M. Shalev, MSc, VMD, Column Editor

USDA to Apply Animal Welfare Regulations to Foreign Air Carriers

On 10 October 2003, the USDA announced and requested comment on its "intent to begin applying the Animal Welfare Act regulations and standards for the humane transportation of animals in commerce to all foreign air carriers operating to or from any point within the United States, its territories, possessions, or the District of Columbia[1]." The purpose of this action was to include all foreign carriers in the same regulations for animals covered by the Animal Welfare Act, with which the US air carriers must already comply.

The comment period ended on 9 December 2003. This regulation will take effect on 7 April, unless the USDA received comments raising substantial concerns related to its implementation.

The US Department of Transportation currently authorizes about 517 foreign air carriers to conduct air transportation to and from the United States. Once this rule is finalized, these carriers will have to meet the AWA regulations' physical and recordkeeping requirements. They will be required to include a copy of the consignor's written guarantee of payment for transportation for C.O.D. shipments; a shipping document; an animal health certificate executed and issued by a licensed veterinarian; as well as instructions for the administration of drugs, medication, other special care, food, and water.

Regulation Updates

DEA Establishes Registration Fees for Using Controlled Substance

On 10 October 2003, following several years of legal deliberations, the Drug Enforcement Administration (DEA) established a fee schedule, effective 1 December 2003, for registration and re-registration fees "relating to the registration and control of the manufacture, distribution and the dispensing of controlled substances. DEA is required to adequately recover necessary costs associated with the Diversion Control Program (DCP) as mandated by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (ref. 2)."

Most investigators conducting research with animals using controlled substances, such as barbiturates, opioids, and other drugs for anesthesia, analgesia, and euthanasia, will be required to follow the new fee schedule (*see* ref. 2).

FDA to Collect Fees for Improving Animal Drug Reviews

On 18 November 2003, President Bush signed into law the '*Animal Drug User Fee Act of 2003*' (ADUFA)[3], which provides user fees to the Food and Drug Administration (FDA) to fund FDA's system for reviewing new animal drugs. This legislation is similar to the legislation established more than a decade ago by the FDA for reviewing human drugs[4].

The Act will substantially reduce the review time for new animal drugs by providing funding to increase the number of FDA Center for Veterinary Medicine employees and for improving the management system.

The Act allows for the waiving or reduction of fees for small businesses and in circumstances where payment of the fees would impede innovation. The FDA will collect four fees (sponsor, establishment, product and an application fee) as follows: $5 million in fiscal year 2004, $8 million in fiscal year 2005, and $10 million in each fiscal year 2006 through 2008.

European Commission Proposes to Regulate the European Chemical Industry

On 29 October 2003, The European Commission proposed a new chemical regulation system in order to improve the protection of human health, the environment, and to reduce the number of animals used to test the safety of chemicals, while maintaining and enhancing the competitiveness and innovation of the European Union's chemical industry[5–7].

The proposed system, called REACH (Registration, Evaluation and Authorisation of Chemicals), would cover all scientific research and development, laboratory-scale research and development, and work supporting reference standards. It will require that animal testing be kept to a minimum, and that companies share existing data in order to reduce the number of animals used and the costs associated with their testing. Companies that manufacture or import more than one ton of any chemical substance a year will have to register in a database.

The proposed REACH system foresees the application of alternative methods to the testing of chemicals produced or imported in quantities above one ton. The Commission advocates the use of non-animal testing methods, including refined exposure information, computer models, and cell culture tests. These new risk assessment strategies are essential for the implementation of REACH and have the potential to significantly reduce the costs associated with it.

References

1. USDA APHIS. Determination to regulate and request for comments. Animal welfare; transportation of animals on foreign air carriers. *Federal Register* **68(197),** 58575–58577 (10 October 2003).
2. DOJ DEA. Final rule. Controlled substances registration and registration application fees. *Federal Register* **68(197),** 58587–58600 (10 October 2003).
3. Animal Drug User Fee Act of 2003. 108th Congress, 1st Session, S 313. (4 November 2003). http://www.fda.gov/opacom/laws/adufa.html.
4. FDA. President signs new law providing user fees to improve animal drug review. *FDA News* (19 November 2003). http://www.fda.gov/bbs/topics/NEWS/2003/NEW00978.html.
5. European Commission Press Room. Chemicals: commission presents proposal to modernize EU legislation. IP/03/1477. (29 October 2003). http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/1477|0|RAPID&lg=EN&dislay.
6. European Commission Press Room. Chemicals: research key to new EU chemical policy. IP/03/1631. (1 December 2003). http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/1631%7C0%7CRAPID&lg=EN&display.
7. European Commission Press Room. REACH—new chemicals legislation. http://europa.eu.int/comm/press_room/presspacks/reach/pp_reach_en.htm.