2-10-09
3:30 agenda
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In reply, please refer to:
File:

Senate Committee on Energy and Environment

Senate Committee on Water, Land, Agriculture and Hawaiian Affairs

SB 237, RELATING TO GENETICALLY ENGINEERED FISH

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

February 10, 2009
3:30pm

Department's Position: The Department of Health offers comments regarding the perceived health risks associated with genetically engineered animals.

Fiscal Implications: None for the Department

Purpose and Justification: This measure amends HRS Chapter 486 with regulatory enforcement assigned to the Department of Agriculture. We defer to other agencies on the effect of genetically engineered fish or wild fish, economics, markets and trade.

We describe the U.S. Food and Drug Administration (FDA) process for the regulation of genetically engineered fish.

On January 15, 2009, FDA released a Final Guidance for Industry – Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs. This document is intended to help industry understand and comply with statutory and regulatory requirements that apply to genetically engineered animals before and after they are marketed to ensure they are safe and effective.

It also includes an environmental assessment to ensure people, animals and the environmental are not adversely affected.

The pre-approval assessment process for genetically engineered animals is cumulative and risk-based. Each component of the assessment forms the basis on which the next step is evaluated. The approach examines both the potential hazards identified at each step along the pathway and the likelihood of harm among the receptor populations (the genetically engineered animals themselves as well as those individuals or populations exposed to the genetically engineered animals).

Once a genetically engineered animal is approved, developers must continue to provide FDA with appropriate required information to include but not limited to all information relevant to the safety or effectiveness of a genetically engineered animal that has not been previously submitted as part of the pre-approval process. These reports, studies and other information collected on the genetically engineered animal must be submitted to FDA every six months for the first two years following approval and annually thereafter.

The pre and post market approval process allows FDA to evaluate potential toxicity and allergenic effects that may arise from inclusion of the recombinant DNA. FDA has the regulatory authority, duty, and expertise to ensure genetically engineered animals that are intended for food use, are proven safe to eat before being marketed.

The Department lacks resources to compare with the FDA on the evaluation of the genetically engineered fish, and in the current fiscal situation are concerned about retaining resources to meet our existing duties for food safety. We would be unlikely to be able to assist enforcement of this measure.

Thank you for the opportunity to testify.