A Bill for an Act Relating to Health.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Section 322-8, Hawaii Revised Statutes, is amended to read:

- "§322-8 [Civil] Administrative penalties. (a) Any person who violates this part or any rule adopted by the department of health to implement this part shall be fined not more than \$10,000 for each separate offense. Any action taken to [impose or] collect the penalty provided for in this subsection shall be considered a civil action.
- (b) The director of health may impose by order the [civil] <u>administrative</u> penalty specified in this section. Factors to be considered in imposing the [civil] <u>administrative</u> penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. It is presumed that the violator's economic and financial conditions allow payment of the penalty and the burden of proof to the contrary is on the violator. For any judicial proceeding to recover the [civil] <u>administrative</u> penalty imposed, the director of health need only show that notice was given, a hearing was held, or the time granted for requesting a hearing has expired without such a request, the [civil] <u>administrative</u> penalty was imposed, and that the penalty remains unpaid.
- (c) In addition to the penalty under subsection (a), the director of health may order the person who has committed the violation to correct the violation at the person's own expense."
- SECTION 2. Section 328-8, Hawaii Revised Statutes, is amended by amending subsection (c) to read:
- "(c) The director may establish rules as necessary for the enforcement of this part[, including but not limited to, the establishment and enforcement of tolerance levels]. The rules shall be adopted pursuant to chapter 91[.]; except that the director may, without regard to chapter 91, establish tolerance levels and regulatory or action levels by reference to the provisions of the regulations or guidelines of the United States established in 40 CFR Part 180 and the United States Food and Drug Administration Compliance Policy Guides as the regulations or guidelines become effective at any time or from time to time."
- SECTION 3. Section 328-25, Hawaii Revised Statutes, is amended to read:
- "§328-25 Director's right [of inspection,] to inspect, require record keeping, demand [for] records, [and seizure;] seize, and conduct hearings. (a)

The director of health or any of his agents may in the performance of their duties:

- (1) Enter at all reasonable hours into any creamery, factory, restaurant, store, salesroom, storage-room, drug store, or laboratory, or any place where they have probable cause to believe that food, drugs, devices, cosmetics, or consumer commodity as defined by this part are made, prepared, sold, or kept, exhibited or offered for sale, and open any cask, tub, bottle, case, or package containing or supposed to contain any such food, drug, device, cosmetic, or consumer commodity, and examine or cause to be examined the contents thereof; [and]
- (2) Adopt rules pursuant to chapter 91 requiring a person to keep records relating to the manufacture, distribution, or sale of food, drugs, devices, cosmetics, or consumer commodity; and
- (3) Demand a person to provide records or copies of records [(2)]relating to the manufacture, distribution, or sale of food, drugs, devices, cosmetics, or consumer commodity which the director has probable cause to believe is adulterated or misbranded; provided that no confidential information concerning secret processes or methods of manufacture secured pursuant to this section by any person who is an official or employee of the department of health within the scope¹ and course of the person's employment shall be disclosed by the person except as it relates directly to the adulteration or misbranding of a commodity, and then, only in connection with the person's official duties and within the scope and course of the person's employment. Any officer, employee, or agent of the department acquiring confidential information concerning secret processes or methods of manufacture who divulges information except as authorized in this section or as ordered by a court or at an administrative hearing regarding an alleged adulteration or misbranding or of any rule or regulation or standard adopted pursuant to this part shall be guilty of a misdemeanor.
- (b) If any food, drug, device, cosmetic, or consumer commodity is found to be adulterated or misbranded within the meaning of this part and the owner or person in charge thereof refuses to comply with the instructions of the director or any of his agents for the proper disposal thereof, the food, drug, device, cosmetic, or consumer commodity shall be liable to seizure. The director or any of his agents shall affix to the article or articles a tag or other appropriate marking, giving notice that the article is, or is suspected of, being adulterated or misbranded, and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or any of his agents or by the court

or judge having jurisdiction over such matters. Upon the request of the director or any of his agents, made to such court, the court shall order and direct that the food, drug, device, cosmetic, or consumer commodity be seized and delivered into the custody of the court, and the same shall be held in such custody until a hearing has been held to determine whether or not it is adulterated or misbranded."

SECTION 4. Section 328-30, Hawaii Revised Statutes, is amended to read:

- "[[]§328-30[] Civil] Administrative penalties. (a) Any person who violates this part or any rule adopted by the department pursuant to this part shall be fined not more than \$10,000 for each separate offense. Any action taken to [impose or] collect the penalty provided for in this subsection shall be considered a civil action.
- (b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director may impose by order the [civil] <u>administrative</u> penalty specified in this section. Factors to be considered in imposing the [civil] <u>administrative</u> penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the [civil] <u>administrative</u> penalty imposed, the director need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the [civil] <u>administrative</u> penalty was imposed, and that the penalty remains unpaid."

SECTION 5. Statutory material to be repealed is bracketed. New material is underscored.

SECTION 6. This Act shall take effect upon its approval.

(Approved April 14, 1984.)

Notes

- 1. Prior to amendment "of" appeared here.
- 2. Underscoring missing.