

## DISCUSSION PAPER

### The International Regime - A Missing Element

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#### Introduction

Despite Terms of Reference (TOR) for the negotiation of an international regime being established by COP Decision VII/19 there is no consensus on what the regime may involve. This paper seeks to identify important elements missing from current arrangements.

#### The International Regime (IR)

The first point to make about the Terms of Reference for the negotiation of the IR is that it reflects that much of the regime already exists. The 16 bodies listed under 'Relevant elements of existing instruments and processes' show this.<sup>2</sup> From this list it is clear that much of the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing will be taken up with understanding the role and contribution of these instruments and processes and what is required to make them work better together, without duplication, or conflict. This same process needs to examine gaps and how they may be filled. Happily the TOR recognizes this under "Process".

However, a key element in the consideration of an international regime on genetic resources is missing. This is the means whereby companies, researchers and other organisations with a stake in the biodiscovery process can demonstrate their adherence to standards of conduct that show they are complying with both the spirit and letter of the CBD. With so many steps involved in the value chain, from initial collection to final product or innovation, the number of 'players' and transactions involved is inevitably large, diverse, and often invisible to third parties. There are a number of ways to respond to this reality. Transparency within the Intellectual Property system through disclosure in patent applications of information about the source of genetic material used to develop a product or innovation is an example of such a response. Another is to create a tracking system to follow material taken and its subsequent development through the value chain via certificates of origin and the use of unique identifiers.

#### Industry Compliance

While regulatory debates focus on the development and application of legal rules and requirements the use of voluntary measures is often down-played in the common belief that financial gain will lead organizations to non-adherence or an unwillingness to submit to external scrutiny.

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<sup>1</sup> The views expressed in this paper are those of the author and do not necessarily represent those of the Australian Department of the Environment and Heritage.

<sup>2</sup> See VII/A9 Annex 'Terms Of Reference For The Ad Hoc Open-Ended Working Group On Access and Benefit-Sharing' para (d) xxiii.

In the field of biodiscovery a system of compliance with industry best practice standards can be a useful mechanism to establish industry normative behaviour, thereby significantly reducing the regulatory burden on resource providers.

#### **Advantages of Industry Standards**

There are a number of reasons why such a system would be attractive generally, and attractive in particular, to industry. They include:

- Establishing the reputation of the company by demonstrating a commitment to good faith conducts;
- Establishing minimum criteria for resource providers in deciding with which organisations to enter into benefit-sharing relationships;
- Establishing a minimum criterion for public research organisations when making decisions about entering into collaborative partnerships with commercial bodies;
- Assisting capital providers when determining issues of commercial and legal liability risk;
- Enabling companies to know what is expected of them - especially valuable for small start-up biotechnology companies;
- Enabling companies to get non-confrontational feedback about their practices.
- Assisting companies in continual improvement;
- Assisting potential shareholders in making investment decisions;
- Assisting institutional investors in forming judgments about the company or organization;
- Becoming a minimum criterion for ethical investment funds;
- Becoming a vehicle for raising standards of industry conduct as regulatory requirements change;
- Becoming a source of feedback to resource providers and regulators; and
- Identifying companies who do not meet standards to regulators, genetic resource providers, competitors, shareholders and capital providers.

The most significant benefit would be, however, to reduce mutual suspicion between resource providers and industry and by so doing, stimulate investment in natural product biodiscovery. For this reason alone, an industry standards system warrants inclusion in the development of an international regime.