

OMB's Control of Regulations
(Through Executive Order 12291)

CHRONOLOGY OF USDA'S ANIMAL WELFARE REGULATIONS
(Or How the Fox Got to Guard the Hen House)

December 23, 1985 -- Animal Welfare Act Amendments are enacted as 7 U.S.C. 2131 et seq. They are to take effect one year after enactment.

The amendments require the Secretary of Agriculture to promulgate standards governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, operators of auction sales, carriers, and intermediate handlers. The standards are to provide minimum requirements for handling, housing, feeding, sanitation, veterinary care, and other related matters.

March 7, 1986 -- The Department of Agriculture (USDA) publishes a solicitation for information in the Federal Register for drafting proposed regulations and standards for the amendments. (51 FR 7950) In the notice, USDA says it anticipates publishing proposed regulations for Part 2 (recordkeeping requirements) during the summer of 1986 and for Part 3 (standards) at a later date.

March 31, 1987 -- USDA's Animal and Plant Health Inspection Service (APHIS) publishes Parts 1 (definitions) and 2 of regulations as notices of proposed rulemaking (NPRMs) in the Federal Register. (52 FR 10292; 52 FR 10298)

April, 1987 -- USDA convenes a panel of expert primatologists and National Institutes of Health (NIH) officials to provide professional expertise on the factors necessary for a physical environment that promotes the psychological well-being of non-human primates. The panel reviews and discusses a draft of the proposed animal welfare regulations.

The panel develops a comprehensive set of recommendations for the appropriate space requirements, environmental enhancements, social grouping and interaction, and other minimum standards considered necessary for the regulations. USDA bases its standards on these recommendations.

May 18, 1988 -- OMB's Office of Information and Regulatory Affairs (OIRA) writes to the chairman of the Interagency Research Animal Committee (IRAC) at NIH asking for help in evaluating the economic effects of the upcoming proposals for Part 3 of the amendments.

July 21, 1988 -- USDA submits draft regulations to OIRA for review under Executive Order (E.O.) 12291. Submitted are: portions of Parts 1 and 2, as final rules, and portions of 1, 2, and 3 as proposed rules.

August 12, 1988 -- OIRA sends the draft of Part 3 to all federal agencies using animals for comment. In particular, OIRA asks for input about the cost of complying with the regulations for federal facilities, the kinds of research federal facilities currently undertake and the regulatory enforcement for those activities already in place, and an assessment of whether the way USDA submitted the regulations (in separate pieces) is best. OIRA asks for a response by September 26, 1988.

September 6, 1988 -- OIRA asks APHIS for more information for the regulatory impact analysis (RIA). Specifically, OIRA questions whether the RIA sufficiently discusses the regulatory alternatives, as well as APHIS's choice of design standards over performance standards.

OIRA also asks for USDA to try to "quantify the indirect opportunity costs of the regulations on biomedical research." To do so, OIRA suggests that USDA "list the contributions of biomedical research to human health-safety that have resulted from animal research and describe the potential losses to society when research costs are increased by the regulations."

In addition, OIRA suggests the RIA needs to discuss more fully the benefits of the regulation. Here OIRA suggests that the draft describe "the current scientific literature regarding 'well-being' of primates and the benefits of exercise to dogs and how that knowledge has been used to develop the standards in these regulations."

September 19, 1988 -- OIRA notifies USDA that it will extend review of Part 3 of the standards.

September 23, 1988 -- USDA writes to OIRA to address OIRA's criticisms of the submission. USDA's letter states, "We believe that the measures you suggest are unnecessary and may unduly prolong the regulatory process. Since there is significant congressional and public interest in this issue, [we] request your expeditious clearance of these regulatory packages."

In addition, USDA notes, "The organizations that supported the amendments, and the many interested members of Congress who secured their adoption, may view your solicitation from affected government agencies of support for re-proposal as disingenuous subterfuge intended to subvert congressional intent through further delay. The comment filed in opposition to the regulations by the State Department, which conducts and funds no research, dramatically illustrates the kind of unhelpful reactions we can expect your letter to provoke. We think your letter to the IRAC was improper and inappropriate."

October ??, 1988 -- The arguments escalate to a higher level. Secretary of Agriculture Richard Lyng writes to OMB Director

James C. Miller III to protest OIRA's actions and request immediate clearance of the regulations.

Lyng's letter criticizes OIRA for soliciting the opinions of "21 other federal agencies" about the proposals. "We believe that this initiative was ill-advised and will not advance our common objective of development regulations to implement the amendments," Lyng writes.

In addition, in reference to OIRA's extension of the review for more analysis, Lyng notes, "we consider such analysis to be unnecessary, and believe that it would unduly prolong the regulatory process."

October 13, 1988 -- Miller responds by explicating the requirements of E.O. 12291 and reiterating earlier OIRA criticism of the draft regulations. Miller's letter also makes clear that OIRA controls the future of the regulations -- not USDA.

In the letter, Miller claims that OIRA has not held up the regulations, rather USDA's "current resistance to fulfilling your agency's obligations presents the most serious delay in the promulgation of these rules." Miller also suggests that Lyng "instruct your staff to cooperate with mine, so that we might resolve any differences within the Executive Branch. Only then can OMB clear these regulations for publication in the Federal Register."

October ??, 1988 -- OIRA sends IRAC's comments on the draft submissions to USDA and requests a meeting between OIRA and USDA to resolve IRAC's concerns.

December 22, 1988 -- In a ruling in Animal Welfare Legal Defense Fund v. Clayton Yeutter, the U.S. District Court for the District of Columbia sets a March deadline for publication of the rules.

November 30, 1988 -- OIRA writes to USDA explaining the status of the review.

December 23, 1988 -- USDA thanks OIRA for forwarding IRAC's comments about the regulations but says "they do not raise any issues that were not considered by the Animal and Plant Health Inspection Service in formulating the final rules for Parts 1 and 2 and our proposal for Part 3. In fact, many of the points raised have been addressed in supplementary information accompanying the rules."

January 6, 1989 -- OIRA thanks IRAC for its help and asks that the committee forward USDA's response to its comments to OIRA. OIRA also asks to arrange a meeting among the three agencies to discuss any unresolved issues.

December 27, 1988 -- USDA tells OIRA it cannot describe the methodology and data used to estimate the regulation's costs

for the private sector because it used a panel of experts whose opinions it aggregated.

January 24, 1989 -- OIRA requests from USDA the individual responses, names, and affiliations of the experts consulted, as well as "the primary data used to determine the standards for minimum space requirements for promoting psychological well-being of nonhuman primates."

OIRA makes it known that if USDA does not agree to provide this information, OIRA has the authority to inspect the agency's records anyway.

January 27, 1989 -- IRAC informs OIRA that its members "agree with your request that we establish a subcommittee to discuss and attempt to resolve issues in the proposed regulations that are of concern to IRAC member agencies." According to the letter, OIRA staff members Jeff Hill "agreed to prepare an agenda and moderate the meeting with representatives from USDA and [OMB] within the next two weeks."

February 1, 1989 -- OIRA informs USDA of a meeting it held with IRAC on January 24, 1989, where IRAC "agreed to establish a subcommittee to discuss and attempt to resolve the outstanding issues." At the meeting, the letter says, representatives of APHIS "similarly agreed to meet with OMB and the IRAC subcommittee as part of this dispute resolution process."

March 6, 1989 -- Portions of Part I of the regulations are cleared as a final rule as "consistent with Executive Order 12291 with change." Portions of Part 3 are cleared in NPRM form as "consistent with Executive Order 12291 with change." Portions of Part 2 are cleared as a final rule as "consistent with Executive Order 12291 with change." Portions of Parts 1 and 2 are cleared in NPRM form as "consistent with Executive Order 12291 with change."

March 15, 1989 -- The rules and proposed rules are published in the Federal Register. (54 FR 10918; 54 FR 10931)

July 13, 1989 -- The comment period closes on the proposed standards.

October 30, 1989 -- In the semiannual regulatory agenda, USDA lists the date of final action on Part 3 of the regulations as "00/00/00." (54 FR 44429)

March 14, 1990 -- The Animal Legal Defense Fund goes back to District Court and files an amended complaint for declaratory and injunctive relief. The complaint names USDA and Secretary Clayton Yeutter, the Department of Health and Human Services and Secretary Louis Sullivan, and OMB and Director Richard Darman as defendants. The complaint contends that they have violated the Administrative Procedure Act and the separation of powers clause of the U.S. Constitution.

March 27, 1990 -- APHIS submits a draft final rule for part 3 of the regulations for OIRA review under E.O. 12291.

April 16, 1990 -- D. Allan Bromley, assistant to the President for science and technology, weighs in with his opinion to Secretary Yeutter. He raises concerns that echo OMB's previously raised concerns -- sometimes in almost verbatim fashion. The concerns focus on the design rather than performance emphasis of the standards and the "lack of scientific evidence that the standards will improve animal welfare."

April 17, 1990 -- OIRA returns the rule to USDA for reconsideration. OIRA's letter of return raises the same concerns it has been raising for two years and reiterates Bromley's letter. OIRA's letter also suggests that USDA's submission was premature, given the "apparent need to obtain greater scientific justification and validation for the regulatory alternative [it] selected," and given that other federal agencies needed to have full opportunity to review "the policy and cost implications of adopting any portion of Part 3."

In addition, OIRA's letter again criticized USDA for writing design-oriented standards rather than performance standards.