

International Journal of Risk Assessment and Management

ISSN online: 1741-5241 - ISSN print: 1466-8297 https://www.inderscience.com/ijram

Domestication matters: risk analyses necessary to prevent zoonotic pathogen spillover from international wildlife trade are constrained by terminology

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DOI: <u>10.1504/IJRAM.2023.10063880</u>

Article History:

01 September 2023
16 February 2024
27 March 2024
07 June 2024

Domestication matters: risk analyses necessary to prevent zoonotic pathogen spillover from international wildlife trade are constrained by terminology

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Abstract: The US is a major importer of wildlife in terms of species diversity and quantity. The wildlife trade has the potential to facilitate the spread of zoonotic pathogens with pandemic-scale impacts. Regulatory policies crafted to prevent entry of zoonotic pathogens should be based on scientifically sound, standardised, comparable risk analyses. In this paper, we explore how the terms *domesticated animals* and *wildlife* are applied across US federal agencies, as well as the implications thereof. We demonstrate how use of these terms strays from their scientific meaning, confounds regulatory authorities and procedures, and thus reduces scientific integrity of US wildlife trade data available for zoonotic risk analyses. To better prevent importation of zoonotic pathogens, we recommend standardising federal terminology based on scientific principles, publication of an updated list of animals recognised as domesticated, and species-specific customs codes. Although these recommendations are US-directed, they are conceptually applicable to national biosecurity regulations worldwide.

Keywords: infectious disease; wildlife trade; domesticated animals; wildlife; risk analysis; zoonoses; LEMIS; Law Enforcement Management Information System; pathogens; terminology.

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Reference to this paper should be made as follows: Kolby, J.E., Pitt, W.C. and Reaser, J.K. (2023) 'Domestication matters: risk analyses necessary to prevent zoonotic pathogen spillover from international wildlife trade are constrained by terminology', *Int. J. Risk Assessment and Management*, Vol. 26, No. 2, pp.95–117.

Biographical notes: Jonathan E. Kolby is an Applied Research Ecologist and Project Manager at the Smithsonian's National Zoo & Conservation Biology Institute in Front Royal, Virginia, in the US. Jonathan studies the relationships between people and nature through the lens of international wildlife trade data and specialises in the accurate interpretation and communication of these data. His understanding of international wildlife trade dynamics was developed while serving for the US Fish and Wildlife Service as a former Wildlife Inspector and Convention on International Trade in Endangered Species of Fauna and Flora (CITES) Policy Specialist. He is also a herpetologist with research that focuses on emerging infectious diseases of reptiles and amphibians, particularly amphibian chytrid fungus and ranavirus.

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1 Introduction

The COVID-19 pandemic caused by SARS-CoV-2 should be regarded as a stern warning to those who oversee the flow of trade and travellers at national borders. Preventing a pandemic is far more cost-effective than addressing the aftermath. Bernstein et al. (2022) concluded that the annual costs of "primary pandemic prevention" actions (~\$20 billion) are less than 5% of the lowest estimated value of lives lost from emerging infectious diseases every year, less than 10% of the economic costs, and provide substantial cobenefits. Prevention may also have far-reaching ethical, moral, and equity benefits when lives (both human and animal) and livelihoods are safeguarded. Risk analysis is a tool employed by governments and other institutions to anticipate, evaluate, and prioritise measures to prevent hazardous conditions and is regarded as the optimal strategy for policy orienting amidst deep uncertainties (Aven, 2016). Since at least 60–75% of known

infectious diseases are estimated to have derived from microbial organisms (pathogens) that originally circulated in non-human animal species (Taylor et al., 2001; Woolhouse and Gowtage-Sequeria, 2005), it is essential to understand the factors that influence pathogen transmission risk (directly or indirectly) between wildlife and humans (zoonotic spillover) (Plowright et al., 2017, 2021). Risk analysis is the commonly accepted method for weighing the potential of harm associated with various biological organisms moving intentionally or inadvertently through trade (Aven, 2016), and accurate data are imperative to produce meaningful outputs.

The US is one of the world's greatest importers of wildlife in terms of recorded quantity and species diversity; from 2000 to 2014, at least 3.2 billion live organisms entered the US (Eskew et al., 2020). Therefore, it reasons that its national borders have the potential to be among the riskiest for zoonotic pathogen entry and that the US places the entire human population in harm's way if it fails to take sufficient mitigation measures. Policies intended to prevent the entry of zoonotic pathogens moving via the international wildlife trade should be based on risk analysis formulated through the application of sound science. This scientific capacity is dependent upon the accessibility and quality of data associated with risk assessment variables - such as the imported species, volumes, countries of origin, and purposes. The US Fish & Wildlife Service (USFWS) has been directed under Section 6003 of the American Rescue Plan Act of 2021 to employ Title 18 of the Lacey Act to mitigate the importation of animals that may introduce pathogens, including parasites, that pose risks to human health, with a goal of reducing the likelihood of future emergence of pandemics from international wildlife trade. Through a competitive process, the USFWS identified the Smithsonian's Conservation Biology Institute as the principal research institution for the scientific and technical aspects of this project.

Clear and consistently applied terminology is the glue adhering an effective scienceto-policy-making process. In the US, the importation of live animals, animal parts, and animal products is regulated and monitored by multiple agencies, each with differing legal authorities, priorities, and terminologies that prescribe conditions for when and how import data are recorded. Terminology impacts how (and if) wildlife is regulated, what technical data become collected, standards of practice for data management, and constraints on data application. These factors directly influence risk analysis capacity and integrity.

In this paper, we explore the implications of a single set of terms - wildlife and domesticated animals - to impact the quantity and quality of data vital for the USFWS to conduct zoonoses risk analyses of US wildlife imports.

Our review of US federal policies and practices revealed a lack of standardised interpretation of these and closely associated terms not only within the USFWS, but also between USFWS and other US federal agencies. Thus, we further explore how these inconsistencies impact whether certain animals become regulated by USFWS upon importation, their impact on the quantity and quality of animal trade data, and the implications for zoonoses risk analysis capacity. We conclude by describing how use of the terms *domesticated animals* and *wildlife* are likely creating gaps in US biosecurity capacity that need to be closed as a matter of priority to safeguard lives and livelihoods from trade-facilitated zoonotic outbreaks. Until this regulatory weakness is sufficiently

addressed, the nation will remain vulnerable to zoonotic outbreaks originating from imported animals.

2 Domesticated animals versus wildlife: the science

In casual conversation, the concepts of *domesticated animals* and *wildlife* are typically accepted without debate. However, these concepts and related terms vary considerably in technical usage within both scientific and regulatory frameworks. Within law and policy, for example, wild animals are not always defined as *wild animals* or *wildlife* in the text of regulations or legislation. Rather, regulatory frameworks may identify them as such by default, essentially regarding them as non-domesticated or other-than-domesticated animals. To implement appropriate US animal trade regulations and associated data collection protocols, it is necessary to establish what defines a *domesticated animal* and to identify which species fall within versus outside of this concept and associated terms.

Domestication is a process that usually occurs over extended periods of time and involves multiple generations of animals that are either directly or indirectly impacted through a variety of human-mediated pathways (Zeder, 2012, Hulme-Beaman et al., 2021). In contrast to popular culture conceptualisations, the process of domestication is fraught with inherent, situation-dependent complexities. Examples of explicit human intentions for animal domestication include animal husbandry as pets, livestock, and beasts of burden. These animals often, but do not always, develop physical, physiological, or behavioural traits that differentiate them from either their present-day wild counterparts or historical ancestors previously found in a natural state absent intensive human management and selection. Sometimes, domesticated varieties of animals accumulate sufficient genetic changes from their wild forms that they become scientifically recognised as distinct species or subspecies, such as the domestic dog (Canis familiaris) selectively bred from wild wolves (Canis lupus) and the ferret (Mustela putorius furo) selectively bred from the wild European polecat (Mustela *putorius*). In other cases, despite the behavioural or phenotypic variations bred to serve specific human purposes, the domesticated version of an animal is still recognised as the same species as its wild counterparts. Examples of this include the peacock (Pavo cristatus) and domesticated white lab rat (Rattus norvegicus), as well as farmed populations of American mink (Mustela vison) and "silver" red fox (Vulpes vulpes) which primarily exhibit consistent sizes, colours, or behaviours unique to captive populations compared to those not managed by humans.

Features that typify *domesticated animals* are not entirely static characteristics. Human behaviour is sometimes the only driving force maintaining the domesticated characteristics of animals classically thought of as domesticated, such as pet cats and dogs or pigs and goats kept as livestock. When released from all human control, these animals have a tendency to adapt behaviourally and/or physiologically, assuming functional roles in ecological systems comparable to those of the same or similar species living in the wild state. These feral domesticated animals may thrive in the wild to the degree that they are considered invasive, as has been widely documented of unowned cats (Loss et al., 2013).

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Numerous species fall somewhere on the spectrum of semi-*domesticated* (also called peri-*domesticated*) without a clear goalpost marking when a species has crossed the human-designated boundary into "full" domestication and qualifies as a *domesticated animal*. Objective classification of all animals into a binary system of either *domesticated* or non-*domesticated* is impeded by the absence of a centralised scientific technical body to rigorously evaluate the ongoing domestication processes affecting a multitude of species globally. Therefore, international animal trade regulation and recordkeeping systems that force all animals to be categorised as either *domesticated animals* or *wildlife* are inherently prone to chronic administrative confusion and scientific incongruity.

Wildlife is commonly accepted as, "living things and especially mammals, birds, and fishes that are neither human nor domesticated" (Merriam-Webster, 2023). This interpretation of *wildlife* includes all animals that continue to exist in their natural forms absent the human influences that cause consistent, multigenerational, directed changes to a species. Although countless wildlife species have been negatively affected by anthropogenic activity, these haphazard and often acute impacts do not inherently pave the way towards domestication. While all animals are subject to varying degrees of human influence, most of the world's species continue to be regarded as *wildlife* by default. However, the proportion of *wildlife* versus *domestic animals* varies widely by taxonomic group and biomass. A recent study by Bar-On et al. (2018) revealed that 70% of all bird biomass on Earth is farmed poultry and 60% of the mammal biomass is livestock (predominantly cattle and pigs). They considered the remaining 30% of bird biomass as wildlife. But, for mammals, 36% of the remaining 40% of biomass was comprised of humans, leaving just 4% of all living mammals to be regarded as *wildlife*.

Adding further confusion, unlike the terms *domesticated animal* and *wildlife* which both describe the type of animal in question and its relationship with humans, the term *wild animal* instead describes a conditional state that is sometimes incorrectly conflated with the term *wildlife* based on context alone. *Wildlife* (i.e., animals that have no history of human control or containment) held in captivity are often still described as *wild animals*. However, the circumstance of being a *wild* animal may refer to any animal not presently held in a human-controlled environment. This includes not only wildlife but also animals that escape or are released from captivity, such as feral hogs (*Sus scrofa*), which originated as domesticated barnyard pigs, and the historically domesticated pigeons (also called rock doves; *Columba livia*) now found in cities worldwide.

3 Domesticated animals versus wildlife: conflicting interpretations among US import regulations

We found that regulatory concepts of *domesticated animals* and *wildlife* neither reflected actual scientific complexities nor were treated uniformly across regulatory frameworks, even within the same agency. The lack of standardised definitions within and among the relevant US regulatory agencies creates ambiguity regarding (a) which specific types of animals are regulated by each agency, (b) under what circumstances those animals are regulated, and (c) how the nuances of regulations affect the quality and quantity of recorded animal import data. Because the first two conditions contribute to the third, this and the following sections explicitly focus on implications for animal import record keeping which, in turn, has implications for data integrity and risk analysis capacity.

According to the USFWS, all wildlife imported into the US is subject to regulation by the USFWS Office of Law Enforcement, whether the species is imported as live animals, animal parts, or animal products (USFWS, n.d.). This regulatory responsibility is primarily enforced by USFWS officers called Wildlife Inspectors. In concept, they have the authority to record and assess all imported wildlife at the species level. Three other agencies also have explicit regulatory authorities pertaining to specific wildlife taxa and/or their parts and products, including the Department of Homeland Security's US Customs and Border Protection (CBP), US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), and the Department of Health and Human Service's Centers for Disease Control and Prevention (CDC). Each of these four agencies implements mission-specific responsibilities and priorities. In some cases, there are overlapping regulatory controls for particular taxonomic groups (e.g., live non-human primates are regulated by USFWS, CDC, and CBP). In other instances, the importation of certain animals is regulated by just one agency (e.g., live captive-bred white laboratory mice are regulated only by CBP). Animal import data are scattered across multiple, non-public federal databases that vary considerably in the intent for data collection and application (e.g., CBP is interested in the monetary value of commerce while the CDC is concerned about safeguarding public health). The regulatory categorisation of an animal as *domesticated* versus wildlife is what often drives information toward one agency versus another. Conflicting interagency interpretations of which animals constitute wildlife versus domesticated animals can therefore result in the loss of data fundamental to zoonotic pathogen import risk analyses among species potentially inconsistently declared to USFWS.

To the best of our knowledge, the USFWS is the only US agency which has formally defined the term *domesticated animals* in their Code of Federal Regulations (CFR) (USFWS, 1996), while other agencies employ this term without having published official interpretations (Table 1). The definition provided by USFWS is found in Title 50 of the Code of Federal Regulations, Part 14.4 and states that, "*Domesticated animals* includes, but is not limited to, the following domesticated animals that are exempted from the requirements of this subchapter B (except for species obtained from wild populations)" (50 CFR 14.4). Meanwhile, USFWS has also defined the term *wildlife* in Title 50 of the Code of Federal Regulations, Part 10.12 as, "…any wild animal, whether alive or dead, including without limitation any wild mammal, bird, reptile, amphibian, fish, mollusk, crustacean, arthropod, coelenterate, or other invertebrate, whether bred, hatched, or born in captivity, and including any part, product, egg, or offspring thereof" (50 CFR 10.12). A variety of contrasting interagency interpretations of these terms have also been expressed (Table 2).

USFWS regulations categorise all *domesticated animals* that do not originate in captivity as *wildlife* (50 CFR 14.4), and under that framework, the same animal could be treated both as *wildlife* and as a *domesticated animal* at different points in life, varying solely based on the conditions under which it was living at any certain point in time. In the context of zoonotic pathogen risk analyses, populations of feral *domesticated animals* may encounter and spread harmful microorganisms in much the same way as non-domesticated *wildlife*, and unnecessary categorisation as either *wildlife* or *domesticated animals* needlessly complicates the processes of animal trade data collection and the scientific rigour of these data.

The consternation over this "feral" classification issue is not limited to the USFWS. The definition of *wild animal* provided by APHIS is ambiguous, wherein a *wild animal* is defined as one that, "...is now or historically has been found in the wild, or in the wild state" (Table 2), and although feral livestock seem to qualify as *wildlife* by this "found in the wild" definition, they are still treated as domesticated livestock by APHIS. The language used by APHIS can also be interpreted to mean that all *domesticated animals* are also *wild animals* because they all have wildlife ancestry that "historically [have] been found in the wild". The language provided by CDC (Table 1) similarly implies that *domesticated animals* continue to be *domesticated animals* even when found living in the wild without human control, unlike the context-dependent characterisation of *domesticated animals* by USFWS.

Federal Agency	USFWS	APHIS	CBP	CDC
Official definition of <i>domesticated</i> <i>animal</i>	Domesticated animals includes, but is not limited to, the following domesticated animals that are exempted from the requirements of this subchapter B (except for species obtained from wild populations). [See Table 2 for species list]	None provided	None provided	None provided
Example of term used in context (verbatim)	 Domesticated animals includes, but is not limited to, the following domesticated animals that are exempted from the requirements of this subchapter B (except for species obtained from wild populations).^a You do not have to pay base inspection fees, premium inspection fees, or overtime fees if you are importing or exporting wildlife that meets the criteria for "domesticated animals" as defined in § 14.4 	living in its original, natural	Domesticated pets such as dogs, cats, hamsters, gerbils, guinea pigs, and rabbits do not require clearance from FWS	(2) Wildlife are undomesticated animals living
Sources of reference to <i>Domesticated</i>	 (1) 50 CFR 14.4 "Domesticated animals"; (2) 50 CFR 14.94(k) (3) "Exemptions to inspection fees" 	9 CFR 1.1 "Wild state"	"Bringing Pets and Wildlife into the United States", CBP Pub. No. 0000–0509	71.51(a) "Cat"

 Table 1
 Varying regulatory definitions and employment of the term *domesticated animals* among US federal government agencies

Federal Agency	USFWS	APHIS	CBP	CDC
Animals regulated as wildlife by USFWS that are treated as domesticated animals by other agencies	N/A	Mink, chinchilla and ratite birds but only when they are used in specific ways. The APHIS definition of the term "farm animal" includes mink, chinchilla, and ratite birds to be treated as domesticated farm animals when they are used solely for the production of meat, fur, feathers, or skins as per 9 CFR 1.1 "Farm animal"		N/A
Animals treated as domesticated livestock or poultry by other agencies that are regulated as wildlife by USFWS	All domesticated animals listed in 50 CFR 14.4 [see Table 2] are regulated as wildlife if they are not declared to have originated from captive-bred sources	The USFWS regulates all peafowl as wildlife irrespective of captive or wild origin. APHIS defines poultry to include chickens, doves, ducks, geese, grouse, guinea fowl, partridges, peafowl, pheasants, pigeons, quail, swans, and turkeys as per the APHIS website: Live Poultry	N/A	N/A

 Table 1
 Varying regulatory definitions and employment of the term domesticated animals among US federal government agencies (continued)

^aSubchapter B describes USFWS regulations for the "Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants", meaning that qualified animals are exempt from import/export regulations.

The treatment of peri-domesticated species across agencies also confounds the USFWS' ability to track species imports effectively. Public guidance about USFWS wildlife import requirements provided by CBP incorrectly states that, "Domesticated pets such as dogs, cats, hamsters, gerbils, guinea pigs, and rabbits do not require clearance from FWS" (USCBP, 2014). To the contrary, hamsters (subfamily Cricetinae of Cricetidae), gerbils (*Meriones* spp.), and guinea pigs (*Cavia porcellus*), do require import clearance from USFWS because they are not recognised as domesticated animals under USFWS wildlife import regulations (Table 3). Additionally, certain kinds of rabbits (all species

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except captive-bred *Oryctolagus cuniculus*), cats (e.g., domesticated cat x Asian leopard cat (*Prionailurus bengalensis*) hybrids), and dogs (e.g., domesticated dog x wolf (*Canis lupus*) hybrids) also require USFWS import clearance. This inaccurate CBP regulatory guidance may be facilitating the entry of significant quantities of these animals into the US without USFWS knowledge and recordkeeping in their wildlife trade database called the Law Enforcement Management Information System (LEMIS).

Term in use	Agency	Definition in context (and source)	Possible inter-or-intra-agency confusion caused
Fish or Wildlife	USFWS	Fish or wildlife means any wild animal, whether alive or dead, including without limitation any wild mammal, bird, reptile, amphibian, fish, mollusk, crustacean, arthropod, coelenterate, or other invertebrate, whether or not bred, hatched, or born in captivity, and including any part, product, egg, or offspring thereof. (50 CFR 10.12 "Fish or wildlife")	The USFWS definition for <i>wild</i> <i>animal</i> neither describes what is meant by "normally found in a wild state" nor addresses how this is measured. For example, if more domesticated pigs (<i>Sus</i> <i>scrofa</i>), rabbits (<i>Oryctolagus</i> <i>cuniculus</i>), or cats (<i>Felis</i> <i>domesticus</i>) were living in the wild as feral animals versus the numbers held in captivity, then these domesticated animals would appear to become captured by the USFWS definition of <i>wildlife</i> and thus become subject to wildlife import regulations
Wildlife	USFWS	Wildlife means the same as fish or wildlife. (50 CFR 10.12 "Wildlife")	Same as above
Wild animal	USFWS	As used in this subsection, the term "wild" relates to any creatures that, whether or not raised in captivity, normally are found in a wild state. (Lacey Act: 18 USC 42)	Certain animals listed by USFWS as domesticated under 50 CFR 14.4 qualify as <i>wild animals</i> under this definition (e.g., European rabbit <i>–Oryctolagus</i> <i>cuniculus;</i> Domesticated rock pigeons– <i>Columba livia</i> <i>domestrica</i>))
Wild animal	APHIS	Wild animal means any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the US, its territories, or possessions. This term includes, but is not limited to, animals such as: deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, wolf, etc. (Animal Welfare Act: 9 CFR AWR (1-1-18 Edition))	<i>animals</i> are simultaneously defined by APHIS as non-wild <i>farm animals</i> when used for their fur or meat (e.g., mink). These operational definitions are based on the intended use of an animal, rather than the species or variety

Table 2	Varying regulatory terms applied to differentiate wildlife, wild animals, and
	domesticated animals among US federal government regulatory agencies

Term in use	Agency	Definition in context (and source)	Possible inter-or-intra-agency confusion caused
Wild state	APHIS	Wild state means living in its original, natural condition; not domesticated. (9 CFR 1.1 "Wild state")	The term <i>domesticated</i> has not been formally defined among APHIS regulatory texts but is used to define the border between animals considered wild versus non-wild
Pet animal	APHIS	Pet animal means any animal that has commonly been kept as a pet in family households in the US, such as dogs, cats, guinea pigs, rabbits, and hamsters. This term excludes exotic animals and wild animals. (Animal Welfare Act: 9 CFR AWR (1-1-20 Edition))	This definition implies that certain common pet animals are domesticated by virtue of exclusion from the APHIS definitions of <i>exotic</i> or <i>wild</i> <i>animals</i> . These species (such as guinea pigs and hamsters) are not recognised as such by USFWS in their list of <i>domesticated animals</i> exempt from regulation
Domesticated pets	СВР	Domesticated pets such as dogs, cats, hamsters, gerbils, guinea pigs, and rabbits do not require clearance from FWS. (CBP Pub. No.0000- 0509 Revised August 2014)	Some of these animals are treated as wildlife in USFWS import regulations (e.g., hamsters, gerbils, and guinea pigs as well as certain kinds of rabbits, cats, and dogs)

 Table 2
 Varying regulatory terms applied to differentiate wildlife, wild animals, and domesticated animals among US federal government regulatory agencies (continued)

USFWS primarily regulates the entry of wildlife into the US based on voluntary selfreporting by importers. In his previous work as a USFWS wildlife inspector, J. Kolby observed the Service's inability to prevent CBP from allowing shipment importation in the absence of USFWS approval, even when USFWS inspection and clearance were required for lawful importation. On many occasions, imported wildlife has been delivered to importers unbeknownst to USFWS and in the absence of federally required inspections, because clearance was provided by CBP before all requirements for lawful importation had been satisfied (pers. obs. J.E. Kolby, 2004–2010). It is impossible to know to what extent "clearance bypasses" affect the completeness of LEMIS wildlife trade data recorded by USFWS. However, it is evident that these "unknowns" could culminate in catastrophic public health consequences.

Species category	Common name	Scientific name (as published in 50 CFR 14.4)	Special conditions
Mammals	Alpaca	Lama alpaca	None
Mammals	Camel	Camelus dromedarius	None
Mammals	Camel (Boghdi)	Camelus bactrianus	None
Mammals	Cat (domestic)	Felis domesticus	None
Mammals	Cattle	Bos taurus	None

Table 3List of animals recognised as *domesticated animals* by USFWS as published in Code
of Federal Regulation Title 50 Part 14.4 (50 CFR 14.4) as of 28 March 2024

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Table 3List of animals recognised as *domesticated animals* by USFWS as published in Code
of Federal Regulation Title 50 Part 14.4 (50 CFR 14.4) as of 28 March 2024
(continued)

Species	<i>C</i>	Scientific name (as published in 50 CFR	Constant and litt
category	Common name	14.4)	Special conditions
Mammals	Dog (domestic)	Canis familiaris	None
Mammals	European rabbit	Ortyctolagus cuniculus	None
Mammals	Ferret (domestic)	Mustela putorius	None
Mammals	Goat	Capra hircus	None
Mammals	Horse	Equus caballus	None
Mammals	Llama	Lama glama	None
Mammals	Pig	Sus scrofa	None
Mammals	Sheep	Ovis aries	None
Mammals	Water buffalo	Bubalus bubalus	None
Mammals	White lab mice	Mus musculus	None
Mammals	White lab rat	Rattus norvegicus	None
Birds	Chicken	Gallus domesticus	None
Birds	Ducks & geese – domesticated varieties	Species not specified	None
Birds	Guinea fowl	Numida meleagris	None
Birds	Peafowl	Pavo cristatus	This species is no longer treated as a <i>domesticated</i> <i>animal</i> by USFWS after its inclusion on CITES Appendix III in 2014, This change in regulation is not currently published in the official 50 CFR 14.4 regulation, but is mentioned by USFWS in their import/export license application at https://www.fws.gov/elicense/ web/elicense/pdf/3–200– 3a.pdf [accessed 27 Feb 2023]
Birds	Pigeons (domesticated)	Columba livia domestrica	None
Birds	Turkey	Meleagris gallopavo	None
Birds	Mallards – domesticated or barnyard: Pekin; Aylesbury; Bouen; Cayuga; gray call; white call; East Indian; crested; Swedish; buff Orpington; Indian runner; Campbell; Duclair; Merchtem; Termonde; magpie; Chinese; khaki Campbell	Species not specified	None

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Species category	Common name	Scientific name (as published in 50 CFR 14.4)	Special conditions
Fish	Carp (Koi)	Cyprinus rubrofuscus	Only considered <i>domesticated</i> <i>animals</i> when they are exported. Regulated as non- domesticated animals when they are imported
Fish	Goldfish	Carassius auratus	Only considered <i>domesticated</i> <i>animals</i> when they are exported. Regulated as non- domesticated animals when they are imported
Insects	Crickets, mealworms, honeybees (not to include Africanised varieties), and similar insects that are routinely farm raised	Species not specified	None
Other Invertebrate	Earthworms and similar invertebrates that are routinely farm raised	Species not specified	None

Table 3List of animals recognised as *domesticated animals* by USFWS as published in Code
of Federal Regulation Title 50 Part 14.4 (50 CFR 14.4) as of 28 March 2024
(continued)

The language in 50 CFR 14.4 specifically prohibits all individual animals from recognition as *domesticated animals* if they are found in the wild, such as feral livestock.

There are circumstances in which shipments of imported wildlife not declared to USFWS are excluded from all federal import recordkeeping systems and thus necessary regulatory scrutiny, thereby adversely impacting our ability to track animals in trade that are potential zoonoses hosts. We provide Figure 1(a)–(c) of hypothetical situations to illustrate how the quality and quantity of wildlife trade data recorded upon importation of wildlife into the US is affected by inconsistent federal agency interpretations of *domesticated animals* and the associated variations in regulatory guidance that an importer may choose to adopt. In each figure, a live mammal shipment with identical hypothetical contents is imported: 5000 live captive-bred golden hamsters (*Mesocricetus auratus*), but the overall transfer of information and data recorded are not identical.

In Figure 1(a), a hypothetical shipment of 5000 golden hamsters valued by the importer at \$1000 USD was declared to USFWS because the importer knew that this species was not included in the list of domesticated species (Table 3) exempt from USFWS declaration requirements. The shipment was also declared to CBP by the importer because the value was greater than \$800 USD. No other government agency, such as CDC or USDA, was notified by CBP of this importation because this event is not regulated by any other US federal agency. In this scenario, species-specific data would have become recorded by USFWS in LEMIS (i.e., 5000 live *Mesocricetus auratus* were imported) while generalised data would have become recorded by CBP (i.e., 5000 other live animals).

In Figure 1(b), the main difference from the scenario described in Figure 1(a) is that this shipment was not declared to USFWS because the importer instead chose to employ

CBP guidance that these mammals are domesticated animals, and thus interpreted them as exempt from USFWS declaration requirements. In this scenario, no declaration is provided to USFWS and therefore no data becomes recorded in LEMIS. Only generalised data become recorded by CBP (i.e., 5,000 other live mammals), and these data prevent identification of which species was imported.

In Figure 1(c), the scenario in Figure 1(b) is repeated with the exception that the shipment of 5000 golden hamsters was instead valued by the importer at \$750 USD instead of \$1000 USD. This lower assessed value triggers CBP's *de minimis* provision which allows for shipments valued below \$800 to be imported without a formal declaration. In this situation, data that describe the entrance of 5000 live mammals into the US are not recorded by any agency, and we can neither calculate the total number of golden hamsters that entered the US in this shipment based on USFWS records nor can we calculate the total number of 'other live mammals' imported in this shipment based on CBP records. Consequentially, these 5000 live animals become completely obscured and untraceable among all federal datasets as having entered the US, together with their potential zoonotic pathogens.

CBP regulations are a facilitating factor in the loss of information essential for zoonotic pathogen risk analyses – most shipments imported with declared commercial values below \$800 enter the United States as informal entries under CBP's *de minimis* provision, whereby the creation of import records with descriptive Harmonised Tariff Schedule (HTS) codes in CBP's Automated Commercial Environment (ACE) is not required because these shipments are exempt from the collection of tariffs (USCBP, 2019; 19 CFR 10.151). HTS codes are the 10-digit classification system used to identify and record shipment contents for the purpose of imposing appropriate duties on imports. Employment of the *de minimis* provision as an exemption from data recording is a common occurrence. CBP noted the arrival of three billion *de minimis* shipments between FY2018 and FY2022, with an annually increasing trend (USCBP, 2023). Therefore, because HTS codes are not assigned, shipments of live mammals not declared to USFWS, but presented to CBP with values beneath their \$800 *de minimis* threshold, are not identifiable as wildlife shipments among CBP import records (Figure 1(c)).

For those shipments declared above the \$800 threshold, a formal customs entry is required, and the live mammals are normally assigned HTS code 0106.19.9195 and recorded in ACE. This HTS code is not attached to the scientific names or other identification variables associated with imported animals, as would be captured in the USFWS' LEMIS data for most taxonomic groups through their use of species codes. Instead, these hamsters, gerbils, or guinea pigs would be generically described and recorded by CBP as, "Other live animals: Mammals: Other: Other: Other" (USITC, 2023) (Figure 1(b)). The precise species and quantities of all mammals classified as "other" are untraceable within the CBP ACE database. With very few exceptions, such as HTS code 0106.33.0000 which represents "Other live animals: Birds: Ostriches; emus (*Dromaius novaehollandiae*)", scientific names are not used among CBP HTS codes to describe imported wildlife, or parts and products made thereof (USITC, 2023).

APHIS and CDC do not offer "safety nets" for wildlife data capture in most cases where declaration to USFWS is bypassed. According to information provided by APHIS, "APHIS Veterinary Services (VS) does not have any animal health requirements related to bringing (importing) a pet rodent into the United States from a foreign country" (APHIS, 2022a). Thus, APHIS would not record rodent imports. Similarly, according to the CDC, "Unless they are included in a specific embargo, such as civets, binturongs, genets, and African rodents, or are known to carry disease transmissible to humans, small mammals (such as ferrets, rabbits, and non-African rodents) are not covered under CDC regulations" and therefore the import of non-embargoed animals would not normally trigger the creation of wildlife import records by the CDC (CDC, 2022). Interestingly, USFWS LEMIS records show that hamsters and guinea pigs are among the top live mammal species imported into the US annually from 2015 to 2020 (USFWS, 2023), and yet the regulatory confusion and inconsistency described herein makes it likely that considerably higher numbers of these kinds of animals are entering the country beyond what the LEMIS data reflect.

Figure 1 Depictions of a hypothetical shipment of 5,000 golden hamsters valued at \$1000 USD (a), a shipment of the same value treated as domesticated animals (b), and a shipment valued at \$750 USD treated as domesticated animals (c). Arrows represent information transfer pathways activated by these different import scenarios and X's denote pathways where the transfer of animal import data is not automatically triggered by the importation event

Importation of a shipment containing 5,000 live captive-bred golden hamsters (*Mesocricetus auratus*) into the United States from the Czech Republic; \$1,000 USD declared value

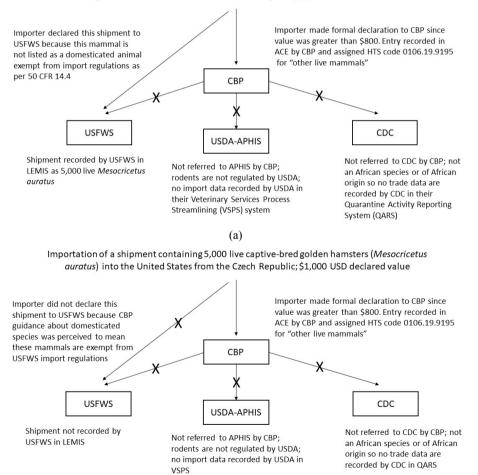
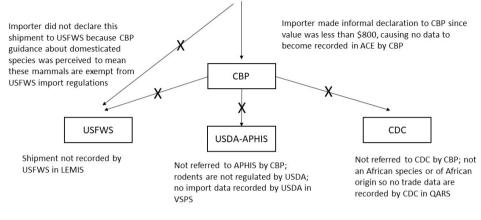


Figure 1 Depictions of a hypothetical shipment of 5,000 golden hamsters valued at \$1000 USD (a), a shipment of the same value treated as domesticated animals (b), and a shipment valued at \$750 USD treated as domesticated animals (c). Arrows represent information transfer pathways activated by these different import scenarios and X's denote pathways where the transfer of animal import data is not automatically triggered by the importation event (continued)

Importation of a shipment containing 5,000 live captive-bred golden hamsters (*Mesocricetus auratus*) into the United States from the Czech Republic; \$750 USD declared value



(c)

For live bird imports, confusion regarding domestic vs. wild animal regulation may arise from narratives on the APHIS website and similarly negatively impact data reporting. The APHIS page titled "Live Poultry" describes regulations that apply to the import of birds often bred and traded in high numbers (APHIS, 2022b). Information on this page states that, "In the United States, the US Fish and Wildlife Service (FWS) regulates the importation of birds protected by the Convention on International Trade in Endangered Species (CITES) and the Wild Bird Conservation Act of 1992 (WBCA). These regulations are part of an international conservation effort to protect some species of wild birds subject to trade. Most non-native US pet birds including parrots, parakeets, macaws, lories, and cockatoos are affected by CITES and the WBCA. However, the budgerigar, cockatiel, and rose-ringed parakeets and peach-faced lovebirds are exempt". This information appears to contradict USFWS import regulations and demonstrates a lack of clarity between domestication and the frequent breeding of certain species in high quantities. This language suggests that bird species not listed under CITES or WBCA import regulations, such as the budgerigar (Melopsittacus undulatus), cockatiel (Nymphicus hollandicus), rose-ringed parakeet (Psittacula krameria), and peach-faced lovebird (Agapornis roseicollis), are exempt from USFWS import regulation. To the contrary, these species are subject to USFWS wildlife import regulations and importers are required to declare these birds and potentially meet additional USFWS requirements. This confusion is reasonable to expect due to the liberal application of the term domesticated animals by APHIS for poultry. Other bird species under the purview of USFWS that may appear to qualify under the same APHIS interpretation for "being frequently bred in high quantities" are not recognised as domesticated animals by USFWS. For instance, APHIS defines grouse and quail to be poultry just as domesticated chickens, but unlike chickens, all species of grouse and quail are still treated as wildlife and regulated by USFWS. Therefore, shipments of highly traded live birds frequently bred in large quantities such as budgerigar, cockatiel, and rose-ringed parakeets may be arriving in the US without declaration to USFWS and recordkeeping in LEMIS due to the incorrect presumption by importers that these birds are not wildlife, based on the erroneous APHIS guidance. Although live bird import data are sometimes recorded by APHIS through veterinary import permits, scientific names are not electronically retained and these animals are instead recorded in general terms, such as "parrot" (pers. comm. APHIS, 23 February 2023). Similarly, any of these shipments declared above \$800 in value that become recorded by CBP would be assigned HTS code 0106.32.00 for "Other live animals: Birds: Psittaciformes (including parrots, parakeets, macaws and cockatoos)". Consequently, neither APHIS import records nor CBP import records can display a complete list of bird species and quantities imported into the US. This deficit results in the loss of two of the most basic data elements critical for species-specific zoonotic pathogen import risk analyses.

4 Variable interpretation of *domesticated animals* within USFWS further affects the quality and quantity of recorded wildlife import trade data

The definition of *domesticated animals* published by USFWS offers decision-making guidance applied by USFWS Wildlife Inspectors to determine which animal shipments imported into the US fall under their regulatory purview (50 CFR 14.4). This definition states that, "Domesticated animals includes, but is not limited to, the following domesticated animals..." (Tables 1 and 3). Although this type of open-ended language provides flexibility to aid regulatory enforcement, allowing the list of species regulated as domesticated animals by USFWS to vary on a case-by-case basis reduces the scientific integrity of LEMIS data. For example, the highly traded guinea pig (C. porcellus) is a species that never existed in the wild but rather emerged thousands of years ago from domestication of the Andean montane guinea pig (Cavia tschudii) (Dunnum and Salazar-Bravo, 2010). Because this animal is not listed in 50 CFR 14.4 as a domesticated species, one Wildlife Inspector could explicitly interpret a guinea pig (C. porcellus) shipment to fall under the USFWS definition of wildlife and require regulation while another Wildlife Inspector could instead interpret the same shipment to contain domesticated animals exempt from regulation. Neither inspector would be "wrong" because USFWS lacks the standard operating procedures and policies necessary to prevent these types of variations in the regulation of peri-domesticated species and the associated personnel biases that affect if and how these wildlife import data become recorded in LEMIS. For this additional reason, the total quantity of wildlife legally imported according to LEMIS records undoubtedly underrepresents the actual quantity of animals, but by which species and to what degree overall is indeterminable.

USFWS published terminology in 1996 to distinguish domesticated animals from wildlife accompanied by a list of species that met their criteria (USFWS, 1996). This list has not been updated in the 28 years since its publication despite USFWS having stated that it was, "...never intended to be all inclusive and many additional species could be added" and that periodic reevaluation would occur (USFWS, 1996). Because of the lapse in reevaluation and adaptation of the list of domesticated species, USFWS has been unable to keep pace with advancements in animal domestication and ensure uniform

Service-wide application of wildlife trade regulations. Further adding to confusion and inconsistency among USFWS policies and procedures, certain animals listed as *domesticated* by USFWS do not clearly meet the conditions that scientifically define what it means to be a *domesticated animal* (Table 3). For instance, USFWS regulates insects and other invertebrates as *domesticated animals* if they have been "routinely farm raised", yet this condition also applies to many animal species that USFWS does not recognise as domesticated, such as the quail and grouse, which APHIS regulates as poultry. Further, when the present definition and list of *domesticated animals* were proposed by USFWS, a wildlife importer suggested that USFWS also include as domesticated several species of reptiles commonly bred in captivity, such as corn snakes (*Pantherophis guttatus*), milk snakes (*Lampropeltis triangulum*), leopard geckos (*Eublepharis macularius*), and bearded dragons (*Pogona vitticeps*) (USFWS, 1996). USFWS declined to include any of these species, although many have been selectively bred through countless generations to display specific colours, shapes, and sizes desirable to humans that are not "natural".

Lastly, USFWS regulatory implementation of the term *domesticated animals* again diverges from its scientific meaning when traded animals listed as *domesticated* in 50 CFR 14.4 originate from the wild. USFWS treats these domesticated animals as wildlife subject to wildlife trade regulation, causing them to become recorded in LEMIS wildlife trade data. For instance, a cow (*Bos taurus*) born on a farm is a *domesticated animal* exempt from USFWS wildlife import regulations, but only if it is harvested from a farm or some other form of controlled environment. If that same cow had escaped and been harvested from the wild or was born in the wild as the offspring of feral cows, then it would instead become subject to regulation by USFWS and recorded as *wildlife*. Thus, USFWS LEMIS wildlife trade import records do not exclusively illustrate the trade in *wildlife*. They are a combination of records that describe trade in both feral domesticated and non-domesticated (*wild*) animals that are cumulatively regulated by USFWS as *wildlife*.

5 An expanded list of domesticated animals would worsen information gaps among wildlife import data

Because *domesticated animals* are exempt from USFWS regulation and thus fall outside their scope of data collection requirements, any additions to their list of domesticated species will diminish the types and quantities of animal import data recorded. Consequently, because USFWS is the only federal agency presently recording species-specific import data for most types of animals, it may become impossible to track future importations of added species. For instance, pets such as hamsters and guinea pigs are among the top live mammals imported into the US annually according to USFWS LEMIS wildlife import records (USFWS, 2023) and no other agency collects comparable data on these imports. Although they are still treated as wildlife by USFWS, commonly traded hamsters and guinea pigs appear to qualify as domesticated animals from a scientific perspective. If USFWS was to add hamsters and guinea pigs to their list of animals officially recognised as *domesticated* under 50 CFR 14.4, then approximately 60% of presently regulated live mammals would fall outside USFWS declaration requirements and no longer become recorded in any species-specific federal database.

This would create additional substantive challenges in evaluating the risk of zoonotic pathogen importation through the live animal trade.

6 Inconsistent wildlife trade recordkeeping can obscure propagule pressure, distort perceptions of zoonotic risk, and stymie rapid public health responses

Propagule pressure is a composite measure of the number of individuals released into an ecosystem to which they are not native. It incorporates both the number of discrete release events (propagule number) and the absolute number of individuals involved in any one introduction event (propagule size) (Lockwood et al., 2005, García-Díaz et al., 2015). Propagule pressure could also be thought of as a coarse-scale indicator of potential contact rates between the imported wildlife (i.e., potential pathogen hosts) and people, wherein the human is the ecosystem and the biological invasion equates to pathogen infection. As described herein, the lack of standardised regulatory implementation of the term *domesticated animals* among federal agencies, as well as within USFWS regulatory frameworks, suggests that the total quantities of *wildlife* and wildlife shipments entering the US as expressed by LEMIS data represent potentially significant underestimates of actual animal importation levels and their associated zoonotic pathogen propagule pressures.

In the context of zoonotic risk analyses, the recordkeeping blind spots and consequent public health risks can be conceptualised through the lens of the evolving COVID-19 pandemic and the continually growing list of wildlife species found to be susceptible to infection with SARS-CoV-2, the virus that causes COVID-19 (Nerpel et al., 2022). For example, golden hamsters (*Mesocricetus auratus*) and rabbits (*Oryctolagus cuniculus*) have both expressed susceptibility to this virus and tested positive for infection, and hamsters have been suspected of transmitting infections to humans (Mykytyn et al., 2021, Shou et al., 2021, Frere et al., 2022, Fritz et al., 2022, Kok et al., 2022, Yen et al., 2022). A European strain of COVID-19 identified in Hong Kong is believed to have been imported from the Netherlands through infected golden hamsters (Kok et al., 2022).

What scale of risk do hamsters present for new COVID-19 strains (or other pathogens of pandemic potential) being imported to the US? This risk may be impossible to determine because neither CBP, APHIS, nor CDC (except for rodents imported from Africa) collects species-specific import data when providing clearance for these mammals to enter the US and as noted above, USFWS records may be incomplete due to inter-agency regulatory confusion resulting in lack of declaration by importers (Figure 1(a)–(c)). Even when declarations are received, USFWS Wildlife Inspectors may variably choose to interpret hamster shipments as *domesticated* and not retain records in LEMIS. As we previously documented, such risk analysis barriers exist for a wide range of animal host species and thus their zoonotic pathogen transmission potential. Clearly, the quality of available US animal import records affects the US's ability to identify and trace novel pathogen introductions and thus rapidly develop effective policies to mitigate harm.

7 Suggestions to improve scientific integrity of wildlife trade monitoring, regulation, and recordkeeping

Undoubtedly, the challenges expressed in this *wildlife* vs. *domesticated animals* terminology assessment are not exclusive to the US federal regulatory system. Similar data recording shortfalls – and the associated pandemic vulnerabilities – will adversely impact the scientific integrity of every country's zoonotic pathogen risk analysis in instances where terminological inconsistency influences trade data collection and information management systems. Thus, any possible solutions envisaged for the US may also similarly provide positive outcomes for other countries. We propose the following suggestions to (a) help strengthen inter- and intra-agency clarity as to which animals are *wildlife* vs. *domesticated animals* and (b) more efficiently streamline data flows to ensure that requirements for both recordkeeping and regulatory compliance have been satisfied among all relevant agencies prior to the ultimate clearance of *wildlife* into the US by CBP:

- 1 Avoid using the concept of *domesticated animal* when communicating which animals fall under the provisions of wildlife trade regulations. This concept and use of terminology could instead be replaced with a list of species and/or populations treated as regulated vs. non-regulated without ambiguous terminological boundaries. This would allow greater scientific precision among regulatory texts, minimise opportunities for confusion among the trade community and between federal agencies, and ultimately improve the scientific integrity of wildlife trade data available to be used for a variety of applications and risk analyses. In lieu of this scientifically optimal action, we suggest two improved ways forward.
 - a Develop standardised intra-agency definitions for the terms *domesticated animal*, *wildlife*, and *wild animal* based on scientific rather than operational principles. For situations where a single unified scientific definition may cause operational challenges among specific federal import regulations and secondary context-dependent definitions become implemented, these specific circumstances should be defined and explained in the same repository as the publication of the primary definitions to provide transparency and clarity. This would allow implementation of the term *domesticated animal* to meet varying operational goals without skewing the primary agreed definition of the term and reduce import data recording inconsistencies and interpretation pitfalls.
 - b Create an updated list of species federally recognised as *domesticated animals*, based on agreed scientific principles that were employed in defining this term. This would better align science and policy goals achieved through regulation and recordkeeping of animals imported into the US, help minimise unnecessary duplication of federal efforts, and improve the scientific integrity of both *wildlife* trade records and records of trade in *domesticated animals*.
- 2 As additional species of *wildlife* are added to the USFWS list of *domesticated animals*, USFWS should continue to collect species-specific declarations and maintain these records in LEMIS. Animals exempt from USFWS regulation are already recorded in LEMIS by discretion, as demonstrated by the presence of USFWS import records for domesticated cows from captive populations. This approach could prevent significant data gaps that would otherwise emerge for

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species newly recognised as *domesticated animals* where scientific names are currently recorded only by USFWS and no other agency.

- 3 Work with other governments to explore the possibility of creating species-specific customs Harmonised System (HS) codes for highly traded species. Increasing the granularity of HS codes has been recommended to aid evaluation of legality and sustainability among wildlife trade (Drinkwater et al., 20202), but in the present manuscript, we also make the case for their importance in a global health context. These codes will need to be adopted by the World Customs Organization (WCO) and updated every five years. Once adopted as feasible, the US can use the new HS codes to revise its country-specific HTS codes discussed previously in this manuscript. This exercise could effectively fill the data recording gaps currently created by the patchwork of federal data collection procedures that allow the loss of certain specieslevel data among records of non-domesticated animals imported into the US. The presence of species-specific HS codes would not only facilitate greater accuracy and standardisation among wildlife trade data recorded by CBP, but these codes could also serve as flagging mechanisms to ensure that all relevant wildlife shipments subject to USFWS import requirements have been reviewed, cleared, and recorded prior to CBP clearance. The adoption of new HS codes is recognised internationally, so the creation of any such codes can provide a common language of classification among customs officers not just in the US but globally.
- 4 Appoint a One Health Chief Information Officer to develop and curate a national database that aggregates and collates all animal import records into one location, including both *wildlife* and *domesticated animals*. All recorded animal importations could be reported to this centralised database where the presence of errors, national data gaps, and novel unpredicted importations of high public health risk could be identified and mitigated by the task team under a more timely, more adaptive, and more sustainable framework to reduce the nation's vulnerability to zoonotic pathogen importation through the international wildlife trade.

8 Conclusions

Government finances and policy-maker attention spans are limited. Priorities for pandemic prevention must be established on a basis of urgency and importance. Thus, we must remove any barriers to risk analysis that hinder timely, effective, cost-efficient decision-making. Federal terminology is clearly one such barrier. The inconsistent use of the terms *domesticated animals* and *wildlife* within and among government agencies opens the door to zoonotic disease outbreaks. Of particular concern are data gaps for species that pose elevated risks of zoonotic pathogen exposure to humans because they are often traded as pets and thus frequently handled and maintained absent biosecurity precautions. Many of these include peri-*domesticated* animals that are incongruently categorised, regulated, and documented among agencies. It is impossible to calculate how many *domesticated animals* have been provided clearance to enter the country that, based on scientific norms, should have otherwise been regulated and recorded in LEMIS as *wildlife* by USFWS according to federally published regulations. Consequently, the propagule pressures associated with the importation of these animals and their pathogens cannot be quantified in zoonoses risk analyses with high confidence. It is probable that

LEMIS records fail to entirely document some wildlife species that enter the US each year and that, for some species, LEMIS records grossly under-document actual import volumes.

In the US and other countries, policies and procedures are not necessarily based on scientific principles, even when science-based decision-making is essential. Instead, the data recorded by governments is directly tied to policies and standards of practice for the collection and management of those data, and data recording policies are often crafted to expedite trade and/or meet law enforcement goals. Clearly, safeguarding the public from zoonotic disease risks warrants an urgent investment in a holistic approach to regulatory harmonisation such that standardised definitions and record-keeping can enable timely, science-based decisions. If the US government fails in this regard, the trade-off will inevitably be measured in human lives lost.

Acknowledgements

We appreciate the many helpful conversations with USFWS, APHIS, CDC, and CBP staff that aided our understanding of the US federal regulatory processes and animal import data management systems. We extend our gratitude to Marshall Jones, Bruce Weissgold, and Jason Kirkey for their pre-submission reviews and feedback which improved this manuscript. Funding was provided through an Inter-agency Agreement (#19145) between the USFWS Office of Fish and Aquatic Conservation and the Smithsonian's Conservation Biology Institute for implementation of American Rescue Plan Act provisions. Opinions expressed in the paper are those of the authors and do not represent policy positions of the Smithsonian Institution or any other federal entity.

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