Interim Briefing and Tentative Recommendations Regarding**:**

THE WORK OF THE ANIMALS COMMITTEE IN ADDRESSING TRANSBOUNDARY MOVEMENT OF BIOLOGICAL SAMPLES

(Item 21 on the Provisional Agenda of AC-16)

This paper is submitted in preparation for the Animals Committee/Plants Committee at the Sixteenth meeting of the CITES Animals Committee in Shepherdstown, West Virginia, United States of America, 11-15 December 2000. It considers the nature and scope of the activities which must be undertaken pursuant to Resolution Com. 11.31. It is offered by the IUCN Environmental Law Centre, an outposted unit of the IUCN Secretariat, as "technical advice" to the Animals Committee pursuant to the Memorandum of Understanding between the CITES Secretariat and IUCN. It addresses only those particular matters which the Animals Committee has been asked to address with regard to the samples issue.

The suggestions contained herein relate to the organisation and commencement of the Animals Committee's program of work on this issue, based on an initial identification of some of the issues and controversies that have been raised in CITES's discussions of this issue. It does not (and is not intended to) offer any opinions as to the validity of any of these concerns.

The conclusions and recommendations of this Briefing are summarized in a one-page annex at the end of this document, entitled "Summary of Recommendations Contained in this Briefing Regarding the Workplan of the Animals Committee in addressing the Issue of 'Trade in Time-Sensitive Research Samples.'"

CONTEXT: COP-11 (Resolution Com. 11.31)

In Resolution Com. 11.31 ("regarding trade in time-sensitive research samples"), CITES COP-11 directed the Animals Committee "(in consultation with the Plants Committee, if necessary)"[1] to "examine the issues related to the international transfer of samples of species included in the CITES appendices" pursuant to the following terms of reference:

> "to examine the following issues with regard to the need to establish or recommend procedures for expeditious transfer of biological samples in specified situations:
>
> 1. identification of the various types of samples transferred internationally for purposes of research;
> 2. categorisation of purposes for which samples are transferred internationally, in terms of their commercial, non-commercial, and strict conservation elements, e.g., veterinary and diagnostic samples;
> 3. categorisation of the institutions and other recipients of such samples; and
> 4. evaluation of the need for expedited transfer of samples in each of these categories."

The resolution goes on to address the responsibility of the Standing Committee, based on the information and conclusions of the Animals Committee, to consider procedural options and make recommendations with regard to these issues and the manner in which they should be addressed by COP-12.

This paper offers suggestions for the work of the Animals Committee, with particular attention to the question of how that work can be structured to be of maximum value in the work of the Standing Committee when it is called upon to develop specific recommendations and proposed mechanisms.

CONTEXT: The Work of the Animals Committee

[1] We recognise that examination of the samples issue could well involve the Plants Committee, however, for convenience, in this paper, we will refer to the "Animals Committee," and by that reference include both committees to the extent that they both participate in this work.

In general, CITES Animals Committee is charged with a broad range of technical and evaluative responsibilities. Its role in the work of CITES is to obtain and assess information on fauna, including nomenclature, status, and management, as well as identifying "problems concerning the biological and trade status of species," and some other specific duties.[2]

Resolution Com 11.31 utilises the special nature of the Animals Committee's role in CITES issues, requiring it to apply both information-gathering and assessment capabilities. In setting the Committees' terms of reference with regard to samples, the Resolution clearly calls upon the Committee, not only to develop a body of information, but to employ its technical and analytical expertise to "evaluate" this information – a process which necessarily includes a

- determination that the information is correct and complete, and
- analysis of the technical implications of that information which may be relevant to future work (legal/institutional decisions) of the Standing Committee that will be based on the Animals Committee's outputs.

ADVICE REGARDING ANIMALS COMMITTEE WORK UNDER RESOLUTION 11.31

1. General Obligations

In addition to the listed "terms of reference," (discussed under headings 2-5, below) the Resolution, either directly or implicitly, places four general obligations on the Animals Committee, in regard to is investigation and analysis of the samples issue –

- To determine whether it will be necessary to undertake this work in conjunction with the Plants Committee;
- To "include input from relevant organizations and experts" in their work;
- To ensure that its deliberations and decisions include an appropriate level of consultation with the Secretariat of the Convention on Biological Diversity; and
- To ensure that their work is guided by its relevance and usefulness to the establishment or recommendation of procedures for expeditious transfer of biological samples in specified situations.

In this connection, it will be important for the Animals Committee to take into account the variety of positions and objectives of parties who have expressed concern about this issue.

a. Involvement of the Plants Committee

The resolution applies to "the Animals Committee (in consultation with the Plants Committee, if necessary)". The determination of the need to involve the Plants Committee will turn on whether the "time-sensitive samples issue" will apply to plant parts and derivatives, as well as those of animals. This decision may be a function of the Animals Committee's initial determination of the ***scope*** of its work. While the COP demonstrated a general (but not universal) agreement about the need to address the issue in certain limited contexts ("veterinary diagnostic samples" and "forensic samples"), many delegates indicated a desire to expand the proposal well beyond those agreed areas. The relevance of input from the Plants Committee may differ depending on which scope of endeavor is chosen by the Animals Committee.

i. Plant Committee Involvement in "Diagnostic and Forensic Samples" Issues

With regard to "diagnostic and forensic samples," Plants Committee involvement may be necessary if it is found

- that plant blights and diseases might necessitate international transfer of samples for laboratory analysis; or
- that forensic analysis might be necessary as evidence in cases of illegal trade in plant specimens.

[2] Resolution Conf. 9.1, Annex 2. In addition, the Committee is regularly entrusted with specific duties, by resolution of the COP.

ii. Plant Committee Involvement in Broader Trade in "Samples"

Many parties in COP-11commented that the scope of the samples issue extended far beyond the "urgent" issues, and suggested that all "research samples" should be addressed. This contention would appear to more strongly require that the Plants Committee be brought into the process of examining the issue, since it would appear that any definition of "research samples" would include both plant and animal research.

Suggestion: The Animals Committee determine the scope of its investigation, and the relevance of Plants Committee participation, as the first step in its investigation of the samples issue.

b. Input from Relevant Organizations and Experts

In discussions in COP-11, four major themes were clearly apparent:

- The desire of researchers (generally represented in the comments of veterinarians' associations) that their research not be delayed. This concern was expressed in the request that research samples not be subjected to lengthy (sometimes multi-year) delays in transit, as a result of CITES permit requirements;
- The desire of some CITES permitting agencies (possibly including the Convention Secretariat) to minimise the amount of paperwork required of overworked staffs, by eliminating permit requirements for "samples" (a term which, to some delegates, referred to any "parts or derivatives" of listed species which are transferred in very small quantities);
- The variously-expressed concern that a general exemption for "samples" might create legal and practical difficulties relating to the enforcement or interpretation of the Convention (*i.e.,* the legal, political, and practical impact of such an exemption);
- The strongly-argued position of many countries that free transfer of some or all "samples" (however defined) might create practical (or possibly legal) problems with regard to critical issues under the CBD, including "access to genetic resources";[3] intellectual property rights relating to the use of genetic resources; and related issues such as ownership of biological resources and ownership of genetic resources.[4]

It is clear, even from this briefest listing of the most commonly expressed concerns, that many disparate issues, concerns and positions have already been stated by many different groups. While veterinary associations and national CITES authorities have been active in addressing this issue in the aftermath of the COP, relatively few of the proponents of other positions have entered into the post-COP informal discussion of this issue, as yet.

The results of the work of the Animals and Standing Committees will be recommendations or draft mechanisms for consideration by COP-12. It seems likely that most, if not all of the positions expressed in COP-11 will continue to be active concerns of the Parties in 2002. As a result, it seems essential to the success of inter-COP efforts to address the samples issue, that all viewpoints be represented and considered in all information, analysis and decision-making processes.

Suggestion: The Animals Committee should actively seek and encourage the participation of representatives of governmental and ngo delegates and experts, representing a broad selection of viewpoints, including at a minimum, all viewpoints raised in COP-11's discussions of this issue.

[3] Generally, CBD, Article 15.
[4] CBD, Articles 15, 16, and see Article 8(j).

c. Consultation with the Secretariat of the Convention on Biological Diversity

As briefly noted above, strong arguments were raised in the COP-11 samples discussion regarding the impact that any change in the processes governing the transportation of samples might have in the area of access to genetic resources and related issues under the CBD. These issues are currently the subject of considerable scrutiny within the CBD meetings and by its Secretariat. Less than a month after CITES COP-11, the CBD COP-5 was held in Nairobi, where it was decided that ongoing work under the CBD on access and related issues should be undertaken through a dual process involving –

- A continuation of the work of the CBD Panel of Experts on Access and Benefit-sharing, to undertake the following work:
  - "assessment of user and provider experience in access to genetic resources and benefit-sharing and study of complementary options;" and
  - "identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes."

  Decision V/26 (UNEP/CBD/COP/5/23 at page 196)
- Establishment of an Ad-hoc Open-ended Working Group, whose objective is to assist parties and stakeholders in addressing –
  - Prior informed consent and mutually agreed terms;
  - Roles responsibilities and participation of stakeholders;
  - Relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use;
  - Mechanisms for benefit-sharing (including through joint research and development);
  - Means to insure the preservation and maintenance of traditional knowledge;
  - Intellectual property issues
  - Legislative, administrative and policy measures;
  - Contracts and other arrangements under mutually agreed terms.

  Decision V/26 (UNEP/CBD/COP/5/23 at page 196-198.)

In addition, access and benefit-sharing issues and case studies are addressed in the CBD Clearinghouse Mechanism (CHM).

At present, however, it appears that the next work to be undertaken on this issue by the CBD will be at the meeting of the Ad-hoc Open-ended Working Group meeting, tentatively scheduled for October, 2001 in Germany. While CITES involvement in this process seems advisable in light of the Recommendation, as well as for owing to more general relevance of the issue to CITES's activities, such participation should probably occur through the Standing Committee or the Secretariat, whose mandates are generally more focused on policy and law issues. It is important, however, that the Animals Committee should be aware of the issue throughout its investigative work.

d. Ensure Relevance and Usefulness to the Recommendation of Procedures Relating to Samples

Perhaps the most important of the overarching responsibilities of the Animals Committee under Resolution Com. 11.31 is the duty to ensure that the information and analysis it provides is "relevant and useful" to the processes of (i) determining whether a mechanism for expeditious transfer of samples is appropriate and necessary; and (ii) developing proposals for the establishment of such a mechanism.

With this as the objective, it is clear that the work of the Animals Committee involves more than simply compiling a list of case studies and examples. CITES relies on the Animals and Plants Committees to address scientific and technical aspects of its operations. In the course of addressing its terms of reference the Animals Committee must take care that its work addresses the following technical points which will be directly relevant to the work of the Standing Committee:

- ***What determinations*** will be made in any mechanism or decision relating to samples?

- ***What clear objectively verifiable criteria*** will be the bases for those determinations? and
- ***How to express those criteria*** in a way that ensures clear and consistent interpretation?

By focusing on this approach, the Animals Committee's work will result in *relevant evidence*, rather than a random list of "examples of international transfer of samples." Hence, these issues *must* be addressed in every aspect of the Animals Committee's work. (For this reason, recommendations in each of the following four discussions (headings 2-5), include specific identification of these issues and the manner in which they can be addressed.)

2. Identification of the Various Types of Samples Transferred Internationally [5]

Discussion of the samples proposal within the COP generally revolved around three categories of samples –

- veterinary emergency ("diagnostic") samples
- conservation enforcement ("forensic") samples; and
- other samples.

There appeared to be a high (but not universal) level of agreement that diagnostic samples and forensic samples can, in many instances, be an urgent necessity, and have a significant impact on the success of conservation efforts, in many situations. In many cases, appropriate laboratory facilities and equipment do not exist in and cannot be brought into countries whose wildlife may be urgently threatened by disease, or whose government officials may be forced to release apparent poachers or smugglers if evidence cannot be presented within a statutory period. These situations offer clear examples of "time-sensitive" demands for transportation of samples. In addition, in these instances, the need for expedited transfer is clearly related to the basic underlying objective of CITES – conservation of endangered species of plants and animals.

Numerous delegates, however, suggested that any expedited mechanism should apply to "other samples," including those used in species-related or other biological research. This suggestion was significantly more controversial, and was not completely discussed during the COP. As a result, the Animals Committee is called upon to consider the question "what types of samples are transferred internationally for purposes of research?"

In this process, the Animals Committee should keep in mind the lengthy and complicated debates in past COPs, in identifying the specific boundaries of the term "parts and derivatives" under CITES. Significant discussion was required in order to determine, for example, that fossils, animal urine and feces are not "parts and derivatives," while other substances, such as milk, are. In essence, any "samples mechanism" will create another new term, which must be clearly understood and objectively applicable.

Suggestion: In order to maximise the value of its information to the overall work under Resolution Com. 11.31, the Animals Committee's work in identifying the relevant "types of samples" should include the following for each type of samples identified:

1. *Specific real-experience examples of all relevant types of samples being collected;*
2. *A list of objectively verifiable* physical *factors on which to distinguish between such samples and other "parts or derivatives";*
3. *Description of the manner in which each of these distinguishing factors can be observed and documented, and the possible parameters which could eventually be the basis for application of the distinction;*
4. *Identification of the evidence that would be necessary in order to ensure that these distinctions are applied correctly and consistently; and*
5. *Identify the level of scientific or technical understanding that would be necessary in order to apply those criteria to individual samples in transit.*

[5] It is not clear from the Resolution, and not clarified in the discussions in COP-11, what the phrase "for purposes of research" means in the context of paragraph a) i).

3. Categorisation of Purposes for which Samples Are Transferred Internationally

One of the thorniest issues in CITES today relates to Convention provisions which tie some aspects of CITES implementation to the question of whether a particular transfer occurs "for commercial purposes." These concerns were always present within the Convention; however, recently, they have increased in light of

- the advent of genetic research,
- increasing ability of laboratories to synthesise natural biochemical properties, and
- a growing expectation that research facilities in governmental and educational institutions must "pay for themselves" by developing and marketing commercial applications of their research.

As a result, it has become more difficult to make traditional distinctions between "research purposes" and "commercial purposes." However, this distinction is an essential component of CITES – in which certain transfers qualify for exemption if they are not motivated by "commercial purposes."

The Biodiversity Convention and its concerns about access to genetic resources must also be taken into account, since the CBD is thought to specifically permit anyone who has legally acquired biological resources to resell them, even as "genetic resources."

In spite of these difficulties, Resolution Com. 11.31 requires the Animals Committee to evaluate the purposes behind various types of transfers of samples, including consideration of their "commercial," "non-commercial," and "strict conservation" elements. The goal of this evaluation is to determine whether these or other purposes should be a critical factor in any expediting mechanism, and whether and how such a purpose determination can be made or documented.

Suggestion: In order to maximise the value of its information to the overall work under Resolution Com. 11.31, the Animals Committee's inquiry into the purposes for which samples are being transferred should address the following, for each identified category of samples:

1. *Identify, as a general matter, all purposes for which such samples may be transferred;*
2. *Categorise the purposes listed under item 1 as either "strict conservation," "commercial," "non-commercial," or "containing elements of more than one category";*
3. *Consider whether there other categories or sub-categories of purpose which are relevant;*
4. *Consider whether the various purposes would be compromised, if the transfer of samples were conditioned on a legal agreement that the samples would not be used for any commercial purpose;*
5. *Describe the possible parameters, if any, for distinguishing among sample transfers on the basis of their purpose or other situational factors;*
6. *Identify the extent and nature of evidence that would be necessary in order to determine the purpose of the transfer in practice; and*
7. *Evaluate whether it is practically possible for administrative or enforcement officials to determine the specific purposes behind any individual transfer of one or more samples; and*
8. *Identify the level of scientific or technical understanding that would be necessary in order to apply those criteria to individual samples in transit.*

4. Categorisation of the Institutions and Other Recipients of Samples

CITES and particularly Resolution Conf. 2.14, already recognise the value of categorisation of scientific institutions. As noted therein, certain types of institutions may register as "scientific institutions" in order to qualify to utilise the exemption for trade between such institutions. For a variety of reasons, including particularly

administrative "economy," it may be advisable to utilise this existing registration process as an initial basis for the development of other categorisation mechanisms, if such are found relevant in addressing the samples issue.

In addition CITES makes reference to other types of categorisation by traditional categories (laboratory, educational institution, zoo, herbarium, botanical garden, etc.), which although not supported by a specific "registration" mechanism, are already applied by national authorities in the implementation of the Convention. It appears advisable to consider these factors, as well as new material in determining what types of institutions are involved in the samples issue, and whether this involvement can be distinguished from other trade on the basis of the nature of the institution involved.

Suggestion: In order to maximise the value of its information to the overall work under Resolution Com. 11.31, the Animals Committee should begin this portion of its inquiry by analysing the existing records concerning registered scientific institutions, and the standards underpinning such registration. This list and standards should be the basis for the following activities for each category of samples:

1- Identify possible recipients by category;

2- determine whether additional categories (individual researcher, other individual, commercial entity, etc.) are relevant and how they should be applied; and

3- list evidentiary and other factors that might be relevant in making legal and objective determinations concerning which category applies to a given institution.

5. Evaluation of the Need for Expedited Transfer of Samples in These Categories

This evaluation calls upon the Animals Committee to consider the entire range of factors described above. Having done a complete analysis, as described in each of the above headings, the Committee would be in a position to develop a matrix of sample categories and purpose categories, and to decide whether expedited transfer of each type of sample, for each type of purpose is or could be "necessary," and whether that decision is affected by the nature of the recipient institution.

Respectfully Submitted,

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ANNEX
Summary of IUCN-ELC's Suggestions Regarding the Workplan of the Animals Committee in addressing the Issue of "Trade in Time-Sensitive Research Samples"

To maximise the value of its information to the overall work under Resolution Com. 11., the Committee should:

- Determine the scope of the investigation, and determine whether the Plants Committee should be involved;
- Actively seek and encourage the participation of representatives of governmental and ngo delegates and experts, representing a broad selection of viewpoints, including at a minimum, all viewpoints raised in COP-11's discussions of this issue.
- Adopt a specific Workplan for addressing each of the terms of reference, including the following elements

1. "Identification of the various types of samples transferred internationally for purposes of research," including the following activities for each type of samples identified:

a) List all relevant types of samples being collected, giving specific real-experience examples;

b) Develop a list of objectively verifiable physical factors on which to distinguish between "samples" and other "parts or derivatives";

c) Determine how each of these factors (1.b) can be observed and documented;

d) Identify the amount and types of evidence needed to apply these distinctions are correctly and consistently; and

e) Identify the level of scientific or technical understanding that would be necessary in order to apply those criteria to individual samples in transit.

2. "Categorisation of purposes for which samples are transferred internationally, in terms of their commercial, non-commercial, and strict conservation elements, e.g., veterinary and diagnostic samples," including the following activities, for each identified category of samples:

a) Identify, as a general matter, all purposes for which such samples may be transferred;

b) Categorise the purposes listed under item 2.a) as either "strict conservation," "commercial," "non-commercial," or "containing elements of more than one category";

c) Consider whether there other categories or sub-categories of purpose which are relevant;

d) Consider whether the identified purposes would be compromised if the transfer were allowed only on condition that the samples would not be used for any commercial purpose;

e) Evaluate whether it would be possible, in practice, for administrative or enforcement officials to determine the specific purposes behind any individual transfer of one or more samples;

f) Identify the extent and nature of evidence that would be necessary in order to determine the purpose of the transfer in practice;

g) Describe the possible parameters for this determination (2.e)), if any; and

h) Identify the level of scientific or technical understanding necessary in order to apply those criteria to individual samples in transit.

3. "categorisation of the institutions and other recipients," as follows, for each category of samples:

a) analyse the existing records concerning registered scientific institutions, and the standards underpinning such registration (this list and standards to be the basis for the following activities);

b) Identify possible recipients by category;

c) determine whether additional categories (individual researcher, other individual, commercial entity, etc.) are relevant and how they should be applied; and

d) list evidentiary and other factors for determining which category applies to an institution.

4. "evaluation of the need for expedited transfer of samples in each of these categories," by developing a matrix which considers all possible combinations of categories of samples, categories of purpose, and categories of recipient, and determines for each what type of need exists for expedited transfer.