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HHS, USDA Establish New Regulations for Use of Select Biological Agents

On 13 December 2002, in accordance with the Agricultural Bioterrorism Protection Act of 2002, the USDA¹ and Department of Health and Human Services (HHS)² established standards and procedures governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a

severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. This interim rule is effective on 11 February 2003.

These interim final rules require facilities that possess select agents or toxins that pose potential threat to human and animal health to register with HHS' CDC and

USDA's APHIS respectively. Both these agencies have established a single unified reporting system in order to eliminate duplicate reporting.

About 33 academic, commercial, and State and Federal government facilities possess listed plant pathogens and 619 commercial diagnostic facilities, university

Regulation Updates

Air Carriers to File Monthly Report on Animal Incidents During Transport

In September 2002, the Federal Aviation Administration (FAA) proposed a rule that would amend 14 CFR Part 119 to require "air carriers that provide scheduled passenger air transportation to submit monthly to the Secretary of Transportation, through the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), a report on any incidents involving the loss, injury or death of an animal during air transport provided by the air carrier³." This development has alarmed some investigators and professionals caring for laboratory animals because it would likely increase paperwork and costs of research animals.

The American College of Laboratory Animal Medicine (ACLAM) is objecting to this rule and its language for a number of reasons: it is unclear about who would make the diagnosis of injury; how long after arrival an injury or death could be attributable to air transportation; and how animal health will be assessed during transportation without jeopardizing the health status of specific pathogen free animals or posing a threat to handlers when dangerous animals are involved. In addition, ACLAM is concerned about the use of the term "guardian" as an alternative to "owner" since it has "unknown legal ramifications." ACLAM is further, concerned that the implementation of this rule may increase research costs and serve as a template for tracking the use of research animals in the future⁴.

FDA Issues Safety Guidance on the Use of Raw Meat for Pet Diets

On 12 December 2002, the US Food and Drug Administration (FDA) released draft guidance for industry on the manufacture and labeling of diets that contain raw meat, or other raw animal tissues, for consumption by companion animals (pets) and captive non-companion (zoo) animals, and laboratory animals⁵.

The guidance, which contains safety and nutritional information on raw meat diets, was prompted by the increased use of raw meat foods for carnivorous and omnivorous companion and captive non-companion animals by owners who may not be aware of the safety and nutritional issues related to these diets, and to protect pet owners and pets from risks involving food safety and nutritional deficiency⁶.

Since these products are classified as "foods", they do not require pre-marketing approval or certification. However, the potential risks from commercial raw meat pet foods to animals and the public are significant, including bacterial contamination and dental or gastrointestinal trauma caused by bone fragments.

The draft guidance recommends that manufacturers, distributors, and retailers adopt measures to minimize contamination and disease transmission. These measures include irradiation of the product after packaging; proper storage (e.g., freeze-drying or freezing); proper transport; participation in USDA's voluntary inspection program; and the development and implementation of a Hazard Analysis and Critical Control Point (HACCP) program.

Canada's Supreme Court Denies Harvard's Petition to Patent Oncomouse

On 5 December 2002, in a 5-4 decision, the Canadian Supreme Court denied Harvard College's request to patent the "oncomouse"⁷, an important mouse model for cancer research. The oncomouse, which models characteristics of various human cancers reliably, was created in Harvard Medical School in the 1980s by manipulating cancer-causing genes. It is used "to study how cancers manifest, and to test new treatments for breast, prostate and other forms of this devastating disease⁸".

In its patent application, Harvard sought to protect both the process of generating the oncomice (*i.e.*, injecting a cancer-inducing gene into fertilized mouse eggs, implanting them to another female, and breeding their offspring) and the product of this process (*i.e.*, the founder mice and their offspring whose cells contain the oncogenes).

The Canadian court, believing that the sole question in Harvard's appeal was whether the words "manufacture" and "composition of matter", within the context of the Canadian Patent Act, were sufficiently broad to include higher life forms, concluded that "A higher life form is not patentable because it is not a "manufacture" or "composition of matter" within the meaning of "invention" in s. 2 of the Patent Act."

Writing for the minority, dissenting Judge Binnie stated that "The oncomouse is patentable subject matter. The extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of the genetic material of which it is composed, is an inventive "composition of matter" within the meaning of s. 2 of the Patent Act", and that "Neither the Commissioner nor the courts have the authority to declare a moratorium on "higher" life patents until Parliament chooses to act."

The United States, Australia, Japan and the European Community have already approved Harvard's patent.

In its response to the denial of its patent⁹ by the Canadian court, Harvard stated that the Court based its decision on technical aspects of a 19th century patent law and was "counter to the recommendations made earlier [that] year by the Canadian government's own biotech committee."

Harvard believes that the oncomouse is an important research resource whose protection by patenting will encourage the rapid development of new scientific discoveries, treatments, and cure of cancer, and is encouraging the Canadian Parliament to reconsider this issue.