



International Chamber of Commerce

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INTERNATIONAL CHAMBER OF COMMERCE

Policy brief



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Convention on Biological Diversity

Pathogens and the International Regime on Access and Benefit- sharing

Highlights

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- Plant Breeding
- Human and Animal Health
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Pathogens¹ and the International Regime on Access and Benefit-sharing

Executive Summary

Business, represented by the International Chamber of Commerce (ICC), supports the elaboration and implementation of a practicable International Regime on Access and Benefit-sharing (ABS IR) based on real-world experience to ensure meaningful benefits and to avoid unintended negative consequences. Therefore, it is important that elements of the ABS IR are carefully considered to avoid any potentially detrimental impact on public health and food/feed safety. In view of the importance of the issue of plant, animal and human pathogens and pests² in this context, business provides further views on this issue in the present paper.

The Convention on Biological Diversity (CBD) encourages the “preservation of biodiversity” and “the sustainable use of its components”. These goals must be interpreted within the context of the clear and reasonable meaning of the explicit text of the Treaty itself. The CBD definitions of biological and genetic resources do not specifically mention pathogens or pests – single cell or multi-cellular organisms which can so often cause damage to human, animal and plant health. Instead Article 2 of the Convention defines biological and genetic resources as those that have either “actual or potential use or value for humanity”. While certain uses of pathogens and pests may be envisaged that merit inclusion under the IR, the conventional understanding of the term “pathogen” or “pest”, where society aims at eradication or control of the organism, does not meet this test. A reasonable interpretation of this article, therefore, would seem to exclude those pathogens and pests which represent only a “threat” to biodiversity and to the overall ecosystem from the scope of the CBD and thereby any corresponding ABS IR.

Certain pathogens or pests that cause harm to plants, animals and humans may already be subject to existing separate international agreements while others are likely to be addressed by new agreements currently under negotiation. In order to show mutual respect for these agreements in other multilateral fora and to avoid duplicating on-going work by other international organizations with greater specialized technical expertise, ICC members believe that such pathogens and pests should be excluded from the scope of the ABS IR.

Whether all other pathogens and pests are, or should be covered by the ABS IR, may be discussed from many different perspectives, including legal and environmental. At the end of the day, it is key that the ABS IR should not hinder the development of materials intended to protect public health and food/feed safety. There is broad understanding that most conventional uses of the terms “pathogen” and “pest” centre on building States’ capacities to protect the health of their human, animal and plant population, and not the exploitation of pathogens for their positive value or benefit to biodiversity.

ICC therefore proposes that, with respect to these other pathogens and pests, only uses which are needed to detect pathogens or pests, prevent diseases caused by them, or cure the damage caused

¹ **Pathogen:** To illustrate how the term is commonly used, see definition online at [MedicineNet.com](http://www.medicinenet.com/pathogen/definition.htm): “An agent of disease. A disease producer. The term pathogen most commonly is used to refer to infectious organisms. These include [bacteria](#) (such as [staph](#)), [viruses](#) (such as [HIV](#)), and [fungi](#) (such as [yeast](#)). Less commonly, pathogen refers to a noninfectious agent of disease such as a chemical. The term pathogen was devised about 1880 and was compounded from [patbo-](#) meaning disease + [-gen](#) indicating a producer. Hence, a disease producer.”

² **Pest:** To illustrate how the term is commonly used, see definition online at <http://wordnetweb.princeton.edu/perl/webwn?s=pest>: “any unwanted and destructive insect or other animal that attacks food or crops or livestock etc”

by them to human, animal and plant health - thus having an impact on public health and food/feed safety - should be excluded from the scope of the IR. In this context, ABS written agreements between stakeholders nonetheless may also address specific issues that arise with respect to pathogens or pests on a case-by-case basis in a similar way as for genetic resources or traditional knowledge: through mutually agreed terms and via agreed benchmarks including front-loaded non-monetary benefits, capacity building, etc.

Needless to say that business remains committed to continue playing its important role in contributing to the solution of current and future health and food/feed problems.

Introduction

Business, represented by the International Chamber of Commerce (ICC), supports the elaboration and implementation of a practicable International Regime on Access and Benefit-sharing (ABS IR) based on real-world experience to ensure meaningful benefits and to avoid unintended negative consequences. In this context it is important that elements of the ABS IR are carefully considered to avoid any potentially detrimental impact on public health and food/feed safety.

In advance of the 7th Ad Hoc Open Ended Working Group on Access and Benefit Sharing (ABS WG-7) in Paris, business provided a paper which outlines general principles on which the ABS IR should be based and provides the business position on the objective, scope and the main elements of fair and equitable benefit sharing, access and compliance of the ABS IR. In view of the importance of the issue of plant, animal and human pathogens and pests in the development of the ABS IR, business provides further views on this issue in the present paper.

Pathogens and Pests in Different Industry Sectors

Plant Breeding

All food and non food crops that are used in agriculture and forestry are susceptible to pests and diseases. Worldwide the health of crops is threatened by some 25,000 plant diseases and countless insects. They are important yield-reducing and quality-impairing factors, especially in the tropics, due to climatic conditions that favor their spread. Annual global crop losses avoided by the use of crop protection products are estimated to be as much as 40 percent. New pests and pathogens are continuously developing. As a consequence, most crops are part of public and private breeding programs in which resistance to new, or new forms of pests and diseases, is a top priority. Resistance breeding, including through more recent biotech solutions, has been protecting crops very successfully. In many more cases, however, pests and diseases have to be managed through integrated measures, including chemical ones. In addition, new problems continue to appear as a result of natural evolutionary processes; a situation which will also evolve because of climate change.

Plant breeders in all crops have to be continuously alert to new forms of the many multi-cellular pests and diseases which appear not to be susceptible to genetic resistance factors, and which are present in the plant varieties in cultivation. At the first indication of this happening, plant breeders start screening all their genetic material with these new forms of pests and diseases in order to find if, and where, effective genetic resistance factors are available. However, most breeding programs take more than 10 years from the discovery of effective resistance factors to when full scale commercial production is possible. In that time, substantial damage can occur, chemical solutions might be available and quarantine can in some cases be effective.

However, all such approaches are dependent on the immediate availability of the new forms of pests and diseases to start the research in how to deal with it; any delay will quickly mean the loss of additional growing seasons. In addition, plant breeders need immediate and easy access to relevant plant genetic materials to start the screening process for new resistance factors plus, of course, the new forms of pests and diseases to do this screening. The ABS IR should not create any barriers to such access.

It is important to realize that the discussion usually focuses on a limited aspect, i.e. a new pathogenic effect of an existing pest or disease or a new pest or disease (alien invasive species). For the purposes of access and benefit sharing, it is therefore not necessary to have access to all of a pathogen and its potential uses. The focus should instead be on access for the use of the pathogen in the search for solutions to the problems it creates; access to other (commercial) uses of the same pathogen is not needed.

On the other hand, it should be realized that pathogenic effects can take many forms; for plants, this can include damage by microbes, viruses, fungi, and insects and other damaging animals but also parasitic plants and weeds.

It should also be realized that most pests and diseases do not respect geographical borders.

Human and Animal Health

Animal and human health is closely interlinked. , Of the 1,461 diseases now recognized in humans, approximately 60% are due to multi-host pathogens;³ whereas 75% of newly emerging diseases (over the past three decades) have been zoonotic,⁴ i.e. transferrable between human and animals.

With respect to animal health and welfare and its effect on food production, it is estimated that the world production of food is reduced by 20% due to disease in farmed animals. So, even where the diseases are concerned are not communicable to humans, human health still is potentially affected due to reduced availability of high value animal protein.

Pathogens (for example, viruses and harmful bacteria) and, as relevant, their vectors which fall under the category of pests mentioned in the section relating to plants, do not respect borders. Therefore strong international cooperation to address emerging diseases is of utmost importance. This is already taking place at the World Organization for Animal Health – the OIE, in close cooperation where appropriate with the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the UN. Recent global initiatives relating to the ‘One World, One Health’ concept take such cooperation even further.⁵

Rapid access to genetic material of pathogens can be vital in allowing the international community to respond to arising threats, e.g. by appropriate development of vaccines or diagnostic kits. This was heavily debated during the avian influenza epidemic. For the animal health community, efforts to facilitate sharing of genetic information of, in particular, influenza viruses were spearheaded by Dr Ilaria Capua, Head of the Virology Department at Istituto Zooprofilattico Sperimentale delle Venezie, Padova, Italy and Head of the National, FAO and OIE (World Organisation for Animal Health) Reference Laboratories for Avian Influenza and Newcastle disease. The discussion resulted in the adoption of Resolution No. XXVI “Sharing of avian influenza viral material and information in support

³ E. F. Torrey and R. H. Yolken: *Beasts of the Earth*, New Brunswick, NJ: Rutgers University Press, 2005

⁴ TAYLOR et al.: *Risk factors for human disease emergence*. *Philos Trans R Soc Lond B Biol Sci* 2001

⁵ http://www.oie.int/download/AVIAN%20INFLUENZA/OWOH/OWOH_14Oct08.pdf and also <http://www.phac-aspc.gc.ca/publicat/2009/er-rc/index-eng.php>

of global avian influenza prevention and control” by the OIE at its 76th General Assembly in 2008. This resolution mandates that OIE Members reporting outbreaks of avian influenza should agree to share animal avian influenza viral material and information about avian influenza viruses through OFFLU (joint OIE-FAO network of expertise on influenza) with the international scientific community.

During the recent events around the novel influenza A H1N1 virus, the debate was forestalled by rapid publication of genetic sequences as they became available.⁶ Key government institutions such as the Center for Veterinary Biologics of the USDA even announced that they would make available master seed virus of the novel influenza strain to interested manufacturers to facilitate vaccine development.

Development of new vaccines is a time-intensive process. For new animal vaccines, this can normally not be achieved in less than 5 years. Delays in making genetic material available, e.g. for vector-borne diseases, can easily result in missing the appropriate time for vaccination and leaving animals unprotected for a whole disease cycle. Especially for fast-spreading diseases, for example Foot and mouth disease, rapid identification of the causative virus strain is critical to enable use of vaccination as a disease control tool.

A special situation exists in respect to vaccines where the strain against which protection should be achieved needs to be varied on a regular basis (such as the annual human influenza vaccine). Regulatory special conditions can facilitate the changing of the virus strain in an authorized vaccine⁷ for antigenically variable viruses (for the EU see the recent guideline on multi-strain vaccine approach) also in veterinary vaccines, but nevertheless a certain amount of time is required to perform the non-negotiable safety tests and ensure availability of a vaccine before the main disease season. The sooner access to genetic material and other material of emerging pathogens is possible, the sooner health solutions can be found. In particular, for potentially pandemic pathogens, it is a matter of the greater public good to ensure rapid access to genetic information.

Certain pathogens are also the subject of WHO agreements and/or negotiations. In the case of the avian influenza virus, a resolution exists (see above) on how viral material and information should be shared. In the case of human influenza viruses with pandemic potential, discussions are on-going at WHO to develop a new access and benefit-sharing system (see e.g. WHO document A62/5 Add.1 on the outcome of the Intergovernmental Meeting on Pandemic influenza preparedness).

Therefore, in order to respect already existing international agreements and to avoid duplicating on-going work at other international organizations, ICC believes that those pathogens should not be covered by the ABS IR.

Pathogens, Pests, the Convention on Biological Diversity, and the ABS International Regime

The Convention on Biological Diversity (CBD) encourages the “preservation of biodiversity” and “the sustainable use of its components”. These goals must be interpreted within the context of the clear and reasonable meaning of the explicit text of the Treaty itself. The CBD definitions of biological and genetic resources do not specifically mention pathogens or pests – single cell or multi-cellular organisms which can so often cause damage to human, animal and plant health. Instead Article 2 of the Convention defines biological and genetic resources as those that have either “actual or potential use or value for humanity”. While certain uses of pathogens and pests may be envisaged that merit

⁶ MIT Technology review of 29 April 2009 [<http://www.technologyreview.com/biomedicine/22569/>]: “Within days of confirming fresh cases of the new [novel influenza A H1N1] in California and Texas last week, scientists at the Centers for Disease Control (CDC), in Atlanta, had sequenced the entire genome of the virus. By [27 April 2009], much of that genomic information was loaded into a publicly available [database](#), allowing the world's scientists to begin searching for clues to the origins of the mysterious virus and the severity of the threat it poses ...”

⁷ See e.g. the guideline for consultation of the Committee for Veterinary Medicines (CVMP) at the European Medicines Authority (EMA) - www.emea.europa.eu/pdfs/vet/press/pr/12656809en.pdf

inclusion under the IR, the conventional understanding of the term “pathogen” or “pest”, where society aims at eradication or control of the organism, does not meet this test. A reasonable interpretation of this article, therefore, would seem to exclude those pathogens and pests from the scope of the CBD which represent only a “threat” to biodiversity and to the overall ecosystem.

A number of further CBD articles would appear contradictory if the conservation goals of the CBD are applied to those pathogens or pests. For example, Art 8(h) requires States to prevent the introduction of, control or eradicate those alien species which threaten species and Articles 14(d) and 14(e) of the Convention require emergency preventive action by States, and international co-operation to support national efforts if required in cases where there is a grave and imminent threat to biodiversity.

In addition, the basic approach of the CBD, i.e. the concept of sovereign rights to control access to, and to secure benefit sharing arising from the use of genetic resources on a bilateral basis, is not easily reconciled with resources that do not respect national borders like most pathogens and pests. In the event that such resources mutate when crossing borders, it is not clear which rights different countries would have in any kind of benefit sharing for a specific resource that may be characterized differently at the time that it is identified in a source country from when it is used in a second or third country.

Certain pathogens or pests that cause harm to plants, animals and humans may already be subject to existing separate international agreements while others are likely to be addressed by new agreements currently under negotiation. In order to show mutual respect for these agreements in other multilateral fora and to avoid duplicating on-going work by other international organizations with greater specialized technical expertise, ICC members believe that such pathogens and pests should be excluded from the scope of the ABS IR.

Whether all other pathogens and pests, are or should be covered by the ABS IR, may be discussed from many different perspectives, including legal and environmental. At the end of the day, it is key that the ABS IR should not hinder the development of materials intended to protect public health and food/feed safety. There is broad understanding that most conventional uses of the terms “pathogen” and “pest” centre on building States’ capacities to protect the health of their human, animal and plant population, and not the exploitation of pathogens for their positive value or benefit to biodiversity.

ICC therefore proposes that, with respect to these other pathogens and pests, only uses which are needed to detect pathogens or pests, prevent diseases caused by them, or cure the damage caused by them to human, animal and plant health - thus having an impact on public health and food/feed safety - should be excluded from the scope of the IR. The following wording could accordingly be employed to exclude such uses from the scope of the ABS IR:

"Use of pathogens and pests of any biological origin, which could (i) cause damage to human, animal or plant health and food or feed safety, or (ii) could be used to detect the pathogen or pest, or (iii) could be used to prevent, alleviate or cure such damage"

ABS written agreements between stakeholders nonetheless may also address in this context specific issues that arise with respect to pathogens or pests on a case-by-case basis in a similar way as for genetic resources or traditional knowledge: through mutually agreed terms and via agreed benchmarks including front-loaded non-monetary benefits, capacity building, etc.

Needless to say that business remains committed to continuing to play its role in contributing to the solution of current and future public health and food/feed problems.⁸

⁸ E.g. for pandemic influenza vaccines see: www.ifpma.org/Influenza/content/pdfs/Publications/2009_05_Industry_Contributions_to_Pandemic_Preparations.pdf

The International Chamber of Commerce (ICC)

ICC is the world business organization, a representative body that speaks with authority on behalf of enterprises from all sectors in every part of the world.

The fundamental mission of ICC is to promote trade and investment across frontiers and help business corporations meet the challenges and opportunities of globalization. Its conviction that trade is a powerful force for peace and prosperity dates from the organization's origins early in the last century. The small group of far-sighted business leaders who founded ICC called themselves "the merchants of peace".

ICC has three main activities: rules-setting, dispute resolution and policy. Because its member companies and associations are themselves engaged in international business, ICC has unrivalled authority in making rules that govern the conduct of business across borders. Although these rules are voluntary, they are observed in countless thousands of transactions every day and have become part of the fabric of international trade.

ICC also provides essential services, foremost among them the ICC International Court of Arbitration, the world's leading arbitral institution. Another service is the World Chambers Federation, ICC's worldwide network of chambers of commerce, fostering interaction and exchange of chamber best practice.

Business leaders and experts drawn from the ICC membership establish the business stance on broad issues of trade and investment policy as well as on vital technical and sectoral subjects. These include financial services, information technologies, telecommunications, marketing ethics, the environment, transportation, competition law and intellectual property, among others.

ICC enjoys a close working relationship with the United Nations and other intergovernmental organizations, including the World Trade Organization and the G8.

ICC was founded in 1919. Today it groups hundreds of thousands of member companies and associations from over 130 countries. National committees work with their members to address the concerns of business in their countries and convey to their governments the business views formulated by ICC.



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Policy and Business Practices

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