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APHIS Request for Comments: Proposed Changes to Research Facility Reporting Requirements

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Food & Drug

In late June, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture issued a request for comments[1] regarding a December 2014 petition (the Petition) submitted by the National Anti-Vivisection Society (NAVS), an animal activist organization, seeking to secure APHIS's agreement to amend its annual reporting requirements for research facilities registered under the Animal Welfare Act (AWA).[2]

Current Reporting Requirements

Under 9 C.F.R. § 2.36(a), APHIS requires each AWA-registered research facility to submit an annual report listing, *inter alia*, the animal research facility locations and, within specified AWA-regulated species, the number of research animals categorized by whether and to what extent they are subjected to pain or distress. The APHIS Form 7023[3] on which research facilities are required to submit this information provides spaces for research facilities to list the numbers of dogs, cats, guinea pigs, hamsters, rabbits, non-human primates, sheep, pigs, "other farm animals," and "other animals" used in regulated activities. For any animals with respect to which the regulated activity involved accompanying pain or distress and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the activity's procedures, results, or interpretation, the facility must attach to the annual report an explanation of the procedures producing pain or distress and why pain-relieving drugs were not or could not be used, such as when the animals comprised the experimental control group. APHIS posts information from the annual reports on its website,[4] although it does not make available to the public information protected by one or more Freedom of Information Act (FOIA) exemptions.

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[1] 80 Fed. Reg. 36251 (June 24, 2015).
[2] Available at http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf.
[3] Available at http://www.aphis.usda.gov/library/forms/pdf/APHIS_7023.pdf.
[4] http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyCzYAKIvEo8DYlTr-zu6OHibmPgYGBiYWRgaeLk4eLuaWvgYGnGXH6DXAARwNC-sP1o_AqAfkArACfE8EK8LihIDc0NMIg0xMAwhVB1g!!/?1dmy&urile=wcm%3apath%3a%2FAPHIS_Content_Library%2FSA_Our_Focus%2FSA_Animal_Welfare%2FSA_Obtain_Research_Facility_Annual_Report%2F.

The Petition

The Petition requests that APHIS amend the current annual research facility reporting requirements to more closely resemble the European Union's corresponding reporting requirements and to add the following requirements not currently addressed by the APHIS regulations:

- Animal numbers for species not currently individually named on APHIS Form 7023.
- Sources from which the animals were acquired (*i.e.*, purpose-bred animals, random-source animals, animals from shelters, or wild-caught animals).
- Genetic status of the animals (*i.e.*, whether the animals were genetically altered and, if so, whether the alteration produced a harmful phenotype) and whether the animals were used to generate a new genetically-modified line.
- The purpose for which the animals are used (including fundamental biological studies, research and development of products for human or veterinary medicine, toxicological and other safety evaluations, and others), and the specific area (such as oncology, cardiovascular blood and lymphatic system, nervous system, etc.).
- The disposition of each animal at the conclusion of the protocol.

The Petition requested that APHIS amend Form 7023 to incorporate these requirements.

These proposals would alter the current reporting regime in several important respects:

1. Unlike current requirements, NAVS's proposals would mean all research facilities would have to disclose in their annual reports the purposes for which animals were used (*e.g.*, for fundamental biological research) and the particular field or subject matter (*e.g.*, oncology).
2. The Petition would require facilities to list the animals' source and the disposition of each animal at the conclusion of the protocol.
3. The proposed annual report would require the inclusion of genetic alteration information.

If APHIS adopts these proposals, it could require disclosure to APHIS and, potentially, to the public under FOIA of highly sensitive confidential business information and information that animal activists, who are opposed to animal testing, could use to cast a negative light on particular research facilities.

APHIS Request for Comments

To assist in evaluating NAVS's proposals, APHIS requested comments on the following questions:

- Whether APHIS should amend its reporting requirements to require research facilities to provide specific information about how regulated animals are used (*e.g.*, for safety testing, teaching purposes, disease research, etc.), and whether and how reporting this information would improve animal welfare?
- If research facilities are required to report the purposes of their research, what types of information should be provided, and why?

- What might be the effect on research facilities if they are required to collect and report this information?
- Whether the current annual reporting form captures sufficient information and, if not, what information is missing?[5]

Resulting Considerations

The period to submit comments on the Petition closes August 24, 2015. Companies and universities that perform animal research should consider commenting on the impact the proposed reporting requirements would have on confidentiality, competition, and exposure to animal activists.

If you have any questions concerning the material discussed in this client alert, please contact the following member of our Food & Drug practice group:

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[5] 80 Fed. Reg. at 36252.