

ANNEX 1: COUNTRY REPORTS: EU MEMBER STATES

European Commission
Study to analyse legal and economic aspects of implementing the
Nagoya Protocol on ABS in the European Union

Country report: Belgium

1 INTRODUCTION

Belgium is primarily a user country, as genetic resources are primordial to keep its leading role in the international pharmaceutical trade. The country is the world's third largest importing country of biopharmaceutical products and the world's one-but-largest exporter (UN Comtrade, 2010). The biopharmaceutical sector is thus a major player in the Belgian economy. It provides the country with more than 30,000 jobs and accounts for up to 40% of private R&D funding. The sector is strongly dependent of international activities and international transfer of genetic resources. Belgium also has a considerable market share in horticulture products and roughly exports 4 to 5% of the world's agricultural products.² Its prime location in the heart of Western Europe and the importance of the port of Antwerp, in the north of the country, make it an excellent global trans-shipment station.

The Belgian situation is particularly complex since most competences relating to biodiversity and territorial issues are scattered around the Federal Government, the Regions and the Communities. The three Regions (Flemish Region, Walloon Region and Brussels Capital Region) have the greatest responsibility in biodiversity-related issues, as they are in charge of territorial matters. The Federal Government pilots the international dimension, even though the three regions each provide a regional focal point to the CBD. The three Communities are responsible for culture, research, education and public awareness. For international environmental matters, these different levels coordinate through the Coordinating Committee for International Environment Policy (CCIEP).

In the 1980s, the Belgian Government created the Belgian Co-ordinated Collections of Micro-organisms (BCCM), which now comprises seven Belgian biological resource centres (BRC)³. In 1992, the BCCM obtained the International Depository Authority (IDA) status from

² <http://www.fas.usda.gov/gainfiles/200501/146118432.pdf>

³ The collection of fungi and yeasts of biomedical importance (BCCM/IHEM) of the Mycology Laboratory (Scientific Institute of Public Health); the collection of fungi and yeasts of agro-industrial importance (BCCM/MUCL) (Université Catholique de Louvain); the bacteria collection (BCCM/LMG) of the Laboratory for Microbiology (Ghent University); the plasmid collection (BCCM/LMBP) of the Laboratory of Molecular Biology (Ghent University); the Diatoms Collection (BCCM/DCG) of the Laboratory for Protistology & Aquatic Ecology (Ghent University); the Mycobacteria Collection (BCCM/ITM) of the Mycobacteriology Unit (Institute

the World Intellectual Property Organisation (WIPO), created under the Budapest Treaty to allow for deposits of microorganisms to be recognized as internationally patented. Other important public gene banks operate outside of the BCCM, like the National Botanic Garden of Belgium and the Walloon Agricultural Research Centre.⁴

Belgium ratified the CBD in 1996, after ratification by the three Regions, the three Communities, the federal Parliament and the federal Senate. The Convention entered into force for Belgium in 1997. FAO's International Treaty of Plant Genetic Resources for Food and Agriculture (IT-PGRFA) has been ratified in 2005.

Belgium signed the Nagoya Protocol (hereafter, 'the Protocol') on 20 September 2011. The implementation and ratification of the Protocol is a high political priority for Belgium. Belgium aims to be a Party at the first Meeting of the Parties (MoP). To prepare for implementation of the Protocol, the Belgian federal state together with the three regional authorities has commissioned a study on the implementation of the Protocol. These authorities are in this respect represented by their respective environment ministries. The study, which is expected to kick-off in December 2011 and to take eight months, aims to identify and evaluate the potential consequences for the internal Belgian legislative and other rules resulting from the signing and ratification of the Protocol. Implementation in Belgium includes implementation at the level of the Federal State and the level of the Communities and Regions. An advisory committee, consisting of representatives of the federal and regional environmental ministries, has been established to award, advise and supervise the study. Prior to this study, it had already carried out a first screening of potentially relevant legislative and other measures.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

Within Belgium currently no legislation exists with respect to access and benefit sharing (ABS). Policy measures are broadly limited to informing stakeholders about ABS and developing voluntary codes of conduct.

2.1.1 User-side legislative and policy measures

Belgium has not introduced comprehensive legislation concerning ABS. A federal law of 28 April 2005 amending the patent law of 18 March 1984 and transposing Directive 98/44/EC on the legal protection of biotechnological inventions (the biopatents Directive) is the only Belgian legislative instrument that specifically takes into consideration the CBD's provisions

of Tropical Medicine); the Polar cyanobacteria Collection (BCCM/ULC) of the Centre for Protein Engineering (University of Liège).

⁴ <http://www.cra.wallonie.be>

on ABS.⁵ Whereas the Directive only encourages the recognition of the geographical origin of biological material used in biotechnological inventions on patent applications, the Belgian law goes a little bit further as it introduces a formal requirement for disclosure of geographical origin, if it is known. In theory, non-compliance with this requirement could result in the patent application not being processed. In practice, however, the Belgian patent office does not check compliance with this requirement as it does not have the authority to do so. The law foresees the further elaboration of this provision through implementing measures, but these have never been adopted. As a result, it is unlikely that an application will not be handled because of a failure to disclose the origin of the genetic resources involved or because the information submitted is wrong (Hoare and Tarasofsky, 2006; Richerzhagen, 2010; Van Overwalle, 2005).

Belgium does not have any measures in place to ensure that genetic resources used within in its jurisdiction have been accessed in accordance with prior informed consent (PIC) or that mutually agreed terms (MAT) have been established, where required by provider countries. Nevertheless, some other user-related measures have been taken.

In 2006 the Government adopted the National Biodiversity Strategy 2006-2016, a document spelling out a range of 15 strategic objectives and 78 operational objectives that aim to reduce and prevent the causes of biodiversity loss. Strategic objective 6 wants to contribute to an equitable access to and sharing of benefits arising from the use of genetic resources by building national capacity and implement the Bonn Guidelines on ABS (CCIEP, 2006).

In parallel, the Government ordered a study to assess the awareness of Belgian users concerning the CBD and the level of implementation of ABS dispositions and the Bonn Guidelines in their activities. The main results indicate that the Convention is better known in upstream activities (e.g. fundamental research) than in downstream activities (e.g. commercial products). Collections and research sectors, both private and public, have a good understanding of the CBD, while other sectors, predominantly composed of private actors, have little or no knowledge. Concerning the implementation of ABS dispositions, the report shows that PIC-related dispositions seem to be relatively widespread, whereas benefit-sharing provisions are nearly inexistent. When benefit-sharing does occur, it mostly implies research cooperation with the providing country (Frison and Dedeurwaerdere, 2006).

In 2010 the federal Belgian government adopted the Federal Plan for the integration of biodiversity in four key sectors. ABS-actions within the plan are mainly focused on awareness-raising and capacity building of the private sector. However, the implementation of these actions has been delayed because of the international negotiations on the Protocol. These actions include the organization of biodiversity training sessions for four target groups concerned with the implementation of the sections 'economy' and 'transport'. One of these target groups is the Federal Ministry of Economy, in particular DG market

⁵ Wet van 28 april 2005 tot wijziging van de wet van 28 maart 1984 op de uitvindingsoctrooien, wat betreft de octrooierbaarheid van de biotechnologische uitvindingen, B.S. 13 mei 2005.

regulation, *inter alia* people dealing with intellectual property issues. The training sessions for this specific target group will address the concept of ABS and provide information on the Protocol and its implications in Belgium. The training sessions are due for 2012 (EU, 2011). However, first priority right now for the Belgian governments is the study on the implementation of the Protocol.

Since the adoption of the Protocol, Belgium has informed and consulted the different stakeholders on the implications of the Protocol through the organisation of a stakeholder workshop in the summer of 2011. Belgium will continue and step up these efforts, amongst other in the framework of its impact study on the implementation of the Protocol. As part of this impact study two stakeholder workshops will be organised during the first half of 2012. The aim of the workshops is to identify the wide range of stakeholders concerned with the implementation of the Protocol in Belgium, to make them aware of the content of the Protocol and its obligations, and to give stakeholders the possibility to explain how they think the implementation of the Protocol will affect them (EU, 2011).

As the Government does not consider the country to be hosting indigenous and local communities that fall within the definition of the CBD, there are no policies regarding traditional knowledge (CCIEP, 2006). However, although it is not directly related to ABS, support to help indigenous communities in developing countries implement the Convention on Biological Diversity has been carried out, from 2003 to 2007, by a convention between the Royal Belgian Institute of Natural Sciences and the Federal Directorate-General for Development Cooperation. The convention has been renewed in 2008 and runs until 2012.⁶

2.1.2 Provider-side legislative and policy measures

Belgium has no comprehensive legislation and policies on access to its genetic resources. Nevertheless, some related provider-side policy measures have been taken.

A team at the Belgian Science Policy Office (BELSPO) coordinates the activities of the Belgian Co-ordinated Collections of Micro-organisms (BCCM). Under the auspices of BCCM, a voluntary code of conduct to facilitate access to microbial genetic resources has been developed. BCCM also developed a Material Transfer Agreement for accessing the resources from its public collection. See section 3 for more details on these and other initiatives.

The Belgian Science Policy Office (BELSPO), together with the Ghent University, developed a pilot project using bioinformatics tools (web crawlers and search engines) to access and make available data and information stored in 60 biological resource centres worldwide.⁷ A standard format to allow for culture collection catalogue information to be exchanged easily has also been developed. Strains cannot be accessed directly through the common catalogue.

⁶ <http://www.biodiv.be/info0405/activities/>

⁷ <http://www.straininfo.net>

Over the last 15 years Belgium made quite some efforts in raising the awareness of the importance of autochthonous genetic resources of bushes and trees. The Flemish Agency for Nature and Forests organized conferences and workshops and developed study material for different government agencies, local administrations and forest owners on the importance of autochthonous genetic bush and tree material, and on possible measures and initiatives to protect these (EU, 2011).

2.2 Other relevant national legislation

The advisory committee for the Belgian impact assessment study (see above) has carried out a first screening of potentially relevant legislative and administrative measures. Many of these measures do transpose the EU legislation listed in section 5 of the main report such as the biopatents Directives, on the placing on the market of products of biotechnology, pharmaceuticals and cosmetics and seeds, on the use of reproductive material in forestry, and on plant and animal health and breeding. Most of these measures have been taken at the regional level, except for the federal law of 28 April 2005 amending the patent law of 18 March 1984 (see above).

The list (resulting from the first screening) also includes federal and regional legislative/administrative measures on nature protection and sustainable use of components of biodiversity such as:

- Flemish Decree of 21 October 1997 on nature conservation and the natural environment and subsequent implementing decisions;⁸
- Decision of the Flemish Government of 15 May 2009 on species protection and species management (includes for instance provisions regarding ban on collecting species);⁹
- Flemish Hunting Decree of 24 July 1991 and subsequent implementing decisions;
- Decision of the Flemish Government on the implementation of the law of 1 July 1954 on river fishing;¹⁰
- Decision of the Walloon Government of 27 November 2003 determining exemptions to the bird protection measures;¹¹
- Decision of the Walloon Government of 20 November 2003 determining exemptions to animal and plant species protection measures;¹²
- Decision of the Walloon Government of 24 July 2003 concerning the modalities of the collection and analysis of biological data on Walloon populations of wild animal and plant species and natural habitats;¹³

⁸ Decreet van 21 oktober 1997 betreffende het natuurbehoud en het natuurlijk milieu.

⁹ Besluit van de Vlaamse Regering van 15 mei 2009 met betrekking tot soortenbescherming en soortenbeheer.

¹⁰ Besluit van de Vlaamse Regering van 5 mei 1992 tot uitvoering van de wet van 1 juli 1954 op de riviervisserij.

¹¹ Arrêté du Gouvernement wallon de 27 novembre 2003 fixant des dérogations aux mesures de protection des oiseaux.

¹² Arrêté du Gouvernement wallon de 20 novembre 2003 relatif à l'octroi de dérogations aux mesures de protection des espèces animales et végétales, à l'exception des oiseaux.

¹³ Arrêté du Gouvernement wallon de 24 juillet 2003 relatif aux modalités de récolte et d'analyse des données biologiques sur les populations wallonnes des espèces animales et végétales sauvages et des habitats naturels.

- Federal Law of 22 April 1999 concerning Belgium's Exclusive Economic Zone in the North Sea;¹⁴
- Federal Law of 22 January 1999 concerning the protection of the marine environment in marine areas within Belgium's jurisdiction.¹⁵

3 NATIONAL ABS PRACTICES

3.1 Belgian research institutions' practices and policies on ABS

In 1997 the BCCM launched the 'Micro-organisms Sustainable Use and Access Regulation International Code of Conduct' (MOSAICC) initiative. MOSAICC is a voluntary code of conduct to facilitate access to microbial genetic resources in line with the CBD, the TRIPS Agreement and other applicable national and international law, and to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing (European Community, 2002).

In 2004, a consortium of 15 microbiological resources providers and users, coordinated by BCCM, launched the MOSAICS project.¹⁶ MOSAICS stands for 'Microorganisms Sustainable use and Access management Integrated Conveyance System'. It is funded by the European Commission (DG Research), under the Sixth Framework Program. The consortium includes partners from developed and developing countries, including culture collections, international organizations, branch federations and specialized research institutes. The project aims to give an answer to questions from culture collections on how to implement the various international and national rules regulating the flows and uses of biological resources, from the CBD to the application of intellectual property rights. It aims in particular to develop an integrated conveyance system that has reliable tools to evaluate the economic value of microbiological resources; that disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists; and, that combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

BCCM uses the general BCCM Material Transfer Agreement (MTA) for getting access to the genetic resources of its public collection.¹⁷ If necessary the MTA can be amended with additional conditions possibly already attached to the biological material. The resources are distributed for a fee covering expenses. The MTA stipulates that anyone seeking to access genetic resources held by the BCCM has the responsibility to obtain any intellectual property licenses necessary for its use and agrees, in advance of such use, to negotiate in good faith with the intellectual property rights owners to establish the terms of a commercial license.

¹⁴ Loi de 22 avril 1999 concernant la zone économique exclusive de la Belgique en mer du Nord.

¹⁵ Loi de 22 janvier 1999 visant la protection du milieu marin dans les espaces marins sous juridiction de la Belgique.

¹⁶ <http://bccm.belspo.be/projects/mosaics/description.php>

¹⁷ http://bccm.belspo.be/services/bccm_mta.php

The National Botanic Garden of Belgium (NBGB) is member of International Plant Exchange Network (IPEN), a network of Botanic Gardens that organises the exchange of living plant specimens. Under the auspices of IPEN and the Royal Botanic Gardens, Kew 'Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions' have been developed.

The NBGB and BCCM are discussing the compatibility of their respective approaches.

A general problem Belgian *ex situ* collections such as the NBGB are confronted with is the *de jure* and/or *de facto* absence of national competent authorities in biodiversity-rich countries in the South.

3.2 Company practices and policies on ABS

No corporate policies or practices on ABS have been identified in Belgium so far, neither by the authors of this study nor by the Belgian ABS officials. This could confirm the findings of the 2006 study on the awareness of Belgian genetic resource users indicating that a large majority of private users have little knowledge of the CBD and related topics.

4 REFERENCES

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5 INTERVIEWEES

Delphine Perremans, Biodiversity Expert, Multilateral and Strategic Affairs, Federal Public Service Health, Food Chain Security and Environment, DG Environment, 8 December 2011, Brussels.

Leen Chanet, Legal Policy Officer European and International Environmental Policy, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.

Dries Van Eeckhoutte, Legal Policy Officer European and International Environmental Policy, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.

Yanne Goossens, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.