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Regulatory Analysis and Development
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RE: Docket No. APHIS-2020-0068; Comments Submitted in Response to Proposed Rule – Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of almost 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is the appropriate conduct of basic and applied animal research to ensure proper protections for animal health, safety, and welfare, while reducing unnecessary burden on researchers and research institutions.

COGR appreciates the opportunity afforded by the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) to comment on the above-captioned proposed rule published on February 22, 2022 at [87 FR 9880](#) (“Proposed Rule”) and to participate in the virtual listening sessions held before the Proposed Rule’s publication. Although the Proposed Rule, governs birds “not bred for research,” its provisions will affect institutions that use wild birds or other birds not bred in captivity for research, teaching, and/or experimentation, and our comments focus on the provisions of the Proposed Rule that impact research and teaching institutions. COGR fully supports the Proposed Rule’s goal of establishing clear standards for the humane care and handling of birds not bred for research. Nevertheless, we are concerned that the Proposed Rule seeks a blanket application of standards that appear to be tailored to research using mammals conducted in laboratory settings, instead of research involving a vastly differentiated class of animals that is frequently, and beneficially, maintained in conditions designed to better approximate natural conditions (e.g., aviaries). Indeed, in the Preamble to the Proposed Rule, USDA APHIS notes that it considers the Proposed Rule’s standards “necessary to maintain consistency with the current regulations for mammals,” but is such consistency necessarily the best way to ensure birds’ health, safety, and welfare? In its comments here, COGR suggests that given the diversity of birds used for research, teaching, and experimentation, birds, as a whole,

would be better served by regulatory standards that incorporate greater flexibility to address each specie's specific needs.

Our comments are organized into two separate sections: (a) Part A, which provides comments on specific provisions of the Proposed Rule, organized by the pertinent section of the Animal Welfare Act Regulations (9 CFR Parts 1- 3); and (b) Part B, which addresses areas on which USDA APHIS specifically requested comments. Note, however, that in Part A, we also have included suggestions on items/areas where additional guidance would be useful.

PART B: SPECIFIC COMMENTS

Definitions, Part 1

Section 1.1, Definition of the Term "Bred for Use in Research": The current definition encompasses birds that are "bred in captivity and [are] being used or [are] intended for use for research, teaching, testing, or experimentation purposes." The phrase "bred in captivity" is not species-specific, i.e., both domesticated species and wild species may be bred in captivity. However, footnote 12 in the Proposed Rule introduces ambiguity on this point when it states "[o]nly those research facilities that use wild-caught birds for research, testing, teaching, or experimentation, *including activities such as investigations into animal propagation,*" are subject to the Proposed Rule. Clearly, wild birds bred in captivity for use in research, teaching, testing, or experimentation fall under the definition of "bred for use in research," and USDA APHIS should revise footnote 12 as follows to resolve this point:

"Only those research facilities that use wild-caught birds for research, testing, teaching, or experimentation, would be subject to the provisions of this proposed rule. Facilities using birds bred for use in research would not be subject to this rule."

Unlike other animals under the Animal Welfare Act (AWA), the regulation of birds depends on the *intent* for which the birds are used, i.e., for research, teaching, testing, or experimentation purposes. As with other rules that concern the issue of intent,¹ we expect that intent would be determined by examining objective evidence and circumstances regarding the birds' use/intended use. Further, when a bird is bred in captivity and intended to be used for more than one purpose, it should not be covered under the Proposed Rule so long as the primary purpose is "research, teaching, testing or experimentation." Additionally, the use/intended use of a bird may not be known at the time it is hatched and/or it may change over time,² and thus, we anticipate that application of the Proposed Rule may change as intent changes. Finally, the rule is unclear as to whose intent is at issue – the owner of the bird at the time it is bred or the ultimate user of the bird.

¹ See, e.g., FDA regulation regarding the determination of intended use for drug products at 21 CFR §201.128 stating that intended use "refer[s] to the objective intent of the person legally responsible for the labeling of an article" and noting that the intended use may change over time. This regulation also discusses the facts and circumstances that serve as evidence of objective intent including persons' "expressions, the design or composition of the article," "circumstances surrounding the distribution of the article," "labeling claims," and "advertising matter."

² *Id.*

Some examples may help illustrate these points and some of the difficulties in applying the Proposed Rule:

- A wholesale supplier breeds birds in captivity that may be sold to many types of consumers, e.g., pet shops, hobbyists, researchers. The supplier does not know the specific use for any particular bird at the time it hatches but recognizes that any of the aforementioned uses is possible. Would birds bred by this supplier and sold to a researcher be considered a bird bred for research based on the researcher's intended use of the bird at the time it was purchased?
- An agricultural school at a university raises ten chickens in captivity, initially uses them for egg production, and then provides them to a veterinary school at the same institution for teaching purposes. The Proposed Rule would not apply to the chickens when they are poultry used/intended for use for food, nor should it apply to the veterinary school's teaching use, because that use also falls within the definition of "bred for research." By the same logic, the Proposed Rule also should not apply if the veterinary school sells chickens used for egg production to a research institution for use in research, but the Rule is silent on such changes in use.

Through the Proposed Rule, or subsequently issued guidance, USDA APHIS should clarify the meaning of the term "intended for use," including how/when intent is determined and whose intent is at issue. USDA APHIS also should clarify that intent is not static, each use/intended use should be evaluated, and the mere fact of a change in use, will not in and of itself, trigger application of the Proposed Rule. Finally, USDA APHIS should provide guidance as to how research institutions should document which birds within their possession meet the definition of "bred for research."

Section 1.1, Definition of "Dealer": As the preamble to the Proposed Rule notes, the Animal Welfare Act provides that a "a dealer or exhibitor shall not be required to obtain a license as a dealer or exhibitor under this chapter if the size of the business is determined by the Secretary to be *de minimis*, and current *de minimis* exemptions are set forth at 9 CFR §§2.1(a)(3)(i)-(viii). We encourage USDA APHIS to consider a *de minimis* exception that would permit registered facilities under the AWA, to engage in a small number of transactions involving birds that fall outside of the "bred for research definition" without the need to acquire a dealer's license. At a minimum, we hope that USDA APHIS will consider modifying the existing exemptions to encompass birds.

Section 1.1, Definition of "Exotic Animal" -- The current definition of this term at 9 CFR §1.1 includes "any animal not identified in the definition of 'animal' provided in this part that is native to a foreign country or of foreign origin or character, is not native to the United States, or was introduced from abroad." This definition would consider as "exotic" species of birds such as parakeets and canaries that were not initially native to the United States, but are now commonly kept as pets, and are not at all "exotic" in the normal sense of the word. Another example is zebra finches, which have been used as research animals for decades. We encourage USDA APHIS to re-examine this definition with respect to birds and consider excluding species of birds that were introduced from abroad long ago and/or that are now commonly kept in captivity in the United States.

Section 1.1, Definition of “Exhibitor”: We note that in some instances educational exhibits developed for a primary purpose other than animal exhibition may “incidentally” include birds, e.g., an indoor arboretum in which wild birds are present, or in which a few birds are kept. In such circumstances, the birds are not being exhibited, but rather, are present in an exhibit of an entirely different nature. We encourage USDA APHIS to consider modifying the definition of “Exhibitor” by including the following text at the end of this definition: “as well as educational exhibits that do not have the primary focus of exhibiting animals, but only incidentally include the presence of a small number of birds.”

9 CFR Subpart C, Research Facilities

Section 2.30(c), Change in Operations – The Proposed Rule does not require a licensee that is in possession of birds on the effective date of the final rule to apply for a new license until the expiration date of its current license. Under current Section 2.30(c), however, research facilities are expected to provide USDA APHIS with notification of any change in operations, including a change in activities or location stemming from birds in their possession, within ten days from the date of such change. COGR respectfully requests USDA APHIS to establish an effective date for the final rule that affords research institutions at least six months to analyze the final rule’s impact on their operations. Alternatively, USDA APHIS should provide research facilities with at least six months to notify the agency of changes resulting from compliance with the final rule by incorporating the following wording into the Proposed Rule: “For research facilities with a current registration, the facility may notify USDA APHIS of any changes in operations resulting from implementation of the Proposed Rule within six months following the Proposed Rule’s effective date.”

Section 2.31(d)(ix), IACUC Review of Activities Involving Animals – COGR supports the Proposed Rule’s provision permitting surgery on birds in non-dedicated facilities. Additionally, we request that USDA APHIS consider an exemption to the mandate that aseptic conditions be used for operative procedures in field studies. The health and welfare of birds in such studies frequently requires the rapid performance of surgical procedures, so that the bird can be swiftly returned to its natural habitat. Requiring aseptic conditions for non-major surgical procedures confers far less benefit on the bird than returning the bird to its habitat as quickly as possible. Accordingly, we request that USDA APHIS add the following text to the last sentence in this subsection: “; provided, however, that aseptic conditions are not required for non-major operative procedures on birds.”

Section 2.36, Annual Report and Section 2.38(l), Contingency Plan – Each registered research institution is required to file an annual report with USDA APHIS on or before December 1 of each calendar year. Additionally, research institutions must have a contingency plan in place for their facilities by July 5, 2022. As noted in our comments regarding Section 2.30(c), research institutions must be afforded adequate time to consider the Proposed Rule’s impact on their operations, including contingency planning, and USDA APHIS should ensure that the Proposed Rule’s effective date provides institutions with at least six months before Annual Reports are due to conduct their analyses. Similarly, we expect that USDA APHIS will afford institutions appropriate time to update their plans to address birds covered by the rule and include appropriate later effective dates for elements such as this, depending on the date the final rule is issued.

Section 2.75(b)(1), Records: Dealers & Exhibitors – This provision requires dealers and exhibitors to keep records of “any offspring born or hatched of any animal” while under the dealer or exhibitor’s possession or control. Although, this specific section concerns records kept by dealers and exhibitors, COGR notes that under 9 CFR Section 2.36(b)(8), research institutions must include within their Annual Reports to USDA APHIS the number of animals “held for use in teaching, testing, experimentation, research, or surgery, but not yet used for such purposes.” COGR agrees with the comments noted in the Proposed Rule’s preamble regarding the difficulty of maintaining records of individual birds kept in large flocks. COGR also notes that the requirement to keep records of wild birds at hatching, may cause undue stress on the birds and interrupt nesting and rearing activities. COGR urges USDA APHIS to amend this provision by adding the following text to the end of the subsection: “to the extent that any identification or counting of offspring can be carried out without unduly disturbing nesting or rearing activities.”

Part 3, Subpart G, Specifications for the Humane Handling, Care, Treatment and Transportation of Birds New

Section 3.150 Facilities, general; Section 3.151 Facilities, indoor; Section 3.152 Facilities, outdoor; and Section 3.153, Primary enclosures – COGR’s main concern regarding these provisions concerning facilities and primary enclosures is that they fail to recognize and accommodate the distinct characteristics of naturalistic housing that may best serve the health and welfare of wild birds used in research. Rather, these provisions presume a setting in which birds are kept in cages, as opposed to larger, walk-in aviaries that house larger social groups of birds. For, example, per Section 3.150(c) surfaces of housing facilities “must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized or removed and replaced when worn or soiled” and “free of jagged edges or sharp points that could injure the birds.” Similar provisions are included Section 3.153(a)(1)(i) and (ix). Although, COGR fully supports the need for housing facilities to be kept clean and free of injurious materials, we believe that these sections should include separate standards tailored to more naturalistic environments that more closely approximate the birds’ natural habit and may include living trees, plantings, and limbs, sticks, or rocks for perching and nesting. In this regard, we support the approach used in Section 3.158(b)(3), which explicitly recognizes the use of natural materials and natural composting/decomposition systems. Additionally, we provide the following specific comments regarding these sections:

- Section 3.151(d) – This section does not mandate indoor pools/aquatic areas, but states that if provided they “must have sufficient vertical air space above the pool or other aquatic area to allow for behaviors typical to the species” including diving and swimming. In some cases, space constraints may allow for aquatic areas that permit some, but not all, of a specie’s behaviors (e.g., swimming, but not diving). We presume that inclusion of such an aquatic area is permitted when the area would continue to benefit birds using it, as determined by the attending veterinarian. Guidance clarifying this issue would be useful in assisting facilities in their compliance efforts.
- Section 3.152(a) -- We suggest adding the following text to the end of this section to expressly acknowledge that captured wild birds already may be acclimated to outdoor housing: “acknowledging, that some birds may not require acclimatization, such as wild

caught birds being housed in outdoor facilities with conditions similar to their natural habitat.”

- Section 3.153(b)(2) – It is unclear whether the “tethering” referenced in this subsection is considered a “restraint device” under Section 3.154(d), and guidance clarifying this point is welcome.

Section 3.155, Feeding – This standard requires that birds be fed at least once a day, however, food may be made accessible to birds through feeders to which they have access *ad libitum*, and there may be no need to refill feed receptacles every day. COGR recommends that this standard be revised as follows to clarify this point: “Birds must be fed at least once a day, or otherwise be provided with access to food on a daily basis, or as otherwise directed by the attending veterinarian.”

Section 3.158, Cleaning, sanitization, housekeeping, and pest control – COGR supports USDA APHIS’ inclusion within subsection (b)(3) of alternate cleaning approaches for primary enclosures that use materials that cannot be sanitized using conventional methods. We urge USDA APHIS to consider expanding the incorporation of such alternate cleaning method for certain hard surfaces that may be used in primary enclosures to replicate the birds’ natural environment but cannot be removed for sanitization or easily replaced (e.g., trees, logs, large rocks).

Part A: Areas on which USDA APHIS Specifically Requested Comments

Use of Physical Alteration Practices such as Pinioning, Toe Clipping, Beak Alterations: COGR believes that the use of these practices may be necessary in some instances to protect the health and safety of birds, and therefore, any need for and employment of these practices should be determined by the attending veterinarian.

Regulation of Birds under both AWA and United States Fish and Wildlife Service (USFWS) Standards (Birds Covered under the Migratory Bird Treaty Act): COGR supports all efforts to reduce administrative burden on researchers by avoiding duplicative regulations. In this respect, we note that in addition to AWA and USFWS standards concerning migratory birds, many such birds also are covered by state fish and wildlife regulations, thus, potentially creating, three separate sets of overlapping, and potentially inconsistent regulations. We appreciate USDA APHIS’ revision of the definitions of intermediate handler and carrier to include an exemption from AWA registration for anyone transporting a migratory bird from the wild to a rehabilitation facility. We also encourage USDA APHIS to continue its work with USFWS to identify and resolve other areas of regulatory overlap and/or inconsistency. In this regard, it would be helpful to researchers for USDA APHIS and USFWS to issue guidance that identifies areas in which both AWA and USFWS requirements intersect and summarizing each agency’s requirements in these areas.

Training and Guidance: COGR appreciates USDA APHIS’ invitation to comment on the types of training and guidance on the Proposed Rule that would be most useful to the regulated community, and the modes by which it might best be provided. In our comments above, we noted specific issues for which additional guidance would be useful. Concerning training modalities, live webinars (recorded for later viewing) that discuss each major section of the Proposed Rule and

that offer adequate time for questions and answers would be useful. Further, it would be extremely helpful if USDA APHIS would establish an email address to which the regulated community can submit questions for prompt agency response, as well as post frequently asked questions/answers on a USDA APHIS webpage.

Conclusion:

We once again thank USDA APHIS for affording us the opportunity to submit these comments. The implementation of the Proposed Rule will require a great deal of planning and consideration by research and teaching institutions that utilize birds not bred for research in their research programs. We believe that our comments here will improve the Proposed Rule and assist in better achieving the goal of standards that will promote birds' health, safety, and welfare. Should you have any questions regarding this transmittal, please do not hesitate to contact Kris West, COGR's Director for Research Ethic and Compliance at KWest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, looping initial "W".

Wendy D. Streit
President