field seemed so divergent from his own expertise as a chemist and food technologist. However, both HACCP programs had the ultimate goal of safeguarding human health by producing safe products. Dr. Flick agreed to assist the medical industry delegates in creating their own HACCP training curriculum and organization to administer the program.

The Medical HACCP Alliance is now chartered as a public interest [(501(c)(3)] organization and Dr. Flick is currently serving as the Chairman. The Vice Chairman is Dr. William Hyman, Head, Department of Biomedical Engineering, Texas A & M University. Board members include representatives from major healthcare product manufacturing firms, such as Johnson & Johnson, Eli Lilly, Guidant, Medtronics, and Safety Management Solutions.

Because of the success of the Medical HACCP Alliance in meeting a critical need of the industry, representatives of the medical device industry and other producers of health care products requested Virginia Tech's CFAST program to assume leadership in the development of an international conference on risk management. The 2002 conference was held in California, and was co-sponsored by several international healthcare product manufacturers. The success of that program has resulted in a request to the Alliance to consider offering another national and several regional Risk Analysis and Risk Management programs for AAMI (the Association for the Advancement of Medical Instrumentation) during 2003.

The HACCP concept involves studying the processes involved in making a product, determining the points within that project where product safety hazards are likely to be introduced, and developing a plan to prevent those hazards from having any effect on product quality. It is a preventive method, and is highly efficient when it is intelligently applied.

The Medical HACCP Alliance, with Dr. Flick's guidance, has now produced a complete curriculum for HACCP implementation. This curriculum includes manuals, courses to prepare HACCP instructors, HACCP courses for industry personnel, and a range of support services, including teaching aids, and a website, for companies developing their HACCP plans. A total of 48 courses have been taught, reaching a total of 1,224 managers and executives within the healthcare products industries. The program, which originally focused on medical devices, has now been expanded to include chemotherapeutics, blood, and tissues.

In an important new development, the Blood Bank of Canada, along with Health Canada became interested in the potential benefits of the Medical HACCP program after learning about it at a risk management symposium in Temecula, CA this summer, and requested that Dr. Flick give a training and informational session at their headquarters in Ottawa, Ontario. At the close of the session, the Blood Bank of Canada, which is responsible for practically all of the blood supply in Canada, announced that it will use the Medical HACCP program developed by the Medical HACCP Alliance to certify the safety of the blood and blood products it produces and distributes within Canadian borders.

Implementation of the HACCP concept in the seafood industry has been a verifiable success. The HACCP concept has been successful because it anticipates problems, and doesn't just rely on destructive testing of the end product. Now the success and increased control that the seafood industry enjoys will be translated into an entirely different industry, producing safer medical devices, blood products, drugs, and other products, and further safeguarding citizens.

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