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Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building
Room 9013, Washington, DC, 20503

By e-mail

To OIRA:

The Ornithological Council appreciates the opportunity to submit comments on the Proposed Bulletin for Good Guidance Practices.

The Ornithological Council consists of eleven leading scientific ornithological societies - the American Ornithologists' Union, Association of Field Ornithologists, CIPAMEX, Cooper Ornithological Society, Neotropical Ornithological Society, Pacific Seabird Group, Raptor Research Foundation, Society of Canadian Ornithologists/La Société des Ornithologistes du Canada, Society for Caribbean Ornithology, Waterbird Society, and Wilson Ornithological Society - that together have a membership of nearly 6,500 ornithologists. It is our mission to provide scientific information about birds to legislators, regulatory agencies, industry decision makers, conservation organizations and others, and to promote the use of that scientific information in the making of policies that affect birds.

Ornithological research – the scientific study of birds - is regulated by a number of federal agencies, including the U.S. Fish and Wildlife Service's Division of Migratory Bird Management, Division of Endangered Species, Office of Management Authority (scientific collecting, bird banding and other forms of marking, import and export), and Division of Refuges (research conducted on National Wildlife Refuges. We are also regulated by the U.S. Department of Agriculture Animal and Plant Health Inspection Service (Veterinary Services, National Center for Import and Export for import and export activities) and the Animal Care division (Animal Welfare Act). Other agencies that have significant authority over our work include the National Institutes of Health, Office of Laboratory Animal Welfare and National Academy of Science, Institute for Laboratory Animal Welfare (Animal Welfare Act and Public Health Act), National Park Service, Bureau of Land Management, and Forest Service (research conducted on public lands). Our profession is also affected by a number of nonregulatory agencies, such as the National Science Foundation and the Office of Science and Technology Policy (Federal Policy on Research Misconduct). And, of course, our profession is also affected by the Office of Information and Regulatory Affairs (Circular A-110, Information Quality Act, Peer Review Guidance)

It is fair to say that at least half our staff time is devoted to issues that arise from the policies and practices developed and issued by these agencies and a very substantial portion of that effort involves guidance or the lack thereof.

Some of these agencies with which we interact develop and issue comprehensive guidance documents. The NIH Office of Laboratory Animal Welfare issues excellent guidance documents that benefit both the "regulators" (the university officials and others who serve on Institutional Animal Care and Use Committees – "IACUCs" - and implement the Animal Welfare Act and the Public Health Act) and those who are regulated by them. However, we have noted a troubling lack of commitment to obtaining input from the entire regulated community. The Animal Welfare Act was not intended to apply to field research – the study of wildlife in its natural habitat. However, the Public Health Service Act makes no such distinction. It covers research involving all live vertebrates, whether in the laboratory or in the field. Nonetheless, the NIH Office of Laboratory Animal Welfare, in writing its various guidance documents, failed to consult with any wildlife biologists. As recently as 2000, the primary guidebook (published by NIH and a private, outside organization) had among its numerous authors, editors, and reviewers not one wildlife biologist. As a result, the section on wildlife biology was incomplete, inaccurate, and misleading. It caused substantial difficulty for scientists whose research required approval from IACUC members who relied on this document. When the NIH and its outside partner decided to revise this document, our organization requested permission to submit suggestions for revisions. The NIH and its outside partner graciously agreed to consider our submissions and published some of the material. To our knowledge, however, the NIH and its outside partner failed to consult with any of the other scientific societies of field biologists, though we suggested that they do so and offered to provide contact information.

The National Academy of Science's Institute of Laboratory Animal Welfare publishes what is considered to be the authoritative pronouncement for animal welfare practices in research settings. Known as the *Guide for the Care and Use of Laboratory Animals*, it was revised most recently in 1996. None of the writers, editors, or reviewers had any apparent experience with wildlife biology. The NIH is now planning to assess the need for revision of this *Guide* (apparently, the Institute of Laboratory Animal Welfare has elected to delegate this revision to the NIH). To its credit, the NIH has published a notice (though not in the Federal Register) seeking information < http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-011.html>. The agency also sent the notice to our organization, but we do not know if it went to other scientific societies of wildlife biologists. The better practice would be publication in the Federal Register, which is regularly monitored by public policy staff of scientific societies. Few, if any, societies of wildlife biologists will see a notice published on the NIH website. Nonetheless, we consider the publication of any notice of an opportunity for public input to be a significant advance. We hope that the agency will make additional efforts to reach out to all sectors of the regulated community in assessing the need for revision of the *Guide*.

In contrast, we find that other agencies have extensive and elaborate policies and procedures that are not committed to writing at all. This leads to extreme confusion and contradictory practices, even among the staffers in a single office. Our organization has devoted several years of intensive effort to elucidating the complex policies and procedures of one regulatory agency, which has not, to the best of our knowledge, issued a guidance document – internal or public –

since the mid-1970s. Our efforts resulted in the publication of a guidance document that devotes over thirty pages to detailed explanations of the agency's policies and procedures. We have suggested that the agency itself use this document – which does nothing more than commit to writing the knowledge that the staffers carry in their heads – to prevent confusing and inconsistent implementation of their policies. It is too early to tell if the agency has accepted our suggestion, but it does not appear that they have distributed the document among their staffers. Furthermore, after extensive consultation with the agency staffers, and after several reviews of the document by those staffers, we are still turning up more unwritten policies that were, for some reason, not mentioned before we published this guidance.

In addition, this agency has a number of apparently unwritten policies that it nonetheless enforces. Some of these policies, which have been developed for commercial imports, are unworkable for scientific imports. When we request adjustments to these apparently unwritten policies, we are told that the agency's Administrator must make the determination. In fact, we suspect that these are not the agency's policies, but are instead only internal practices that have been developed and implemented in an ad hoc manner.

Finally, we find that some agencies have used guidance to "embroider" regulations without complying with the Administrative Procedure Act. We recognize the need for subregulatory interpretation, and for interim implementation of policies during the development and promulgation of formal regulation. It can take years to develop formal regulation. The agencies obviously have a need to address regulatory gaps or changes in circumstances while they develop formal regulation. We not only appreciate this need, but we encourage this practice. In fact, this practice has been beneficial to our community in more than one instance. Had the agency forced us to wait for updated practices while waiting to develop and issue formal regulation, our community would have sustained significant burden for a number of years. At the same time, this same agency has, for decades, implemented a highly restrictive and scientifically unwarranted policy that imposes unjustified restrictions on the research conducted by our members. We have been discussing this problem with the agency for over a decade, with no resolution in sight. The agency agrees with the scientific basis for a change in this policy, and has drafted guidance that will make the change, at least in part. However, the guidance has never been completed and so the agency's regional staff may choose to continue to implement the "current" unwritten policy. In fact, some regions do just that. Another agency uses its "Manual" to create policies that limit the issuance of permits despite the fact that these restrictions are not included in the regulation that establishes the standards for issuance of these permits.

It is with this extensive and varied experience that we evaluate OIRA's proposed bulletin.

1. Definitions

Guidance is defined too narrowly. Guidance should include all aspects of the agency procedures and subregulatory policies that affect the public. By "subregulatory" we mean those interpretations or applications that need not be promulgated in accordance with the procedures mandated by the Administrative Procedures Act, or interim policies that will be incorporated into the agency's regulations in the future.

*2. Guidance should be **required** for all procedures and subregulatory policies that affect the public*

We suggest that OIRA begin by **requiring** every agency to issue a guidance document that describes its standard operating procedures and interpretive policies insofar as those procedures and policies affect the public. The absence of guidance is a far worse problem than guidance that may not have been developed in accordance with best practices. The lack of guidance allows the agency to make ad hoc and arbitrary decisions, leads to inconsistent and faulty implementation of regulations, and causes substantial confusion on the part of the regulated public. So, for instance, one agency that regulates import of material for scientific research requires a certificate that the material has been treated so as to inactivate pathogens. The agency claims to have specific standards for these certifications, though those standards are never shared with the scientists who are bringing research materials into the United States. When they arrive at the port, they are told that their certifications are inadequate. The materials may be confiscated. The scientists have thus lost valuable research material, collected at substantial cost, and are unable to conduct their research. Only after years of questioning by a representative of their professional society does the agency reveal its standards for these certifications – and then, only verbally. No written document is ever proffered.

In other words, it is not enough to require agencies to adhere to certain practices *if* they choose to issue guidance. They should be required to issue guidance. The goals of transparency, clarity, and consistent should apply to all agency practices that affect the public. Nothing could be less clear or less transparent, or more susceptible of inconsistent application than the complete lack of guidance.

3. Internet access

All guidance documents, not just significant guidance documents, should be posted on the internet. The significance threshold is high. Much useful and important guidance will not meet this threshold. There is no compelling reason not to post all guidance documents on the internet. The burden is in the development of the document. Posting on the internet is a minor effort. The public needs these documents, whether or not they meet the significance threshold.

4. Public input

We suggest that agencies be required to seek public input on all guidance, not just significant guidance. We recognize that OIRA is attempting to use a definition of significance that is consistent with the Paperwork Reduction Act and other OIRA applications of the PRA definition of significance (such as the Information Quality Guidelines). However, little guidance will rise to that level, yet it has substantial impact on the regulated community.

We therefore suggest that agencies make all – not just economically significant - guidance documents available in draft form and seek comments, in a process analogous to that required by the Administrative Procedure Act, rather than posting and accepting complaints. It may seem like a distinction without a difference, but we have found that the earlier the opportunity for comment in the process of developing policy, the more likely that the policy will address the concerns of the regulated community.

We realize that it might be burdensome for the agency to respond to comments in all cases, but suggest that it be considered a best practice (rather than a requirement) to do so.

In addition, we recommend the addition of a best practice that urges the agency to determine which sectors of the public are directly affected by or most likely to need the guidance, and to make efforts to communicate directly with those sectors, particularly if those sectors are represented by professional societies, trade organizations, or other nongovernmental entities. Though of course this outreach must be undertaken in a manner that does not violate the Federal Advisory Committee Act or related constraints on government policy making, we think this is an important measure. We have found that some agencies have little or no understanding of the research practices of our members. As a result, their policies and procedures are a poor fit and compliance is difficult. These agencies must then adjust these policies and procedures – a time-consuming and frustrating process for all involved. Note that we are not recommending special rules or exceptions for a given type of activity. We are simply suggesting that if an agency knows something about the activities it regulates, it is far more likely to develop workable policies and procedures that help the regulated community to comply.

We especially applaud the option to join a listserv for automatic notification.

5. OIRA oversight; limitation on use of guidance as a substitute for formal regulation

We suggest that copies of comments on guidance documents be automatically sent by the agency to OIRA. The OIRA should monitor these comments to determine when agencies are falling short in terms of clarity, transparency, or compliance with the Bulletin. Further, OIRA should monitor guidance to determine which aspects of guidance should be incorporated into formal regulation. Again, we understand the need for interim changes, but agencies should not be permitted to substitute guidance for regulatory change. Every aspect of guidance that should ultimately be incorporated into regulatory revisions should be flagged by the agency. When there are enough of these changes to warrant the time-consuming burden of a regulatory change, the agency should be required to initiate that process. At a minimum, the agency – which, in our view should be periodically reviewing its regulations - should “elevate” those aspects of guidance that warrant regulatory change to formal regulation no less than every five years.

Finally, we would like to express our gratitude to OIRA for its efforts to improve agency guidance practices. As you can see, our experience with guidance documents has been mostly problematic, and we have long been considered about the need for standards and oversight. This is particularly true with regard to the practice of using guidance to embellish regulations rather than complying with the Administrative Procedure Act.

We thank OIRA for considering our comments, which we hope prove to be helpful in the development of this Bulletin.

Sincerely,

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