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Submission from the Entomological Society of America to the Department of State
Re: The Use of Digital Sequence Information of Genetic Resources

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Please accept the following comments submitted on behalf of the Entomological Society of America (ESA) in response to the Department of State's Public Notice: 11095, which invites stakeholders to provide comments on the use of digital sequence information (DSI) of genetic resources. To inform policy development and international messaging in the context of the Convention on Biological Diversity (CBD), Nagoya Protocol, and other access and benefit sharing (ABS) mechanisms, ESA includes in this submission:

1. A brief overview of entomology, including examples of benefits facilitated by the international sharing of DSI;
2. ESA concerns about applying existing ABS mechanisms to DSI;
3. Specific examples of the potential impacts on entomological research and collections that could occur if tracking and benefit sharing for the use of DSI were required for research collaborations, international sample sharing, and academic research with related recommendations to reduce those impacts; and
4. Examples of how entomologists track genetic resources already, which may inform efforts to address DSI in a way that will not cause unintended consequences on entomological research.

ESA is the largest organization in the world serving the professional and scientific needs of entomologists and individuals in related disciplines. Founded in 1889, ESA has more than 7,000 members affiliated with educational institutions, science agencies, private industry, and government. For more information about the Entomological Society of America, please see http://www.entsoc.org/.

Overview of Entomology

Entomology is the branch of science concerned with insects. Entomological research and collections can inform solutions to many global environmental challenges and are key to promoting biodiversity conservation. Over 50 percent of known global biodiversity are insects and related arthropods. Insect and arthropods are critical to ecosystems as pollinators, decomposers, natural enemies against

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invasive species, sources of new genetic and medical breakthroughs, and food for many other organisms.

For the past several decades, entomology has heavily relied on the generation and analysis of genetic data. For example, in the field of entomology, the use and sharing of genetic information across international borders has informed domestic and international efforts to: (1) address invasive pests that affect agriculture, forestry, public health, and food security; (2) limit and prevent the spread of many insect-borne diseases; (3) develop methods to control pests in homes, schools, restaurants, and throughout the built environment; and (4) utilize insects to develop genetics-based technologies that advance other scientific disciplines including genetics, pharmaceuticals, and biomedical sciences. In addition, entomologists utilize genetic sequencing to explore biodiversity, improve understanding of the natural world, inform decisions about conservation, and protect ecosystems from negative impacts.

ESA Concerns about Applying Existing ABS Mechanisms to DSI

ESA supports the idea that benefits associated with the use of genetic resources, including data and knowledge, should be shared in a fair and equitable way. Entomologists openly share these benefits by publishing their research and archiving genetic sequences for public access. ESA welcomes improvements to existing data sharing practices. At the same time, ESA has significant concerns about any expansion of the existing ABS mechanism to address DSI that would restrict or otherwise control access to and use of DSI, which is difficult to assess without clarity on how a proposed expansion would be implemented.

First, as described in the CBD technical paper "Digital Sequence Information on Genetic Resources: Concepts, Scope and Current Use," there are many technical questions of how to define "DSI" scope and terminology that must be answered before policy makers can determine how ABS mechanisms could be implemented and before potential risks of such approaches can be estimated. Given that the use of genetic data is ubiquitous across so many sectors, many relevant to entomology, ESA suggests further analysis is necessary before parties can make an informed decision about whether or not DSI can be addressed under the CBD and its Nagoya Protocol. Deciding international policy before a consensus on what DSI is and how it could impact scientific research would be irresponsible, as it is likely to increase the risk that the CBD and the Nagoya Protocol may prevent biodiversity conservation and disincentivize data sharing and collaboration among scientists.

Second, ESA is concerned that traditional ABS mechanisms, which rely on bilateral agreements developed between providers and users, cannot be appropriately applied to DSI since DSI is not

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equivalent to *physical* biological material in terms of use and benefit. Whereas there is a value to a single biological specimen, the value of individual genetic sequences is less clear. Instead, the value of DSI comes from the ability to share and compare many sequences, which collectively provide information that helps monitor similarities, differences, changes, and/or patterns. Thus, the transactional framework established under ABS, which relies on arrangements between the producer of a genetic resource and the user, cannot be easily extended to genetic information in the traditional sense. Further, the value of DSI is not limited or diminished when shared in contrast to physical specimens, which can be damaged and cannot simultaneously be used by multiple groups.

For the sake of illustration, consider the challenges of applying ABS to the DSI generated from whole genome sequencing efforts, which are key to informing many significant biological questions in entomology and other fields. Although the production of genomes was initially limited to model organisms, high-throughput sequencing technology and the simultaneous development of bioinformatic tools have "democratized" this science to a degree and enabled researchers to generate *de novo* draft genome sequences by collecting genetic information from multiple specimens. This effort to sequence genomes effectively decouples genetic sequence data from individual specimens and/or a specific geographic location. This is especially relevant since many species, including many insects and arachnids, do not recognize geopolitical boundaries. In other words, while a biological specimen may be collected in a specific country, the genetic information encoded by that sample may not necessarily be unique to that location. Similarly, historical collections may have specimens from which DSI could be derived from territories that have been under different political control, and for which it may be unclear which country "owns" the right to be considered the "producer" of the data. For these reasons, a regime like existing ABS mechanisms that ascribes one country as being the "producer" of that information may not be easily applicable to DSI.

Third, while countries have sovereign authority over physical genetic resources under the CBD, it is not clear from a legal perspective that "DSI" can be treated as either physical or intellectual property. Whereas physical biological material can be possessed, genetic data are information separated from the biological material from which it was derived. In fact, the process to derive genetic data results in at least partial physical destruction of the materials from which they were generated. Thus, the expansion of the Nagoya Protocol to cover DSI is equivalent to regulating information flow.

The primary aim of intellectual property law is to create incentives to innovate or to disclose innovations. This rationale does not justify providing countries with a right to control DSI. DSI is not "invented," nor does it result from innovation. A rule allowing countries to control or limit research

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based on DSI and the sharing of related data would thus be contrary to the aims of intellectual property—it would make it *harder* for researchers to innovate.

This much is consistent with foundational principles of intellectual property law, as recognized by the Supreme Court of the United States. In *Association for Molecular Pathology v. Myriad Genetics, Inc*., the Supreme Court held that human genes cannot be patented in the United States because DNA is a "product of nature." The Court decided that because nothing new is created when discovering a gene, there is no intellectual property to protect, so patents cannot be granted. This is a common distinction in U.S. as well as international intellectual property law, and the same principle explains why there is no intellectual property-based reason to restrict the use of DSI. The rationale of the CBD is not based on intellectual property, but instead is based on the idea that countries have national sovereignty over physical genetic resources. National sovereignty as a general matter does not cover information. Hence it is not clear how the Nagoya Protocol could extend to address DSI.

Potential Impacts of an Expansion of the ABS Framework to DSI on Entomological Research

If parties decide to expand the existing ABS framework under the Nagoya Protocol to address access to DSI, in addition to *physical* biological materials, we anticipate significant negative impacts on entomological research and collections. Entomologists have already been impacted by the access and benefit sharing obligations set forth in the Nagoya Protocol, but we anticipate additional impacts to be more significant if producer countries develop and/or expand their national frameworks to extend to DSI. In this section, we discuss the foreseen impacts, using specific examples from entomology. We also provide some recommendations to reduce the anticipated negative impacts.

Reduced International Collaboration, Publication, and Innovation – If utilizing DSI derived from international sources and publishing related scientific findings requires a bilateral agreement to proceed, it will be a significant deterrent to international collaboration, publication, and innovation. To avoid personal and professional liabilities and/or spending large amounts of time trying to navigate the domestic frameworks of provider countries, scientists will be disincentivized from conducting work that relies on the use of DSI from countries that are Nagoya Protocol parties. This is likely to significantly limit or impede entomological research and research in other areas critical to the broader objective of biological conservation. Collaboration is of mutual interest to the provider of the DSI and the user when it comes to international research. Thus, introducing ABS requirements to academic research that utilizes DSI could be a barrier to fostering international collaborations, a detriment to the scientific community writ large, and to many developing countries whose scientific enterprises would benefit from the capacity building and training enabled through international collaborations. Many of the countries rich in biodiversity lack capacity, training, funding, and

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resources necessary to conduct certain types of scientific research. In addition, many do not have the cyberinfrastructure to permanently archive, publish, or otherwise share DSI.

Managers of entomological collections have already invested significant time, energy, and other resources to understand how to comply with Nagoya Protocol obligations as they pertain to new and existing physical specimens of international origin. The fact that each country has its own enforcement and compliance mechanisms under the Protocol complicates understanding of which organisms are covered, which uses of genetic resources are restricted, and which agreements and permits must be obtained. Further, the information required for compliance changes rapidly and in the absence of any standardized language for these agreements and a method of posting new changes in a single location, these changes further complicate the regulatory landscape. Entomologists managing particularly large collections struggle to conduct the bilateral negotiations with providers of genetic resources for the thousands of insect samples they receive each year. Since, under Nagoya, work cannot start without agreements in place beforehand, the existing requirements have reduced the amount of work that can be done to build and study biological collections, to the detriment of biodiversity and conservation efforts. Similarly, there are numerous examples of scientific work that has been indefinitely and unnecessarily delayed when parties fail to agree on terms in material transfer agreements (MTAs) or when permit conditions are unclear because of country-by-country differences.

> **Recommendation 1:** If parties decide to move forward with an expansion of the Nagoya Protocol to include DSI, we strongly encourage them to consider developing a cataloging mechanism, possibly through a genetic database like the National Institutes of Health National Center for Biotechnology Information, which would enable the transfer of DSI without bilateral negotiations on a country by country basis to avoid disincentivizing innovation, international collaboration, and publication.

Prevention of Time-Sensitive Science to Address Pressing Global Needs – The significant bureaucratic burden of the Nagoya Protocol has already led to major disruptions of scientific research to address critical time-sensitive, pressing global needs. In the case of entomological research, the scientific community often needs to respond in real time to prevent the spread of invasive species or vector-borne diseases that can have harmful and widespread ecological and economic impacts. Preventing the sharing of DSI across international borders because of ABS and Nagoya related concerns would simply add to the bureaucratic burden, posing a great risk to public health, food security, and biodiversity conservation.

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DSI is routinely used to identify where new invasions of pests originated. Rapid, early surveying of invasive insects is essential to assess the source of the invasion and mount an appropriate control intervention. This requires collaborative sharing and analysis of DSI by scientists across borders in real time and across international networks. *Drosophila suzukii* is one example of an invasive fruit crop that has spread from east Asia to a near global distribution in just over ten years. Genetic studies have shown that introductions of this fly came from multiple sources. For example, while the first introduction to the United States came from eastern Asia, the United States was the source of introductions to Brazil. The use of DSI in tracking movement of invasive species highlights the need for enhanced screening of global goods to ensure food security. If ABS mechanisms were expanded to address DSI, there could be delays to the sharing of valuable genetic information across borders that could help prevent the spread of invasives during the limited time to stage successful interventions.

> **Recommendation 2:** To avoid parties from having to make the distinction between what research is time sensitive, parties should extend exemptions to ABS requirements to enable DSI to be utilized for research and for biological collections. This is analogous to the "fair use" doctrine as it relates to copyrighted material in the United States.

Disincentivize Sequencing and/or Sharing of Legacy Materials – The expansion of the Nagoya Protocol to address DSI could disincentivize the sequencing and sharing of information from existing entomological collections. For example, museums and collections already possess thousands of biological specimens that originated from international sources. By sequencing these specimens and publicly sharing the data, there are significant global benefits; however, if there is not any clarity on who "owns" this data under the Nagoya Protocol, biological collection managers are more likely to avoid allowing sequencing of these samples altogether, or will instead sequence the information and store it on private databases. A potential impact of the Nagoya Protocol could be to shift away from the open and transparent sharing of DSI.

Even in situations with specimens already housed in collections for which all necessary permits and agreements were obtained, expansion of the Nagoya Protocol to include DSI could add additional layers of bureaucracy to an already complicated regulatory landscape. Further, it would be tantamount to retroactively renegotiating the terms of a pre-existing and legally binding document about what can and cannot be done with a specimen, even if such new terms were never intended to be included at the time of their collection. For that reason, ESA contends that the inclusion of DSI under the Nagoya Protocol should only apply to future materials collected and that legacy materials should be excluded.

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Recommendation 3: Ensure that the policy would only apply to future materials collected after approval by Parties and that this is clearly communicated to the scientific community.

Communication Challenges – We expect significant confusion over how an ABS mechanism could apply to the use of DSI in entomological research and collections. Six years after the Nagoya Protocol entered into force, many entomologists and managers of biological collections are still not aware of the Nagoya Protocol and its implications for the sharing of physical biological samples across international borders and the personal and professional liabilities if one falls out of compliance with requirements of Nagoya party governments. The expansion of the Nagoya protocol to include DSI would cause further confusion and put collections in jeopardy of non-compliance without a significant training component to address both physical specimens and digital sequence information.

Recommendation 4: If the Nagoya protocol and/or other ABS mechanisms are expanded to address DSI, the scientific community would benefit from publicly-funded outreach to ensure that institutions and individual scientists understand their obligations pertaining to the access and benefit sharing of physical specimens and to DSI.

Potential Tools that can be Applied to Benefit Sharing of DSI Without Hampering Research

Biological scientists, including entomologists, that use genetic sequence data as part of their research already expended significant effort to openly share data, not just through their publications, but also by archiving sequences for public access in various data initiatives like the Consortium for the Barcode of Life (CBoL), Barcode of Life Data System (BOLD), the National Center for Biotechnology Information database (GenBank), and many other publicly accessible data sources for genetic sequence data, biodiversity collection data, etc. The journal *Nucleic Acids Research* regularly publishes a list of biological databases that store DSI-type data, and the last listing in the 2018 issues included 180 such biological databases that archive and provide public access to DSI, suggesting that the scientific community is already working to ensure that the benefits associated with DSI are shared in a fair and open way that promotes collaboration and research.

Although the following collaborative and international projects are not insect-specific, entomology plays a sizable role in all of them. The Centre for Agriculture and Bioscience International (CABI), a not-for-profit inter-governmental development and information organization, collects and analyzes agricultural pest information to help farmers and researchers across the globe. The Encyclopedia of Life is a vital resource to document Earth's ever-declining biodiversity. This project highlights the intertwined nature of DSI and physical specimens, as there may come a time for many species where specimens in a museum collection are all that remains of the species. The Earth Microbiome Project

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(EMP) is a global effort to understand the microbial communities in built and natural environments. Discoveries from this initiative may lead to the identification of novel antibiotics or other breakthrough technologies. EDDMapS, while only available in North America now, is a useful tool that brings together citizen scientists and experts to document the spread of invasive species across landscapes. Any of these existing databases could be expanded to include DSI if they do not currently, as in the case of CABI and EMP.