A review of USDA's rule on contingency plans

Andrew D. Cardon, Matthew R. Bailey & B. Taylor Bennett

On 23 October 2008, the US Department of Agriculture (USDA) published in the Federal Register a proposed rule on the Handling of Animals; Contingency Plans with a 60-day comment period ending on 22 December 2008 (ref. 1). On 19 December 2008, that comment period was extended an additional 60 days until 20 February 2009 (ref. 2). By the end of the comment period, USDA had received 997 comment letters. Organizations within the research community expressed the following concerns: (i) the proposed rule was silent on how USDA would evaluate the adequacy of the plans and thus the basis for potential citations for noncompliance with the regulations; (ii) the regulatory language did not recognize the difference between two distinct and disparate events, emergencies and disasters, in terms of an institution's ability to appropriately respond; (iii) requiring handlers and carriers to develop contingency plans could lead to loss of access to air and ground transport of animals; and (iv) the training requirement would apply to all institutional employees and not just those identified in the plan.

USDA's final rule

USDA published a final rule on Contingency Plans in the Federal Register on 31 December 2012 (ref. 3). The final rule is nearly identical to the proposed rule, with the following exceptions: (i) the lack of a requirement that all institutional employees be trained and familiar with the plan, (ii) the inclusion of specific dates for implementation and training, (iii) the addition of "mechanical failures" in §2.134 and (iv) the changing of "facility" to "licensee or registrant" in the same section. Regarding intermediate handlers and carriers, USDA did not share the concerns of the commenters, expecting them to include contingencies in their plans for weather-related problems, animal escapes and mechanical problems.

Regarding questions about the lack of specificity for what makes a contingency plan acceptable, USDA responded by posting guidance documents that were intended only to provide suggestions rather than to prescribe specific measures that must be undertaken⁴. In doing so, USDA emphasized that compliance with the final rule would be dependent upon the development of an "appropriate plan" and the training of personnel. Although it failed to address the language in the final rule that required the contingency plan to be followed, USDA did indicate that an "adequate contingency plan is one in which the minimum criteria considered necessary for a successful plan have been addressed. Enforcement action may be taken on a case-by-case basis"³. USDA also indicated that should one of its inspectors identify a potential disaster that is not covered in a facility's plan, the inspector would notify the facility of this fact and allow the facility some time to address the issue. USDA did not specify exactly how much time would be allowed.

Regarding the issue of emergencies versus disasters, USDA indicated that it would not be practical to prescribe detailed contingency plans for all situations and that the final rule set the minimum criteria necessary to ensure a successful contingency plan. Such a plan would need to address those emergencies and disasters most likely to occur and would not be required to address all possible disasters. The final rule considered both the terms 'disaster' and 'emergency' to mean "those events which disrupt the ability of a facility to continue with a normal business routine and would be expected to be detrimental to the health and well-being of the animals"³.

In response to comments regarding training, USDA indicated that the decision as to who should be trained was best left to the facility, with the caveat that "…we expect all personnel who may be involved in or impacted by an emergency or disaster to be trained at an appropriate level"³.

Recent developments

On 15 February and 21 February 2013, USDA hosted a webinar during which its representative indicated that a contingency plan represented "a strategy and course of action to be taken in response to an emergency system failure or disaster"5. The representative also indicated that the planning component of this process was the most important and that the written plan was merely evidence that a facility had gone through that process. As a result of this process, a facility is expected to show that it has thought through a plan, shared it with staff and put in place a process to review the plan at least on an annual basis. The USDA representative also indicated, "There is nothing in the regulations about [APHIS] reviewing the functionality of the plan" and there is "not [a] requirement that APHIS review how well the plan worked."

According to the final rule, facilities were required to have their plan available for review during inspections by 27 September 2013. However, on 31 July 2013, USDA published a notice of a Stay of Regulations so that it could undertake a review of its requirements published in the final rule on Contingency Plans⁶.

- USDA APHIS. Extension of Comment Period: Handling of Animals; Contingency Plans. Federal Register 73, 77554 (19 December 2008).
- USDA APHIS. Final Rule: Handling of Animals; Contingency Plans. *Federal Register* 77, 76815– 76824 (31 December 2012).
- USDA. Contingency Plan Guidance Document (31 December 2012 and 22 January 2013).
 http://www.regulations.gov/#!docketDetail;D= APHIS-2006-0159>
- USDA. Contingency Planning Webinar Presentation (15 February and 21 February 2013). http://www.aphis.usda.gov/animal_ welfare/awa_contingency_plan.shtml>
- USDA APHIS. Stay of Regulations: Handling of Animals, Contingency Plans. *Federal Register* 78, 46255 (31 July 2013).

National Association for Biomedical Research, Washington, DC.

USDA APHIS. Proposed Rule: Handling of Animals; Contingency Plans. Federal Register 73, 63085–63090 (23 October 2008).