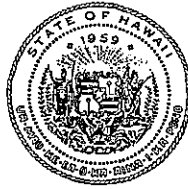


2-10-09
3:30 agenda
LATE

LINDA LINGLE
GOVERNOR OF HAWAII



CHIYOME LEINAALA FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

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

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

3 **Fiscal Implications:** None for the Department

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

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

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

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

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

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

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

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

21 Thank you for the opportunity to testify.