

# BIODIVERSITY AND BIOPIRACY

GRI Standards : 304-1, 304-2, 304-3, 304-4 : Biodiversity

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## I. BACKGROUND

“Biodiversity” or biological diversity, refers to the variety of life on earth. It encompasses three categories: genetic, species, and ecosystem diversity:

- Genetic diversity refers to the variation of genes within species.
- Species diversity refers to the variety of species within a region.
- Ecosystem diversity refers to the different communities or habitats found in a given location.

Biodiversity is vital to maintaining the balance of life on our planet. The world’s natural ecosystems are deteriorating at a rate unprecedented in human history. Preserving biodiversity and ensuring the sustainable and fair use of natural resources stand out as key issues worldwide. Today they are an essential part of any Corporate Social Responsibility (CSR) policy, and are considered critical topics for Sanofi.

The pharmaceutical industry places a great deal of importance on biodiversity, because natural resources are critical for the discovery and development of new drugs. Natural resources have valuable potential as sources for new chemical substances and active ingredients. Despite the decline in the use of natural products for drug discovery, biologists consider natural resources to be the treasure troves of pharmacopoeia in the 21<sup>st</sup> century, given the remarkable diversity of their substances and active ingredients.

### Our strategic approach

Sanofi concentrates on three key issues relating to biodiversity:

- Ensuring the preservation of biodiversity surrounding Sanofi sites and beyond, particularly in fragile or protected zones;
- Determining the fair distribution of benefits resulting from putting this type of resource on the market;
- The controlled use of natural plant and wild animal species in research projects to discover new drugs.

To translate our approach into action, Sanofi committed to:

- Sanofi complies with local regulations. Regarding the preservation of protected natural areas surrounding the concerned sites, Sanofi carries out relevant environmental impact assessments;
- Ensuring that all new relevant contracts are in line with the CBD and The Nagoya Protocol and take into account the CITES convention and the International Union for Conservation of Nature (IUCN) Red List criteria;
- Verifying, prior to placing an order, that relevant plant species are not on the lists established by the Convention on International Trade in Endangered Species (CITES) of Wild Fauna and Flora. See [www.cites.org](http://www.cites.org);
- Ensuring that suppliers produce, if necessary, the official authorizations that allow them to collect the plants, animals or/and micro-organisms that have been ordered.

## II. BIODIVERSITY AND SANOFI SITES

### 1. Planet Mobilization & Biodiversity

According to the Planet Mobilization Program 2015-2025, we have a global commitment to manage the biodiversity of our sites. The first step was to perform a sensitivity analysis of all our non-urban sites. This identified a list of priority sites that required further assessment, and potentially risk management plans. All priority sites identified as “at risk” will have to have a management plan by 2020. And by 2025, all of our sites will have embarked on a biodiversity awareness program for their employees.

## 2. Preserving biodiversity around Sanofi sites and beyond

Sanofi pursues many initiatives designed to preserve biodiversity at our sites, in the surrounding areas and beyond.

Sanofi is committed to have a management plan for 100% of our priority sites by 2020.

In order to identify priority sites, in 2014, an independent consultant undertook a desktop-based mapping of the biodiversity sensitivity of our industrial sites. The evaluation was based on six criteria:

- Proximity to a natural/semi-natural area
- Proximity to a restricted and/or classified sensitive area
- Proximity to wetlands
- Potential to be integrated into an ecological network
- Potential presence of sensitive species/habitats
- Anthropic pressure

In 2016, we undertook a more in-depth analysis by identifying the potential endangered species of mammals, birds and amphibian that may be close to these industrial sites. Initial results indicate that only six sites (off which five are in Europe) being in an area with high sensitivity to biodiversity. We seek to refine the knowledge of our sites' environment through local biodiversity studies, starting first with sites identified as being in areas sensitive to biodiversity, called priority sites.

In 2017, Csanyikvolgy in Hungary has been chosen as pilot site. Since 2002, this site, located near the border of a National Park, has been working with a local expert to regularly survey lichen and plants around the site in relation to sensitivity to air pollution; no negative impacts have been reported. The result of the study will enable us to establish the site biodiversity risk management plan in relation to a dedicated monitoring program with the expert third-party. The Biodiversity program will be extended to 5 other priority sites : 4 in Europe and 1 in India.

Other examples of initiatives implemented locally :

### **At our Waterford site in Ireland, "La Marche"**

Enabling future planning for business development required the creation of a wildlife pond to provide a breeding and hibernation habitat for a protected species, the common frog (*Rana temporaria*), which inhabits a wetland area on site. We took advantage of this opportunity to incorporate a Slí na Sláinte 1.7km walking track.

Taking on board the imperative of protecting the frog population in the wetlands within our landbank and the aspiration to develop a pleasant walking route that would encourage daily outdoor exercise, the Health, Safety & Environmental team developed a project to create a pond and walkway around the frog habitat. This conserves the protected ecosystem and species but also enhances the area and makes it more accessible on a clearly marked pathway. The Irish Heart Foundation-designated Slí na Sláinte (Path to Health) makes walking outdoors simple, satisfying and safe. At Waterford, the route features an eco-friendly "outdoor room" with benches and potted lavender. In developing the model, the team were very aware of the need to deliver return on investment and to minimize expenditure. In this context, the idea was developed of delivering the project in partnership with voluntary bodies. These included the Red Cross and Scouting Ireland, both of which had Genzyme personnel involved locally. To further boost employee buy-in, we invited volunteers from the site team to take part in the physical works at weekends. In all, 200 people from the company and community volunteered at various stages. A naming competition boosted interest and generated the "La Marche" brand. There is a real sense of ownership and the habitat and related walking route are impeccably maintained year-round. All materials used in the works were environmentally-friendly, safe, sustainable and durable.

### **At our Brazilian headquarters site**

A local partnership was established in 2016 with an NGO which aims to plant 15,000 native trees of the Atlantif Forest. Internal actions of engagement to environment issues will be conducted in 2017 with employees. This is a five-year project. The production of native seedlings of the Atlantif forest was carried out in 2016; the planting has started in 2017.

## At our Mount Pleasant (Tennessee, US) site

As part of the remediation of former manufacturing site, 10 acres of wildflowers were planted in areas distributed during reprocessing of aluminium oxide. The wildflower mix was chosen to enhance the local pollinator environment. Seeds were planted in late 2016.

The planting of 10+ acres of native wildflowers in formerly developed areas, restoration of impacted streams and wetlands, and the planned dredging and restoration of Arrow Lake, a local fishing haven for past generations was one of the ways Sanofi has engaged with the Mount Pleasant community and in supporting the creation of Arrow Lake Foundation. Through this foundation, Sanofi has funded local Science, Technology, Engineering and Math (STEM) education projects at the Mount Pleasant High School.

### 3. Employees awareness

Throughout the world, every site will have a biodiversity awareness program for employees by 2025.

More globally, initiatives to protect and promote biodiversity that involve employees located at all our sites have already started. An internal World Environmental Day is organized each year. In October 2017, 150 sites were involved and demonstrated the commitment of Sanofi through the Planet Mobilization program, many employees were sensitized with actions linked with biodiversity and planting trees.

#### A global project: Plan Bee®

Pollinator decline (as well as biodiversity, as a consequence) is not solely a governmental or individual problem, but one which urgently requires a multi-organizational solution. Starting in 2015, a Sanofi Beekeeper employee has decided to have a direct impact on pollinator decline but also have an indirect impact by means of climate change through the **Plan Bee®** initiative.

**Plan Bee®** project consists in setting up Beehives on Sanofi's sites according to a calibrated governance and process which embarks, volunteers across the world and sponsors.

Plan Bee is a kind of incubator platform deployed across 26 sites with the participation and strong commitment of 325 volunteers who are going through a learning curve, with the seasons.

Year 2018 enabled the pick up of 662Kg of Honey sold to the employees; the income providing from the selling of the honey was donated to the internal charity "Enfants de Sanofi". This project contributes to reinforce the circular economy.

## III. BIODIVERSITY AND VALUE CHAIN

### 1. Natural substances used in R&D and production

The actions implemented to comply with the CBD and the Nagoya Protocol, as well as with Sanofi's position on biodiversity, focus on the use of natural substances to develop new drugs. They entail:

- Limiting the quantities of genetic resources used for research
- Identifying protected natural substances (CITES list) and finding alternative solutions
- Establishing contracts with suppliers, stipulating that they must comply with international conventions and national regulations on preserving biodiversity
- Adhering to the principle of sharing benefits generated by Sanofi with countries that give access to their natural resources, as well as with local populations having specialized know-how, whenever products made from natural substances are commercialized (see "Biopiracy" section, below)

To facilitate these actions, Sanofi has developed and adapted a tool to manage strain collections and ensure compliance with the CBD and the Nagoya Protocol.

## Adhering to the principles of biodiversity preservation

### **Recognition of the Convention on Biological Diversity (CBD)**

The Convention on Biological Diversity (CBD) entered into force on December 29, 1993 (and has now been ratified by almost all countries except the United States). It has 3 main objectives:

- The conservation of biological diversity
- The sustainable use of the components of biological diversity
- The fair and equitable sharing of the benefits arising from the utilization of genetic resources

Sanofi recognizes the CBD principles for obtaining and using natural resources, and stipulates that suppliers must comply with the CBD. Collaboration contracts set out conditions for sharing the benefits arising from the use of these resources.

*For more information, see: [www.cbd.int](http://www.cbd.int)*

### **Internal implementation to comply with The Nagoya Protocol**

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* is a supplementary agreement to the Convention on Biological Diversity. It was designed to contribute to the conservation and sustainable use of biodiversity.

This international agreement provides a legal framework to ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources, directly addressing one of the three objectives of the CBD.

The Nagoya Protocol has been at the center of debate in the business world and society at large, and Sanofi has taken an active part in these discussions.

The Nagoya Protocol entered into force on October 12, 2014 and has now been ratified by 117 countries including the European Union. National legislations are being adapted to ensure compliance with this protocol.

Compliance with the local regulations stemming from the Nagoya Protocol requires coordinated efforts across all Sanofi entities. In 2015, a project team was set up to monitor the worldwide implementation of the Nagoya Protocol and to analyze its implications for our business, focusing on efforts to identify what biological materials are used in the discovery, development, manufacture and packaging of our products, and to document the originating country and acquisition date for these materials, in compliance with Sanofi's own guidelines.

During 2016 and 2017, the project team created appropriate documents and policies regarding Nagoya. A dedicated intranet site designed for all Sanofi employees has been launched, aiming to raise general awareness about the Nagoya Protocol. In addition, key departments received specific employee awareness/training during 2017.

The project mode ended end of 2017. To continue internal implementation and to ensure Sanofi compliance, a Nagoya expert group was set up and reports to Sanofi Bioethics Committee.

The Nagoya expert group keeps working on questions arising from the implementation of the protocol in the different signatory countries. The objective is to keep track of the evolution of practices according to feedback from the parties. For instance, one subject still under discussion is the use of digital sequence information on genetic resources.

Sanofi's biodiversity approach is summarized in Sanofi's position paper, which is available in our Download Center. This paper demonstrates that biodiversity and the fight against biopiracy are key issues for Sanofi, and establishes a clear position on combatting all forms of biopiracy.

### **Biopiracy**

Biopiracy refers to the commercial utilization of endemic resources and local know-how without sharing the profits with the communities or countries that are the source. The CBD and the Nagoya Protocol describe the principles governing such utilization, although national regulations vary to a great extent.

From now on, each time Sanofi will investigate the use, for R&D purposes, of a new product isolated from natural sources, a due diligence will be performed to comply with the CBD and the Nagoya Protocol. This commitment aims to safeguard against biopiracy.

## 2. Inventory of natural substances and Responsible Sourcing

In 2013, Sanofi launched a review of active substances used in R&D and production sites for industrial purposes. This is done yearly in collaboration with Procurement, Global Quality and CSR departments.

This inventory consists of reviewing our database in order to identify APIs (Active Pharmaceutical Ingredients) originating from, plant- and animal-based natural substances. According to the information collected to date, no plant or animal included in the CITES lists or UICN are used in our production activities.

Suppliers are asked to provide botanical information or location and crops of origin of these substances.

We are developing processes to protect and preserve biodiversity that call for:

- monitoring suppliers responsible for collecting natural resources used in research projects to discover new medicines;
- sourcing biological materials and related services from suppliers who apply appropriate environmental and biodiversity preservation standards.

In accordance to Planet Mobilization Program, we are reinforcing the Responsible procurement policy.

Environmental and social issues are part of the global approach, as we need to anticipate the CSR challenges (including the potential environmental and social impacts of our procurement policies, sourcing, and specifications) to be prepared for evolving regulatory requirements (energy consumption, carbon footprint, waste treatment), and to ensure that our suppliers comply with environmental and social requirements.