sanu durabilitas

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# The biotechnical utilisation of genetic resources and its regulation

An integrative approach

# Contents

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Sanu durabilitas, the Swiss Foundation for Sustainable Development, was established in 2012 by the Swiss Training Centre for Nature and Environmental Protection (sanu), founded in 1989. As a scientific think tank, it works together with actors in the field and at educational establishments to raise awareness of important issues and challenges for the sustainable development of Switzerland and to develop and disseminate appropriate solutions. It adopts an international perspective, working closely with European experts, and sees its work as Switzerland's contribution to sustainable global development.

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The next edition of «Durabilitas» will focus on the topic of social change and social cohesion and is due to be published in 2015.

# The biotechnical utilisation of genetic resources and its regulation

## An integrative approach


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# Introduction

The aim of this report is to examine the development – very dynamic, but only partially known by the public – of biotechnology. The report investigate the extent to which it either poses environmental risks and ethical concerns or, conversely, provides an opportunity to increase social prosperity by creating a type of economy requiring less material and energy consumption and causing less environmental pollution. Under the term biotechnology[1] we combine three uses of genetic resources: targeted breeding, genetic engineering and synthetic biology. The use of genetic engineering and gene therapy on humans is not dealt with in this report because of the peculiarity of the standards applying to it.

Biotechnology as a technology of the future is the subject of much debate in various circles. There are therefore discussions about plant and animal breeding which are prompted by the concern that a permanent yield increase might lead to the loss of native breeds and biodiversity. Other disputes revolve around the risks and benefits of genetic engineering.[2] Another topic area regards the access to genetic resources and the sharing of the benefits resulting from their exploitation. Further disputes pose the question of patenting living organisms. The debate on synthetic biology (for an explanation of the term, see page 8) has hardly come to the attention of the public so far. Great controversy surrounds the debate over the limits of the manipulation of human life. These and other discussion fora have hitherto been largely unconnected. They have split into rival camps and have been repeating the same positions for years or are at risk to fall into such stalemates.

The discussion fora on animal and plant breeding, the risks of genetic engineering, patenting living organisms and access to genetic resources are largely unconnected.

The purpose of this report is to merge those separate debates. We suspect that an overview can be achieved by identifying a common point of reference for the topics debated. Therefore, although debate has hitherto been sparked on certain phenotypes, like the appearance of organisms such as “turbo pigs”, “killer viruses”, “chimeras”, we propose to deal with the genotype. This will allow us to recognise that the various discussions have something in common. They can, hopefully, be made more transparent by providing a new thematic structure and new explanations, solutions and explanations.

These separate discussions can be merged, with actors focusing on genotype as a resource in their debates.

This report first explains its specific approach, determining a resource – genetic programmes – and focusing the debate on it (Chapters 1–5). It discusses the different uses of the resource (Chapter 6) and then turns to the question of political and legal measures. They consist of sovereign and property rights (Chapter 7), promotional strategies (Chapter 8) and a complex regulation that pursues such different objectives as the securing of social benefits (Chapter 9), the prevention of health and environmental hazards (Chapter 10), the consideration of ethically/culturally-defined social attitudes (Chapter 11), and finally the fair sharing of the benefits obtained (Chapter 12).

1) Biotechnology is any technological application that uses biological systems, living organisms, or products made from them to manufacture or modify goods or processes for a particular use. For the purposes of this text, we use the definition contained in Article 2 of the Convention on Biological Diversity (CBD). In this context, whether “products” also include biochemical compounds – as the Nagoya Protocol to the CBD prescribes – is irrelevant.

2) Genetic engineering is the alteration of the genetic material of organisms in ways that cannot be achieved through natural crossbreeding or recombination. We use this term in accordance with the Gene Technology Act (see Art. 5 para. 2 Federal Act of 21.3.2003 on Non-Human Gene Technology).

# 1

# From the use of phenotypes to the use of genetic programmes

Man has always used living natural resources in various ways. Microorganisms, plants and animals – man himself as an integral part of nature will not be discussed here – are bred and propagated for a wide range of purposes: for food, cultivation, the manufacture of products, energy production, convenience (e. g. as pets or landscapes), labour, etc. The phenotype-based approach, i. e. based on the outward form of living organisms, is typical of this exploitation.

Since the discovery of the chemistry of the genetic makeup of organisms, the direct utilisation of the genome[3] of organisms has come to the fore. The processes of utilisation, as a result, no longer intervene merely at the level of organisms, populations and ecosystems, but also, and increasingly, at the more basic level of cells and their genomes. Admittedly, genomic alteration has always been the outcome of breeding, but it has hitherto availed itself of naturally occurring techniques such as sexual and asexual reproduction, mutation, selection, etc. The technique for effecting immediate, targeted changes to DNA and RNA is new. It has enormously expanded the modification options and, in particular, it has accelerated them because species boundaries that have traditionally been decisive for breeding can now be crossed.

The current processes of utilisation no longer interfere merely at the level of organisms, populations and ecosystems, but also, increasingly, at the more basic level of cells and their genomes.

The technique embraces the approximately 20-year-old genetic engineering of organisms and is currently developing into synthetic biology, which not only slightly alters existing organisms, but also radically changes genomes and merges them into new cells and organisms. Its ultimate aim is to be capable of generating life artificially in the future. In parallel with genetic engineering, breeding methods have also become more artificial: for example, the targeted generation of mutations. This calls into question the existing systematic separation of breeding from genetic engineering/synthetic biology. But nowadays even traditional, less intrusive breeding incorporates the genomic level, since it relies on genomic analysis for the selection of individuals (e. g. high-yielding cattle). Overall, a very dynamic science of biotechnology has emerged, but for the sake of this report we mainly focus on the techniques of targeted breeding, genetic engineering, and synthetic biology.

Swiss law follows this shift away from phenotypes to genomes. To take the example of farming, the traditional utilisation of natural resources is regulated by agrarian law, spacial planning law, nature conservation law, the law on the approval of varieties, the law on the protection of varieties, livestock breeding law, etc. The Genetic Engineering Act, which concerns the genomic level, was added later on. This law is only a harbinger of future regulations that must take into account the full spectrum of genome-based biotechnology. In addition to the risk-oriented Genetic Engineering Act, another law is being developed that concerns the benefits of the technique, organising genomic research and development (R&D) processes and providing for the distribution of their benefits.

In addition to the risk-oriented gene technology law, another kind of law is being developed, which organises the genomic research and development processes and provides for the distribution of their benefits.

3) The entirety of the material carriers of the hereditary information of a cell (genotype)

In the realms of science, technology and economics and at a legal level, a shift away from phenotype to genotype is observed, whose significance has not been sufficiently analysed yet. We recommend a more in-depth theoretical analysis, societal reflection and political evaluation.

# 2

# Fragmentation of the sectors of utilisation and their regulation

As indicated above, the types of utilisation of natural resources are developing and becoming increasingly numerous. In a free society this is welcome and desirable. However, as far as the government's measures for regulating and promoting this utilisation are concerned, an overall view is required in order to determine which lines of development are worth promoting and which need to be regulated because of their risks or for distribution purposes. Without such an overview, government measures become fragmented on account of the obstinacy of exploiting industries and of short-term political trends. The fragmentation is shown by the wide variety of legal matters, which are decisive for the utilisation of natural resources, including their genetic makeup. The legal regulations on agriculture have already been addressed above. They need to be supplemented by norms on forestry and fishing. The law on industrial manufacturing processes, on marketing hazardous products – e. g. pesticides, fertilisers, chemicals – on intellectual property such as patents and trade secrets, on research institutions, on tort liability law, on waste disposal, etc. should also be discussed.

Without an overall view, government measures become fragmented because of the self-interests of resource users.

Owing to the cross-border development of biotechnology, an extremely important role is played by international trade rules, such as the EU regulations on the marketing of food and genetically-modified food and feed[4], the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures, the Cartagena Protocol on Biosafety, and the Nagoya Protocol on access to genetic resources and benefit-sharing, as well as several agreements on the protection of plant varieties and on patents, etc. The old and new regulations discussed in this report are based on political processes that produce strategic papers and implementation plans: biodiversity strategies, agriculture development programmes, biotechnology strategies, etc. They are also reflected in a variety of ad-hoc authorities, R&D institutions, think tanks and NGOs.

The increasing variety of techniques, effects, programmes, organisations and regulations may easily cause disorientation. The sectors tend to deal separately with their subject matters and their points of view. A general overview from which an overarching strategy could be developed, however, is difficult to obtain. The purpose of the approach suggested here is to define the key resource, then to systematically identify and assess its utilisation and impact, and – if necessary – to establish a set of laws governing it.

We propose to start by defining the key resource, then to systematically identify and assess its exploitation and impact and – if necessary – to provide a legal framework. This approach will make it possible to establish a common denominator for the types of utilisation, which are usually dealt with on a sector-by-sector basis.

4) Regulations (EC) 178/2002 and (EC) 1829/2003.

# 3

# The concept of the actor-centred approach to resources

The structural starting point for our approach to resources (Knoepfel 2007) is not biotechnology, but a resource: genetic programmes (see Chapter 5). This has the advantage of identifying, in addition to the opportunities and risks of the technology chosen, the utilisation potential of the resource, its ownership and the holding of the rights of utilisation on it, as well as the distribution of the benefits derived from its utilisation. It also alerts to the fact that the utilisation of resources is affected by cultural factors. Nevertheless, the techniques using genetic programmes are referred to, also from a resource-oriented perspective, as biotechnology.

Our approach to resources does not take biotechnology but a resource – genetic programmes – as its starting point.

It is to be noted that, unlike natural resources such as water, air, soil, forests, or animals, genetic resources do not become scarce as a result of their direct exploitation. It is true that this involves risks for humans and human health, but not through direct access (for instance when clearing a forest), because it is often enough to pick a few specimens of an organism of interest from which a whole R&D line can then be worked out. Rather, risks emerge as indirect results of R&D processes, for example when a genetically modified plant passes on its foreign gene to the environment, causing system disturbances.

Our approach centres on actors, because not only does it investigate the utilisation of resources focusing on its impact on certain tangible values (in particular benefits, risks, cultural factors, distribution), but it also takes into account the actors behind these effects, since the effects of the utilisation are not only objective processes, but are also caused, enjoyed, suffered and experienced by humans. Only when the public voices objections to all this individually and in the media is there a political basis for regulations and the need to involve the public in their formulation and application in an orderly manner.

The effects of the resource utilisation are caused, enjoyed, suffered and experienced by humans. Only when the public voices objections to all this, is there a political basis for regulations.

# 4

# The actors and their rivalries

For an analysis of the current and future debates it is necessary to identify the main actors who make direct use of genetic programmes or are indirectly involved with them. Mention should be made of:

- Public and non-profit institutions that conduct research in the fields of green biotechnology (agriculture), red biotechnology (pharmaceuticals and cosmetics) and/or industrial biotechnology (energy generation, data processing, etc.)
- For-profit companies that conduct research and development in the above fields
- Interest groups in the fields of agriculture, pharmaceuticals, cosmetics and industry
- Non-governmental organisations in the fields of consumer protection, environmental protection and ethics
- Authorities responsible for agriculture, economy and trade, health, environment, ethics, research and innovation
- Media
- Politics
- Churches and religious communities.

Various rivalries emerge among actors, around, for example, research funds, scientific prestige, profit opportunities, cultural assessments, management potential, health and environmental effects and much more. Underlying these rivalries is a conflict of a more fundamental nature, one concerning the limits of man's alteration of nature, in other words the dilemma between preserving genetic resources and creating new ones. While supporters of preservation insist that the genetic makeup resulting from evolution has enough potential to be raised and carefully improved by working on phenotypes (in particular, by breeding), proponents of creation maintain that it opens up a new world of artificial organisms which may ensure increasing levels of well-being and prosperity.

Various rivalries emerge among actors, around research funds, health and environmental effects, profit opportunities etc.

The conflicts over utilisation give rise to regulations.

In this report we try to find a solution to the conflicts among actors involved in the utilisation of genetic resources as well as to the fundamental conflict over the limits of man's alteration of nature, through five key questions. These are:

- Who should own genetic programmes and the results of the research and development conducted based on them?
- What social benefits do the use and modification of genetic programmes provide? What economic profit opportunities and inherent utility arise?
- What risks to society and the environment are posed by the use of genetic programmes, how can those risks be minimised and what risks may be taken considering possible benefits?
- Who should benefit from the use of genetic programmes?
- What limits do cultural and ethical factors impose on the modification and use of genetic programmes?

The conflicts over utilisation have given rise to regulations, which have to be analysed individually. Our top priority in a rational management of resources is, in principle, their sustainable exploitation. We advocate a “strong” version of sustainability, which gives priority to the preservation of the natural basis of life over short-term social and economic benefit.

Our focus in the following analysis is the sustainable use of the resource in question.

# 5

# Characterization of the “genetic programmes” resource

## 5.1 Conceptual scope

Since, as previously mentioned, the genetic makeup of organisms is becoming increasingly important for recent scientific and economic developments, it is recommended that it be understood and described in detail as a separate resource. It should be considered whether the term “genetic resources”, which was introduced by the Convention on Biological Diversity of 1992 (CBD), can be used in this broader context. The CBD defines “genetic resources” as any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.[5]

The “value” component referred to in the above definition has no particular distinguishing content because almost everything in this world has at least a potential value, even if only the value of the mere preservation of the resource itself. The “material”, “origin” and “units of heredity” components of the definition are more important. The “material” nature of the resource differentiates it from the knowledge about it. Of course, possessing that knowledge is not negligible, but knowledge is relegated to the category of utilisation processes, as the object and product of tradition – the CBD bases the protection of traditional knowledge of genetic resources on this – and of modern R&D.

The term “genetic resources”, introduced by the Convention on Biological Diversity of 1992 (CBD), is not sufficient in this broader context because it does not include artificial sequences.

The “origin” component of the definition refers both to nature as a source and to genetic engineering, which is also included because it is based on the alteration of natural organisms, while a large area of synthetic biology is not and is therefore not included. This is a new technology that radicalises genetic engineering by synthetically manufacturing cell contents (DNA, proteins) on an increasingly large scale, giving them new forms that do not occur in nature (Baldwin et al. 2012). The further this process of artificialization progresses, the further synthetic biology moves from its natural origins. Since, however, synthetic biology should be included in this analysis to a quite large extent, it is advisable to define the underlying resource regardless of the CBD terminology.[6]

We use the broader term “genetic programmes”, which also includes the products of synthetic biology.

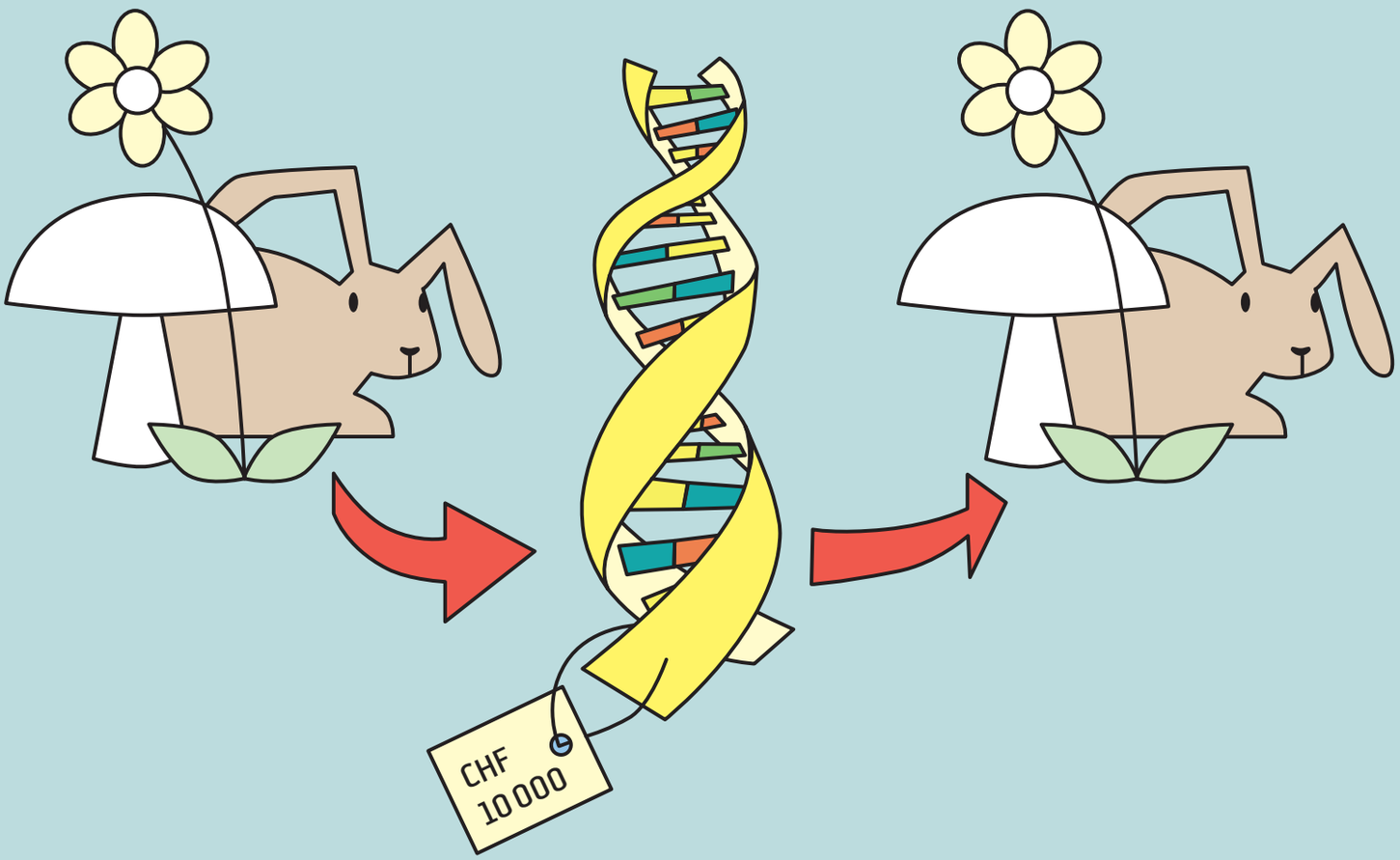
This also proves reasonable as regards the “units of heredity” component in the concept of genetic resources, because synthetic biology manufactures not only cells capable of hereditary transmission, but also cells that cannot reproduce themselves, as well as subcellular material, i. e. material found at an infra-cellular level, the so-called bio parts, which are not viable alone but are able to survive within host organisms. Since they are intended to be included in the spectrum of this approach, the definition of the resource should not be limited to units of heredity capable of reproduction.

We therefore propose to define DNA and RNA sequences as the sources of the socio-economic development to be analysed and to describe it as a genetic programme. It can be of either natural or artificial origin. It is normally found in cells or incorporated into them, but can also be produced and used separately at a subcellular level.

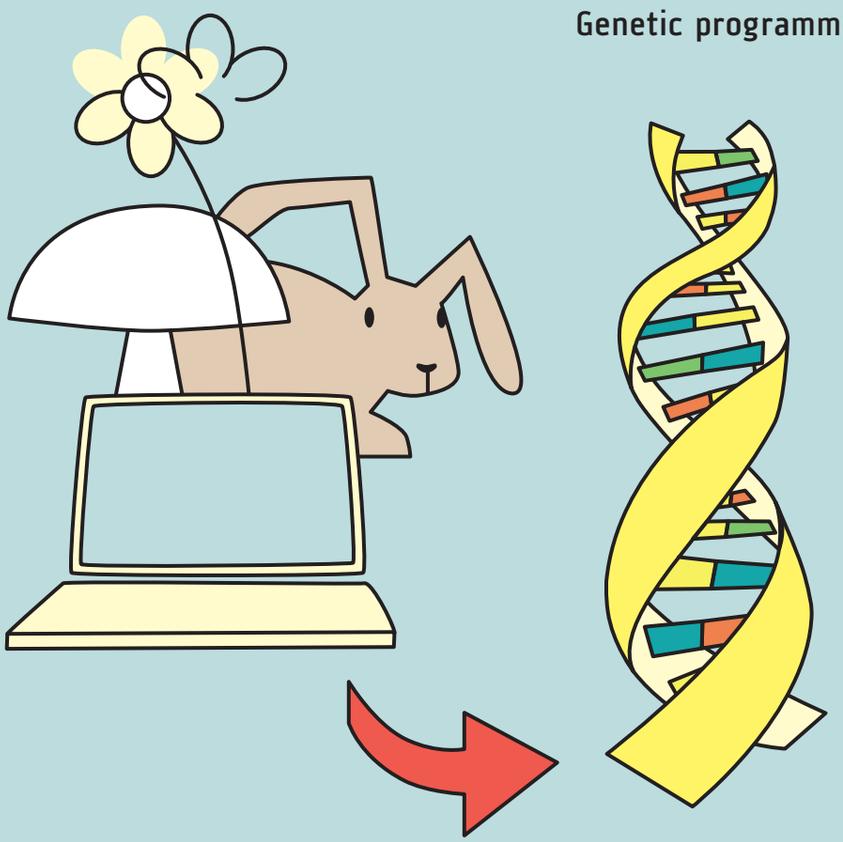
5) Combination of items 6 and 8 of Article 2 of the CBD.

6) It should be remembered that the definition of “genetic resources” according to CBD also comprises “other origin”. This may mean synthesis and artificial design. Since Article 15 (1) of the CBD recognises the “sovereign rights of States over their natural resources”, it can be concluded that term “sovereign rights” also refers to the genetic resources artificially created in a State. Thus, they could even be derived from the CBD.

Genetic resources




Genetic programmes



## 5.2 Materiality and originality of genetic programmes

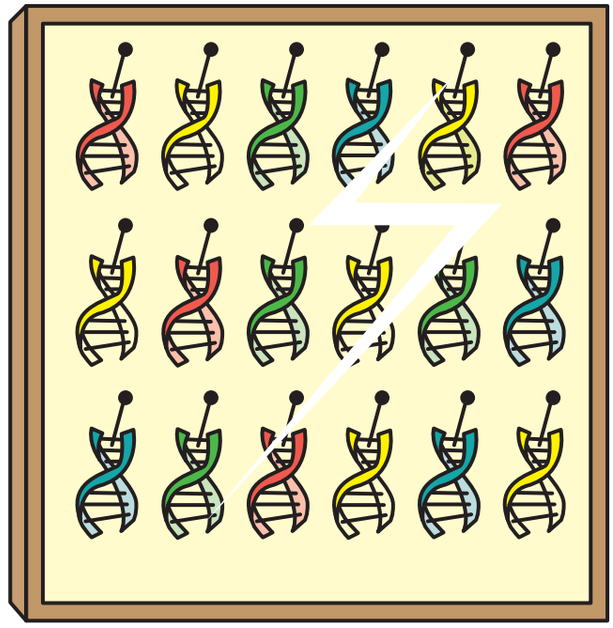
Genetic programmes are to be understood as real, existing matter and as their potential effect, as nature's objective, effective "information" and not merely as man's subjective intellectual knowledge about that information.[7] Of course, this knowledge is essential for understanding and using genetic programmes. The objective programme is visualised on a computer. If the genetic programme needs to be changed, first it is modelled on the computer. Some refined in silico programming makes many experimental steps of in vitro programming – i. e. programming in the lab – superfluous. Nevertheless, it should be noted that the resource at issue is an objective fact.

Genetic programmes are to be understood as real, existing matter and as their potential effect, not merely as man's intellectual knowledge about that potential.

The greater the proportion of synthetic and artificial design, the more chemistry-based the nature of the resource becomes. Life, however defined, whether as the ability to metabolise, the ability to grow, or the ability to reproduce, then appears only to be a property of certain combinations of chemical molecules (Church 2012). This contrasts with the "vitalist" idea that life is a primary force that has unfolded enormously during evolution (Schelling 1799, 80; Bergson 1941, 85, 103, 232). Although the mechanistic view of natural sciences prevails, there are questions to which it still can provide no convincing answer: Where does the life that chemical molecules are believed to contain come from? Can life be created chemically or mechanically? Even if this were possible, could the faint flicker of partial life-like functions – which can be obtained if need be – come close to the well-ordered diversity of "life's grandeur" (Gould 1997) created by evolution?

For these reasons we understand genetic programmes to be such that even if produced artificially, in origin they contain natural life that they cannot create alone.

7) Of course, the objective existence can also simply be thought of, but the content of that thought is different depending on whether a physical material or a mental construct is imagined. Spotting this difference has proved pragmatically useful. See the concept of "objectivity in parenthesis" of the constructivist Maturana (2000: 226 et seqq.)



## 5.3 Location of genetic programmes

Genetic programmes are contained in organisms, i. e. microorganisms, plants and animals, whether occurring in nature or artificially altered. In addition they are found in cell cultures or exist as independent subcellular units. Being a component of organisms, they are kept in the environment (in situ) or in an artificial environment (ex situ), such as botanical gardens or laboratories. Cell cultures, conversely, are entirely dependent on the laboratory environment (in vitro).

The place in which a genetic programme is found can be determined geographically and by state borders. Genetic programmes can also be exported and imported. This raises the question of to what extent genetic programmes from internal sources can be used, imported and exported in a given State, and to what extent they can be produced and marketed abroad under the control of that State, in natural or modified forms, as the case may be.

The place in which a genetic programme is found can be determined geographically and by state boundaries. Genetic programmes can also be exported and imported.

Switzerland, for example, uses genetic programmes available locally in the fields of breeding and of the genetic modification of seeds, livestock and microorganisms. Its R&D facilities maintain close contacts with foreign institutions. For a limited number of crop species, plant material is exchanged within the framework of the so-called Multilateral System of the International Treaty of Plant Genetic Resources for Food and Agriculture (ITGRFA) (Kamau 2013). For further plant species, for animal species and for microorganisms, exchange practices are included in a variety of rather informal transnational networks (Chiarolla/Louafi/Schloen 2013; Biber-Klemm/Temmermann 2011). Switzerland also possesses its own ex situ collections of plants, animals and microorganisms. In the future, collections of bio parts and recombined, i. e. new genetically composite, cells and organisms are likely to be added. Those collections provide an infrastructure and a "bank" to serve a variety of uses. But they are also costly to run, and their purposes must therefore be justifiable.

As far as genetic engineering is concerned, internal release experiments with genetically modified seeds are allowed very hesitantly because of public protests.[8] Commercial cultivation at this time cannot be authorised at all owing to the moratorium adopted by the Swiss Federal Assembly and extended to 2017. However, the Swiss R&D institutions, which are active in this field, perform release tests abroad. There they have also obtained authorizations for marketing genetically modified seeds, food and feed. For instance, Syngenta owns EU approvals for eight varieties of genetically modified maize.[9] The marketing of genetically modified products abroad is thus arranged and managed from Switzerland; however, those products are not necessarily in their home market.

Collections of organisms provide an infrastructure and a "bank" to serve a variety of uses.

We suggest that national and cross-border collections, exchange networks, and research and development activities related to genetic programmes in Switzerland be surveyed in a separate study and evaluated as to their performance and cost.

8) So far four release tests have been approved, namely those conducted in 1991 and 1992 by the research institute Changins (now Agroscope Changins-Wädenswil, ACW) with virus-resistant potatoes, those of 2004 performed by ETH Zurich with bad-smelling smut-resistant wheat and those of 2013, conducted at the University of Zurich with mildew-resistant wheat.

9) EU Register of Authorised GMOs, available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

# 6
# Utilisation processes

## 6.1 Techniques

Utere, fruere, fungere – the use of a thing, the taking of fruits and the transfer of the thing – are the typical uses of dead and living resources owned by a person, as defined in civil law since Roman times: a cow is used as a draught animal or for its meat, as a milk-producing animal it bears fruit, and it can be bought and sold. The "use" aspect has long included the modification of an object as well, to enable it to provide a greater yield. This modification has been radicalised by three new techniques, namely targeted breeding, genetic engineering and synthetic biology. They are summarised here under the term biotechnology.

Animal and plant breeding traditionally consists in selecting the best from among different offspring and letting them reproduce, thus exploiting naturally occurring mutations. However, more artificial and targeted methods have been developed that, without being genetic engineering as defined by law, achieve a depth of intervention similar to that of genetic engineering.[10] This leads to faster, safer performance, but it also increases the risks of adverse effects on animal welfare, consumers' health, the environment, etc.

10) Without explaining them in detail, we give only their names here: agroinfiltration, cisgenesis, intragenesis, oligonucleotide-directed mutagenesis, grafting, RNA-directed DNA methylation, reverse breeding and zinc finger nuclease. See Vogel (2012), p. 98.

**The depth of intervention of modern breeding techniques questions the boundaries between breeding and genetic engineering. We therefore recommend the reconsidering of these boundaries between by law defined genetic engineering and modern breeding techniques.**

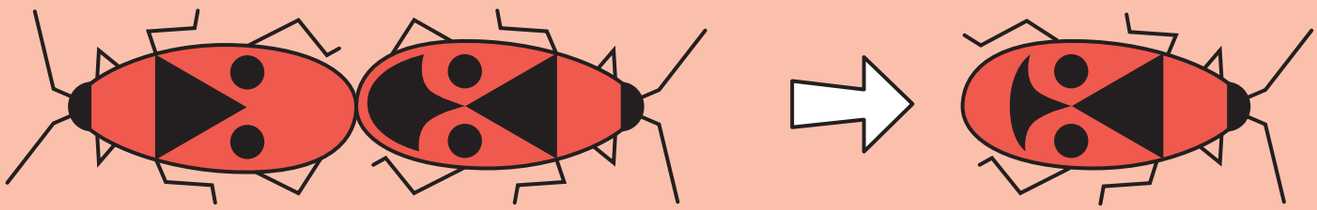
Classic genetic engineering is defined by law as the modification of the genetic material of organisms in ways that cannot be achieved through crossbreeding or natural recombination alone.[11] This is usually done by isolating certain genes that contain a programme for a desired characteristic (in other words, that "code" for it) from a parent organism and inserting them into a host organism. Take for example the gene coding for insulin, which is introduced into a bacterium from a pig and then produces insulin.

Synthetic biology radicalises this technique by fully removing a cell and replacing its content through genes from other organisms or with a new design. Xenobiology goes even further, replacing the four nucleotides (i. e. the bases adenine, thymine, guanine and cytosine), which are the only building blocks of all known genomes, with other bases. Modularization and mechanistic thinking are typical of synthetic biology: the highly complex genetic programmes are divided into modules, which code for certain properties. The cell is reduced to a minimum viable unit or synthesised as such (as a so-called protocell). The modules are then incorporated into this minimal cell that acts as a "chassis". This creates a new organism with – in theory – precisely defined functions and living conditions, which can be useful but also risky for the environment.

**Synthetic biology radicalises the redesign of existing organisms and questions therefore its boundary versus genetic engineering. We recommend the reconsidering of this boundary as well.**

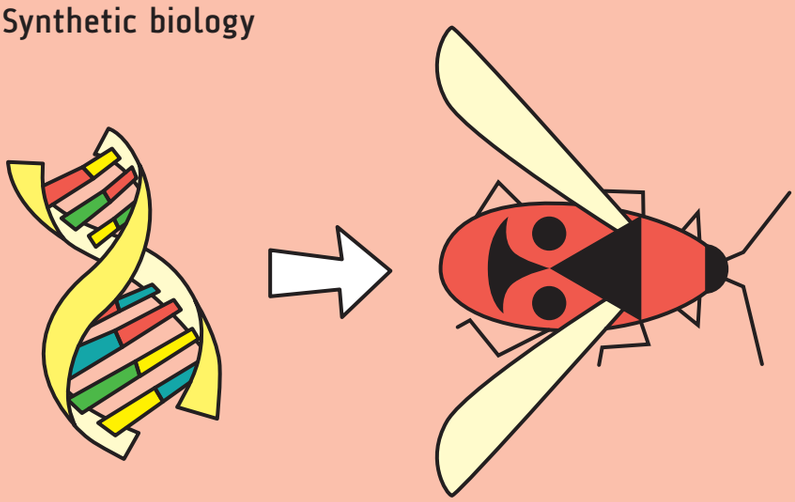
11) Art. 5 para. 2 Gene Technology Act.

Breeding



Genetic engineering

Synthetic biology



## 6.2 Research and development processes

The process of valorisation of genetic programmes using biotechnical methods presupposes some knowledge (taxonomy) about the host of a genetic programme and about its living conditions. It continues by breaking down the genome into its single genetic programmes (sequencing), goes on to manipulate the programme and obtains modified organisms that generate certain desired products or processes (known as derivatives).

## 6.3 Types of utilisation

The directions in which the valorisation of genetic programmes evolves can best be structured by dividing biotechnology into different types. Four areas are usually distinguished: green biotechnology is engaged in agriculture (e. g. seeds, animal breeding), red biotechnology deals with medicine and pharmaceuticals, white biotechnology with the industrial production of various products such as food, chemicals (e. g. acetone, butanol), drugs (e. g. aspirin), fuels (e. g. bioethanol), vitamins, amino acids and many more, and blue biotechnology with marine organisms (e. g. transgenic fish, heat-stable enzymes for detergents).

The following areas, which are structured based on the product generated, are of interest to Switzerland: agricultural products (including forest products and fish), energy, environmental management (e. g. plant protection by microorganisms), waste treatment (e. g. treatment of contaminated soils), medical and pharmaceutical applications (e. g. diagnostics, drugs), and cosmetics. In synthetic biology, the areas of interest are computing applications (biochips), applications for artistic purposes (self-organising and growing paintings and sculptures) and applications for creative experimentation and leisure.[12] The fact that the increasing standardisation of synthetic biology is creating a new industry that contributes to the R&D process through genome sequencing and DNA-synthesising should not be neglected.

In synthetic biology computing applications (biochips) are to be expected, in particular.

We recommend investigating further whether the lines of development of biotechnology in Switzerland offer the best opportunities for insights and utilisation, or whether other lines should be developed.

12) See Church/ Regis 2012, p. 189 et seqq., for the developments of synthetic biology in the US garage culture.

## 6.4 Public and private spheres of use

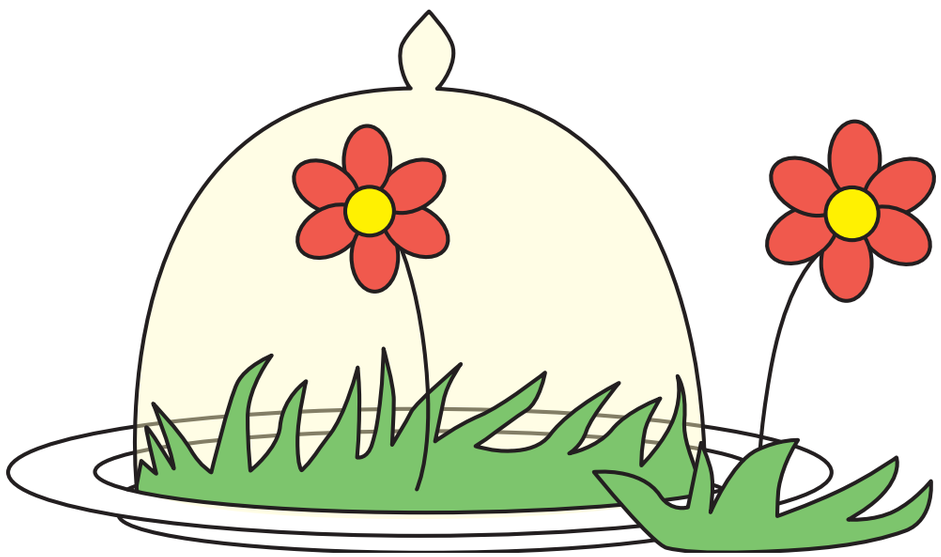
The concept of spheres of use should help determine whether the use of genetic programmes occur more often in the private than in the public sector. In Switzerland, as in most other countries, mainly public institutions conduct research. They conduct basic research to understand living organisms and life. Public institutions, however, are increasingly involved in the field of genetic manipulations and in the development of products. Conversely, commercial private institutions traditionally focus on application-oriented development activities. However, they also conduct basic research, in particular where it regards commercially exploitable genetic programmes.

In addition to the institutional dimension (private/public) and the dimension of contents (basics/application) of R&D, it is significant whether R&D results are privatised based on intellectual and factual property or are made available within the public domain.[13] Public institutions – such as universities – that traditionally work for the public domain are increasingly looking for the protection of intellectual property rights in order to generate profits from their R&D results. Those types of privatization counteract a trend towards strengthening the public domain, which makes research results available to the general public at low cost. This occurs increasingly through electronic tools, particularly databases. Research results can be structured into databases concerning the genetic level (such as GenBank for genes and UniProtKB and SwissProt for proteins) and into databases covering the organismic and ecosystem levels (such as the Global Biodiversity Information Facility GBIF) (Fedder 2013; Winter 2013). For synthetic biology, materials and bio parts databases are also available (Baldwin 2012). Private institutions are also largely involved in the maintenance of the public domain, as far as basic knowledge, which is not directly exploitable, is concerned. Because of this mix of functions, a clear difference between publicly and privately funded R&D is barely recognizable. This needs to be reconsidered and must bear consequences on public funding programmes.

Public institutions – such as universities – that traditionally work for the public domain are increasingly looking for the protection of their intellectual property rights in order to generate profits from their R&D results. Such types of privatization counteract the trend towards a strengthening of the public domain.

As a basis for political discussions and decisions, we recommend further investigation of the extent to which the R&D process aims at privatization or at bringing its findings to the public domain, as far as genetic programmes are concerned.

13) Public domain is defined as a body of knowledge, which is freely accessible to everybody and may be further developed. The public domain can also refer to material or products, which may then be used by anybody free of charge or for administrative fees only.



# 7

# Sovereign and property rights

## 7.1 General aspects

Property rights are to be distinguished from regulations on the use of property. Property in principle assigns a resource to an owner, who may bar others from using it and may resist government intervention in the use of the resource. Although the use may be limited by regulation, this is subject to proportionality and – if the property is seized – to compensation. Because of the importance of this basic assignment, the question of ownership must also be raised for genetic programmes.

An owner may bar others from utilisation. A State too has ownership of a resource if it may bar other States from its utilisation.

The question of ownership is relevant at an international level as the question of the sovereign rights of a State. They represent the fundamental attitude of one State towards other States, in that it may bar other States from the utilisation of its resources.

Sovereign and property rights are part of the fundamental conflict between the private and the collective spheres. This conflict over genetic programmes regards all forms in which the programmes appear in the process of valorisation, namely as a component of a host organism, as information resulting from R&D conducted on them, and as a modified programme in an organism which is marketed under certain circumstances. Appropriation or communality appear at an international level as trends towards sovereignty and/or the common good and at a national level as trends toward either private or common property. States are divided on the question of whether they practice appropriation or communality externally and/or internally (Chart 1).

States are divided over the question of whether they practice appropriation or communality externally and/or internally.

The design alternatives will be examined in even greater detail with reference to the three stages of valorisation in the following chapters.

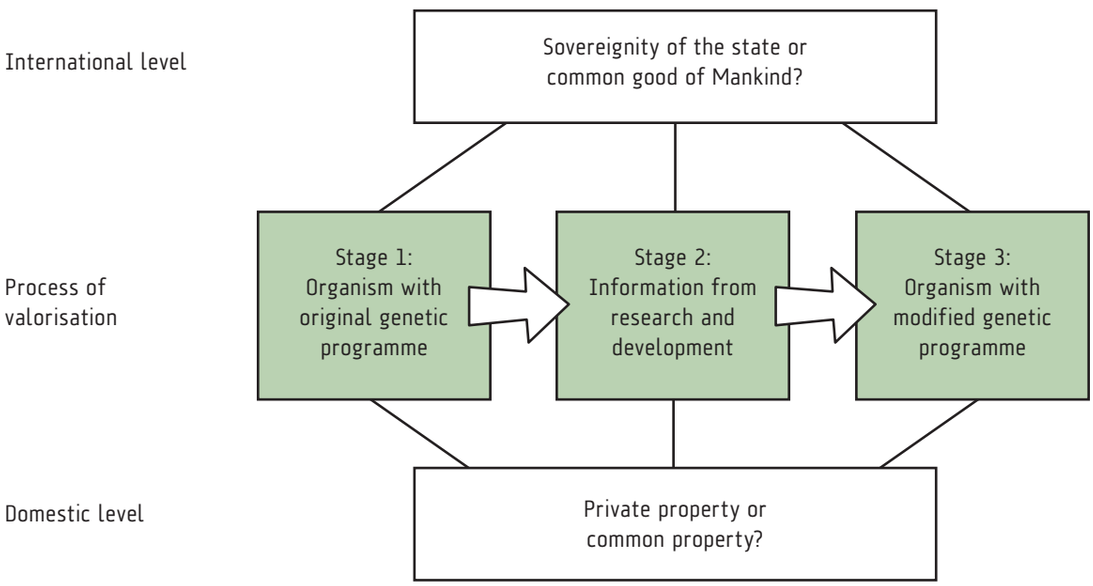



Chart 1: Sovereign and property rights in the process of the valorisation of genetic programmes. The stages 1 to 3 will be described in even greater detail in the following chapters.

## 7.2 Property rights on the original genetic programme

In compliance with the internationally acknowledged principle of the territorial sovereignty of States, the jurisdiction of each State also extends to the plants, animals and microorganisms living in its territory or coastal waters, as well as in its exclusive economic zone and continental shelf (Chart 1, Stage 1). With this principle traditionally applying to phenotypes, the decision as to whether the genetic makeup of organisms should be considered State property or public domain of Mankind remained a controversial issue for a long time. A valid argument in favour of the latter is that the genetic makeup of species is identical across borders and subject to only marginal local and individual variations, which, in any case, do not follow political borders. However, developing countries struggled to impose the predominance of State ownership and the CBD of 1992 recognised the sovereign rights of States over "their" genetic resources.[14]

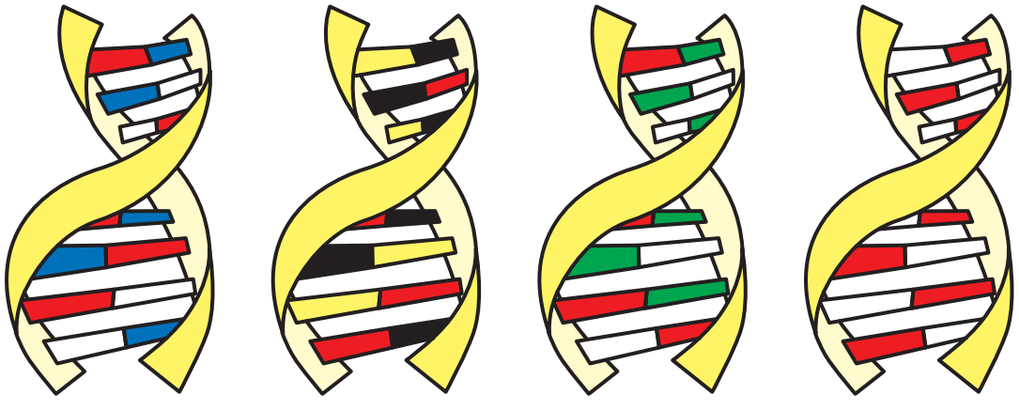
The decision as to whether the genetic makeup of organisms should be considered State property or the public domain of Mankind remained a controversial issue for a long time. Nowadays, States are attributed sovereign rights on their genetic resources.

No final decision has been made in Switzerland about the rights to ownership of genetic resources. The ownership of the plant rests irrefutably with the farmer cultivating it, who also materially owns the plant's genetic material. However, the genetic potential that is present in the plant is not a property and remains "unowned".

Access to genetic resources in Switzerland is permitted to non-proprietors, including foreign users, who can freely access, research and further develop the genetic resources present in the country. Nonetheless, the ownership of the plant or animal in which the genome is located must be respected, i. e. the genome may be extracted only with the owner's consent, unless such extraction is considered common practice. Obviously, users must also comply with environmental laws, including laws on the protection of rare plant and animal species and hunting regulations. In its capacity as a State that can grant access to its genetic resources (so-called "Provider State" according to the definitions of the Nagoya Protocol), Switzerland has exercised its sovereign rights so far by granting free access to these resources.

Up until now, non-proprietors and foreign users could freely access, research and further develop any genetic resources located in Switzerland.

14) Art. 15 (1) CBD.



## 7.3 Property rights on research and development based information about genetic programmes

The question of private or collective ownership arises also in connection with information obtained through R&D activities (Chart 1, Stage 2). A distinction should be drawn here between patent law and copyright.

**a) Patent law:** Information on gene sequences, that is DNA chains forming the genetic program, is patentable. In the past, this approach was advocated and also partially implemented for sequences, while today it is generally requested that the function for which the sequence codes be described.[15] Likewise, microorganisms that are identified taxonomically can be patented.[16]

Information on gene sequences, so DNA chains forming the genetic program, are patentable, on condition that a description of the sequence's function is provided.

A problem is posed by the fact that these are not inventions, but rather discoveries of natural phenomena.[17] As a rule, no absolute rights are granted for certain types of discoveries, as in the case of a chemical compound, a star, a mathematical formula and so on. This privilege could almost be seen as a violation of the equality principle. Furthermore, patent rights on discoveries are widely believed to hamper R&D activities in general (Rimmer 2008). On the other hand, one could hardly argue that no investments would be made in research if the findings could not be patented. For the basic research under discussion here is conducted to a large extent by publicly funded research centres, or at least this would be the case if private research were abandoned because of the impossibility of obtaining patents.

Patent rights on discoveries are widely believed to hamper R&D activities in general.

The unrestricted patenting of discovered gene functions actually reinforces the trend towards the modification of genetic programmes. At the root of these developments lies a lack of awareness of the nature of organisms and their environments that can only be understood and developed through a holistic approach.

Our general opinion is that discoveries regarding genetic programmes should be understood as improvements to the shared knowledge of society. We therefore recommend that Switzerland vote against the patentability of discoveries in international negotiations. Patents should be admissible only in the later stages of the process of valorisation of genetic programmes.

15) Art. 1 b para. 2 and Art. 8 c Patents Act (Federal Act of 25.6.1954 on Patents for Inventions)

16) Art. 2 para. 2 lit. b Patents Act

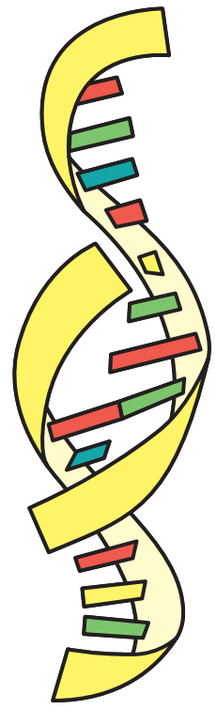
17) Patent laws in the USA exclude natural phenomena from patenting; see 35 U.S.C. § 101 in the Interpretation of the Supreme Court. Cf. the very clear distinction drawn in the case Association for Molecular Pathology, et al. v. Myriad Genetics, Inc. 569 U.S. (2013) and US Patent and Trade Mark Office (2014).

**b) Copyright:** Information on genetic programmes concerns not only patent rights, but also copyrights. Broadly speaking, patent law can be said to focus on the content of information and especially on its commercial applicability, while copyrights focus on the form of information and especially on its utilisation for publication. Also the private property right based on the copyright is seen in antithesis to collectivity or public domain. The opportunity exists for authors to surrender their intellectual property and make their information freely available to the general public, as for example in open access databases. Several templates are available for this purpose, e. g. the "Creative Commons Licence".[18] At first glance, this liberalisation may appear to be in favour of R&D processes. However, it should be considered that publishing media deserve some revenue to survive, insofar as they ensure the quality of information, provide archiving capacity, systematise information, make it more easily accessible etc., and need to be financed somehow.

Patent law focuses on the content of information and especially on its commercial applicability, while copyrights focus on the form of information and on its utilisation for publication.

18) http://creativecommons.org/licenses/by/2.5/au/legalcode

We recommend that the findings from basic research on genetic programmes should become part of the public domain as much as possible. However, provisions should also be taken to make sure that the costs for the unbiased and lasting storage and availability of the relevant data are covered.



## 7.4 Ownership of genetically modified organisms

Intellectual property rights can be claimed for organisms modified through either breeding or genetic engineering (Chart 1, Stage 3). Seeds are regulated by plant variety rights based on the law for the protection of new plant varieties, while patent rights apply to modified microorganisms. Animal species and plant varieties are not covered by patents.[19] Units at sub-organism level such as modified cells and modified gene sequences continue to be patentable.

Plant variety rights grant more limited absolute rights than do patent rights. Plant variety rights permit continuation of breeding (derogation for breeders) and growing of propagating material for own use (derogation for farmers).[20] Switzerland did not implement the clause of the Convention for the Protection of New Varieties of Plants of the International Union for the Protection of New Varieties of Plants (UPOV Convention) setting out that propagation for own use may be subject to a plant variety right-holder's fee.[21] The exemption of farmers from the payment of a propagation fee is appreciated because it supports the promotion of small-scale farming. We suggest examining the effects of this regulation in practice.

Plant variety rights apply to seeds, patent rights apply to modified microorganisms. Animal species and plant varieties are not covered by patents in Switzerland.

Patent law tends to overlap with plant variety protection rights. This happens mostly in four ways:

1. More and more often, gene sequences with specific traits are introduced in plants. If they are covered by patent, the patent extends also to the utilisation of the plant.[22]
2. When the introduced gene modifies the plant significantly, the latter becomes a product obtained with the help of microbiological processes. As such, the plant becomes patentable.[23]
3. Inventions that concern several plant varieties can be patented.[24]
4. The exclusion from patenting of "essentially biological procedures for plant production" and their products is increasingly being questioned. It is argued that traditional breeding methods – which are the reason for the mentioned exclusion[25] – have been replaced by modern and more accurate methods with a technical quality level that now equals that of microbiological methods.

When the introduced gene modifies the plant significantly, the latter becomes a product obtained with the help of microbiological processes. As such, the plant becomes patentable.

A similar trend can be observed in animal breeding. Unlike plant varieties, animal breeds do not enjoy sui generis protection rights, and this has given rise to complaints by some breeding companies. However, there have been several developments that have actually expanded patenting possibilities: first, patentability of individual animals that do not constitute an animal breed, as for example the oncomouse developed for carcinogenicity testing. Second, patentability of extraneous gene sequences which are transferred to an animal by means of microbiological procedures. Third, patentability of modified or discovered gene sequences that several animal breeds have in common and fourth, of the more advanced high technology breeding methods (Biber-Klemm/Temmermann 2011).

19) Art. 5 Federal Act for the protection of new plant varieties (Bundesgesetz vom 20.3.1975 über den Schutz von Pflanzenzüchtungen); Art. 2 para. 2 lit. b Patents Act.

20) Art. 6 lit. c and art. 7 Federal Act for the protection of new plant varieties.

21) Art. 14 para 2 UPOV Convention. Cf. Lochen (2007) p. 77.

22) Art. 8 b Patents Act

23) Art. 2 para. 2 lit. b Patents Act.

24) Art. 2 para. 2 lit. b Patents Act.

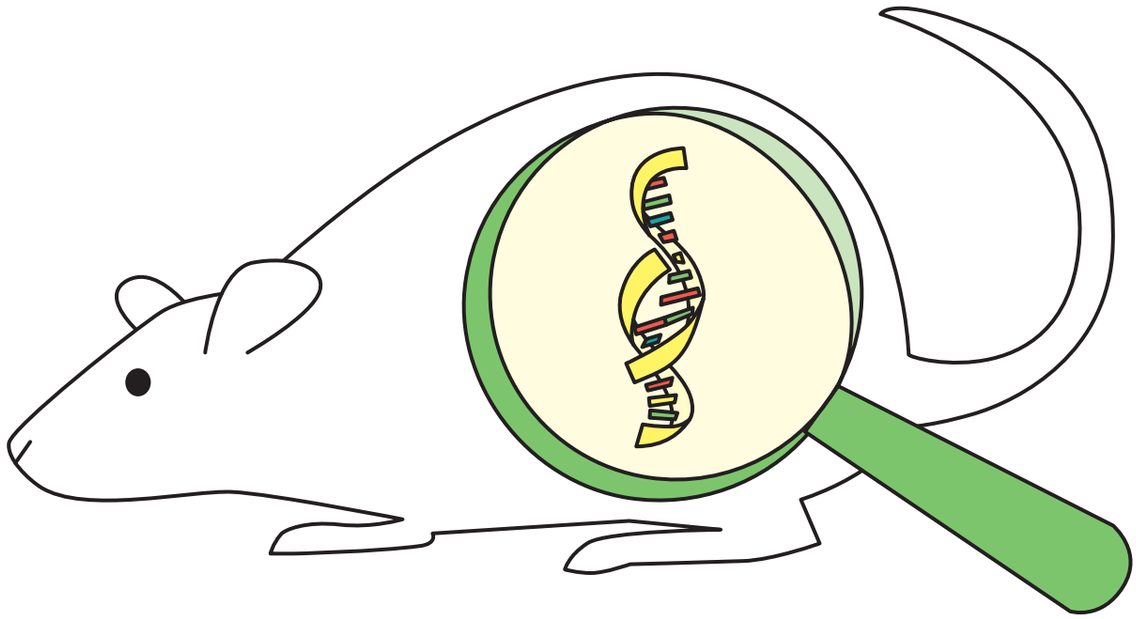
25) Art. 2 para. 2 lit. b Patents Act.

These developments have increasingly submitted the plant and animal realm to patent law with adverse consequences for small-scale farming, as the opportunities for own breeding have been reduced and the costs for seeds and breeder animals have risen. Besides shifting income opportunities, this trend jeopardises the very survival and breeding of traditional and diverse native breeds. Farmers wishing to propagate protected plant varieties can still do so. However, they need the authorisation of the patent-holder for a specific plant trait before they can sell the plants. Alternatively, they have to breed out the trait. If a farmer owns a patent for the plant variety, he can continue breeding in Switzerland;[26] however, authorisation before distribution is needed also in this case, unless all components covered by patent are bred out. Moreover, the modularity of traits and the presence of several patent-holders pose a problem for industrial breeding too, because of the need to obtain an increasing number of approvals from other subjects. Patent pools provide a way out of this problem. However, patent pools lead to closed shops that are shielded against competition and resemble an oligopoly. As a result, small farmers remain largely excluded from such patent pools (Gelinsky 2013). Intellectual property rights owners are progressively taking possession of living things, thereby accelerating the ongoing industrialisation of farming with all its critical social and environmental consequences.

Intellectual property rights owners are progressively taking possession of living nature, thereby accelerating the ongoing industrialisation of farming with all its critical social and environmental consequences.

26) Art. 9 para. 1 lit. e Patents Act.

We therefore recommend exploring ways of limiting patentability in the plant and animal domains.



# 8

# Strategies for the promotion of research and development activities

Switzerland promotes R&D activities on genetic programmes by providing project-based financing and a research infrastructure. Other forms of funding are provided in parallel by the private sector. All types of applications are supported by either private or public funding. It is difficult to have a complete overview of these activities. Due to the very dynamic development of biotechnology, there is a risk that research funding and researchers are lured into following fashion hypes. Especially the synthetic biology is often proposed as the solution – in theory – to many problems (Schummer 2011). Importantly, the promotion of research on novel biotechnologies should be linked to research on their effects on health and the environment, as well as to studies on the social and cultural perception of these innovations. The National Research Programme 59 on the benefits and risks of the release of genetically modified plants is a favourable example that could be replicated for modern breeding and synthetic biology.

It is difficult to get a complete overview of the funding activities for research on genetic programmes.

In order to ensure a balanced distribution of research funds, we recommend introducing a pluralistic decision-making mechanism. The Swiss Agronomy Research Board may provide a model example:[27]

"(1) The permanent Agronomy Research Board is appointed by the Federal Council and includes up to 15 members. Stakeholders must be represented appropriately on the Agronomy Research Board, which includes representatives from among farmers, consumers and scientists.

(2) The Board issues recommendations to the Federal Council on agronomic research and its long-term planning."

Representatives from the field of environmental interests are however missing on the Board. Nonetheless, the Confederation is legitimated to promote the cultivation of "ecologically valuable crops" and the breeding of livestock that is "adapted to the country's natural conditions".[28]

Due to the very dynamic development of biotechnology, there is a risk that research funding and researchers are lured into following fashion hypes.

Public research institutes usually choose the subject matter and research procedures for their R&D activities independently. However, these R&D activities are increasingly being used to serve governmental or private interests. As already mentioned, they are also increasingly pressed to patent their findings. This is an undesirable development.

Funding for R&D in biotechnology should critically reflect its benefits and be accompanied by studies on the side effects on human health and the environment. We recommend that funding programmes should be developed involving representatives of environmental interests. Besides programme driven research, freely initiated research should continue to play a major role. Governmental and private priorities should not interfere with the principle of self-determination of research during selection and conduction of R&D activities.

27) Art. 117 Agriculture Act (Federal Act of 29.4.1998 on Agriculture).

28) Art. 140 para. 1 lit. a and art. 141 para. 1 lit. a Agriculture Act.

# 9

# Regulation of the social benefits

In market economies, the value of a product is usually determined by the free interplay of supply and demand. State intervention is limited to protecting market players from unfair competition, e. g. by prohibiting misleading advertising or imposing labelling standards to ensure that consumers are provided with product information. However, with respect to specific products, the State is also responsible for quality controls. Public supervision is introduced when the quality of a product is crucial for the public interest, as with medicines for human use or pesticides for the protection of plants.

Quality testing procedures have been developed for the use of genetic programmes in seeds and livestock. Quality standards ensure that farmers and the population are provided with high quality material and sustenance respectively (Garbe 2012 no. 106). Quality testing procedures are organised in three steps: approval and registration of a novel variety in the National Catalogue of Varieties; recognition/certification of propagated seeds of the approved variety; recommendation of specific varieties for cultivation. To be included in the National Catalogue of Varieties, a variety must meet the criteria of distinctness, homogeneity and stability.[29] These procedures are aimed at checking the benefits of varieties, though they focus on their industrial applicability more than on their inherent quality.[30] A further requirement is, however, that the variety "should prove more suitable for farming or use than the other existing varieties".[31] Compliance with this requirement is assessed in cultivation tests.[32] The examined parameters are: agronomic properties (e. g. stability, ripening period, security of yield in different weather conditions); resistance to pests; productivity and product usability for different purposes (e. g. protein content, baking quality).[33]

We are undecided as to whether the above-menioned criteria are primarily instrumental to protecting and increasing productivity, as well as to ensuring an efficient response to consumer expectations, or if they also reflect environmental concerns (e. g. the ability of the variety to achieve good yields also with a reduced use of plant-protection products, growth accelerators and chemical fertilisers). Environmental considerations do seem to be taken into account, insofar as the suitability of plants for cultivation and use in Switzerland is tested under conditions of extensive farming, i. e. without any use of fungicides or growth regulators. This implies that the seeds can also be used in integrated production, with an optimised use of plant protection agents and fertilisers. In the past, an additional test was conducted in conditions of organic farming, i. e. with no use of herbicides or commercial nitrogenous fertilisers. This test was suppressed after the evaluation of the results of plant variety examinations over a number of years showed that no clear differences could be detected in the ranking of varieties between the extensive farming and the organic farming trial network.[34] However, it should be pointed out that in addition to the test under extensive farming conditions, a test under intensive farming conditions – including the use of fungicides and growth regulators – is also conducted in some cases and the final evaluation for variety recommendation combines both test results.[35]

The State conducts quality controls on products of public interest (pharmaceuticals, pesticides, etc.). Tests on genetically manipulated seeds and livestock ensure that farmers are provided with high quality material and consequently that the provision of sustenance to the population is guaranteed.

We therefore recommend investigating the agro-ecological impact of the Swiss variety testing method more closely. As a preferred option, a comparative study should be conducted with selected EU countries.

The Swiss testing system could prove, despite possible shortcomings, comparatively more developed from an environmental perspective. If this is true, Switzerland may not be ready to recognise the varieties in the EU Common Catalogue of varieties[36] without further scrutiny.[37] The non-specific and unambitious wording used in the formulation of the EU principle of "satisfactory value for cultivation" gives rise to concerns.[38]

29) Art. 5 para. 1 lit. a Ordinance on the production and marketing of vegetable propagating material (Verordnung vom 7.12.1998 über die Produktion und das Inverkehrbringen von pflanzlichem Vermehrungsmaterial).

30) See how these three criteria are interpreted by the UPOV (2002).

31) Art. 5 para. 1 lit. b Ordinance on the propagating material. In EU law, this corresponds to the criterion of satisfactory value for cultivation and use, see art. 4 para. 1 and art. 5 para. 4 of Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, OJ L 53, p. 2.

32) Directives of the Federal Office for Agriculture (FOAG) on the inclusion of varieties in the National Catalogue of Varieties Bern, July 2009.

33) Directive on seeds and seedlings of the Federal Department of Economic Affairs, Education and Research (EAER), Annex II. Testing is conducted by Agroscope.

34) Information provided by the Federal Office for Agriculture.

35) Federal Office for Agriculture (2008), p. 36.

36) Cf. Directive 2002/53/EC.

37) Art. 5 para. 1 of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products (Agriculture Agreement) of 1.6.2002 as subsequently modified on 1.6.2009.

38) See art. 5 para. 4 Directive 2002/53/EC: "The value of a variety for cultivation or use shall be regarded as satisfactory if, compared to other varieties accepted in the catalogue of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived therefrom. Where other, superior characteristics are present, individual inferior characteristics may be disregarded."

Cultivation recommendations also constitute an issue. Recommendations are based on an accurate assessment of information on varieties and are also tailored specifically to the geographical conditions of a country.[39] Cultivation recommendations for wheat in Switzerland, for example, include about 25 wheat varieties, out of a total of 4000 varieties inscribed in the Common Catalogue of varieties and the Swiss National Catalogue. These recommendations are not officially mandatory, but farmers are indirectly pushed to comply with them if customers so require or product certificates use them as a reference, as in the case of the "Swiss Garantie" certificate of origin.

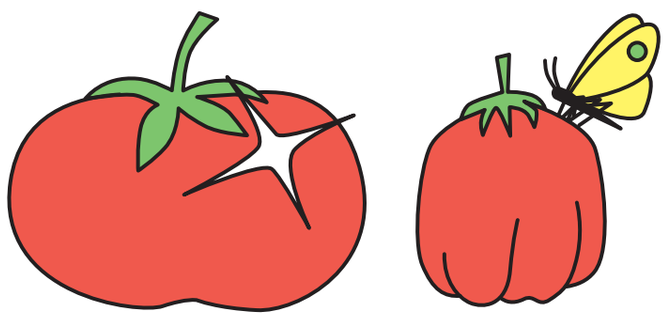
Since the great majority of farmers do follow the informal cultivation recommendations, we recommend examining the actual purpose of the official catalogues of varieties. It might well be that their role as quality guarantors has been superseded by the more applied cultivation recommendations.

When analysing benefits, one should consider that variety approval procedures constitute a barrier to market entry that usually proves insurmountable for small farmers because of the associated costs for the provision of evidence. This creates a de facto monopoly to the advantage of those seed producers that can afford to pay for the costly administrative approval procedure. At the same time, it also represents a threat to the diversity of native breeds, varieties and crops. A welcome change in this respect was the introduction of the so-called "approval for niche varieties" in Switzerland in 2010, exempting determinate seeds from meeting the requirements of distinctness, uniformity and stability. [40]

We recommend examining whether the niche approval for native breeds is serving its purpose or whether a further extension of approval opportunities should be provided for small-scale farming.

39) Cf. Hiltbrunner et al. (2014)

40) Art. 29 Ordinance on seeds and seedlings of the Federal Departement of Economic Affairs, Education and Research (Verordnung des WBF vom 7.12.1998 über Saat- und Pflanzgut von Acker- und Futterpflanzen- sowie Gemüsearten).



# 10

# Regulating threats to health and the environment

Despite achieved benefits, R&D as well as economic activities on genetic programmes may also pose risks to health and the environment. The proposed approach to genetic programmes does not imply that the risk analysis can be conducted at the molecular or cellular level only. Quite the opposite, as a change at this lower level has an impact also on higher levels such as the individual organism, populations and ecosystems. In fact, the interactions between the genetic level and several other factors occurring at other levels should be taken into consideration.[41]

41) See the example of Bt-Mais and the risk analysis by Breckling/Böckmann/Reuter (2012).

42) Art. 29a Environmental Protection Act (Federal Act of 7.10.1983 on the Protection of Environment)

43) Art. 5 para. 1 Ordinance on the propagating material

44) Cf. the study conducted by the Canton of Zurich upon commission of the Federal Office for the Environment (2012) "Grundlagen für die Klärung offener Fragen bei der rechtlichen Regulierung neuer Pflanzenzuchtverfahren".

## 10.1 Risk control in genetic engineering, breeding and synthetic biology

So far, the strictest control system has been put in place for genetic engineering. This system is based on the Genetic Engineering Act that provides essentially the same level of protection ensured by the corresponding EU law. If not employed in closed systems, genetically modified products are submitted to an accurate risk analysis before being released and marketed.

Compared to genetically modified products, bred plants and animals are subject to fewer controls with respect to the risks they pose to health and the environment, although breeding methods are becoming increasingly invasive and their related risks are increasing. For example, a rapeseed that has acquired insecticide characteristics, not through genetic engineering as defined by the law but rather through selective mutations, could transfer the gene responsible for this characteristic to wild varieties via pollination. Likewise, it might pose a risk to the health of consumers under certain conditions. The Environmental Protection Act sets out that organisms can be modified only if this does not cause adverse effects to the environment and human beings and upon condition that biodiversity is preserved,[42] but the required risk assessment is significantly less demanding than controls imposed by the Genetic Engineering Act. Similarly loose controls are imposed by variety approval regulations, which set out that in addition to examining the distinctness, homogeneity and stability of a plant variety, it should also be assessed whether such variety "proves more suitable for farming or use than the other existing varieties".[43]

Surprisingly, bred varieties and animals are subject to fewer controls with respect to the risks they pose to health and the environment in comparison to genetically modified organisms, although breeding methods are becoming increasingly invasive.

We therefore recommend extending the scope of the Genetic Engineering Act to the most invasive breeding methods, or improving the risk assessment requirements for such methods in the existing environmental and variety approval legislation.[44] Moreover, risk assessment models should be tailored to the specificities of selective breeding methods. A more detailed study is required on the state, benefits and risks of the new breeding methods that radically modify the genome.

The need might arise to extend the scope of the Genetic Engineering Act also to synthetic biology. As mentioned before, the Genetic Engineering Act deals with modifications in organisms. Synthetic biology works differently, because it reduces the source organism to a minimal life-sustaining cell that becomes a chassis into which an artificial system of modular genes is integrated. Certainly, this technology cannot be said to modify an organism, as it is becoming increasingly oriented towards the creation of novel organisms. The novel organism is not designed by nature but at the computer, and instead of being constituted by the available genes, it is generally synthesised chemically.[45]

The Genetic Engineering Act regulates the modification of organisms and not their creation.

It should not be excluded that products of the synthetic biology, which are supposed to live only in artificial environment, might interact with the natural environment and cause damage.

The risks posed by synthetic biology have barely been identified and examined. Because of the increasing artificiality of the produced formations, it is often assumed that they can only survive and reproduce, if ever, in artificial conditions. This "orthogonality", i. e. total extraneousness to natural conditions, is especially pronounced in xenobiology, which goes so far as to replace the four basic components of DNA. However, it should not be excluded that some products obtained through these technologies might interact with the environment and cause damage. It is therefore questionable, that the Swiss Academies of natural and engineering sciences should deem it necessary to take measures only in 5 to 10 years' time.[46] By then, path dependencies may have already been established which, we believe, might pose an obstacle to an objective and detailed risk analysis.

45) See the detailed and non-academic explanation by Baldwin et al. (2012).

46) See Swiss Academy of Sciences and Swiss Academy of Engineering Sciences (2010), p. 22. An opinion in favor of a concurrent risk analysis was expressed by the Federal Ethics Committee on Non-Human Biotechnology in its 2010 report.

We recommend starting studies on the lines of research in synthetic biology that are most likely to pose risks to human beings or the environment, with a view to including them in the scope of the Genetic Engineering Act.

Should these lines of research be made to fall under the scope of the Genetic Engineering Act, questions may arise as to whether the currently used risk assessment methods are suitable to assess the risks posed by synthetic biology. The answer should be no: when this discipline works within closed systems, risk classes and confinement systems should be gauged accordingly. A totally new assessment approach must be developed for any instance that includes an output in the environment. Traditionally, the core criterion for genetic engineering risk assessment has been familiarity, i. e. the risks of genetic modified organisms (GMO) are usually derived from the risks of the parental organisms (the donating and the recipient organism).

Traditionally, the core criterion for genetic engineering risk assessment has been familiarity. This criterion will be unsuitable if, like in case of products of the synthetic biology, the relevance of the parent organisms is minimized.

It is generally assumed that the risks of the derived organism are small when the risks of the parental organisms are small too. The application of this criterion to genetic engineering is controversial, as it proceeds merely on the basis of addition and neglects the dynamics ensuing from the combination of foreign genes. And it is completely unsuitable for synthetic biology, where the importance of parental organisms is reduced to a minimum or even totally suppressed (Winter, to be published). The potential risks that are most likely to occur and need to be examined more closely might be inferred from the characteristics of the minimal cell, the modular bioparts it incorporates and the system design of the novel organism.

We recommend developing new risk assessment methods that are specific to synthetic biology. Such methods should identify appropriate tests to be conducted on the produced organisms.

## 10.2 Evaluation of residual risks and benefits

Another issue that concerns all biotechnologies considered here is the risk assessment stage. As a rule, the result of risk assessments is that the risk cannot be ruled out altogether, although the hazard is usually rated to be "uncertain", "unlikely", with "low likelihood", "negligible", etc.[47] The wording used warns us that the evaluation in the risk analysis requires closer scrutiny. The risk assessment should contain at least some mention of the fact that the tested organism also provides some benefits; were this not the case, it would not make sense to accept an even remotely likely hazard. However, as a rule these benefits are not explicitly described and supported by evidence. A description of the benefits should be demanded, as the effects of GMOs on the environment are highly complex and there will always be a certain degree of uncertainty, which should not be tolerated unless the GMO generates a measurable benefit.

**Whenever a risk assessment comes to the conclusion that the remaining risk is uncertain, unlikely or negligible, we recommend requesting that the usefulness of the organism examined also be described and justified in detail.**

An agronomic and ecologic benefit would be acceptable, such as the reduction of artificial fertilizers and chemical plant protection products (v. Kries/Winter 2011). It remains to be seen whether the two main lines of development in the genetic engineering of plants – resistance to insects and herbicides[48] – really do provide such benefit: pest resistance can result in pests developing immunity, while herbicide resistance incentivizes the use of larger quantities of herbicides in addition to combining two environmental hazards, namely genetic modification and the use of chemicals (Then 2014). An alternative could be found in some kind of "soft genetic engineering" that fits into the agricultural and environmental cycles; in the example of herbicide resistance, soft genetic engineering should not confer the plant the ability to survive chemical herbicides, but rather provide it with a growth advantage over the weeds.

47) See the formulation in Scientific Opinion on application (EFSA-GMO-CZ-2008-54) for placing on the market of genetically modified insect resistant and herbicide tolerant maize MON 88017 for cultivation under Regulation (EC) N° 1829/2003 from Monsanto, EFSA Journal 2011: "The EFSA GMO Panel concludes that potential adverse effects of maize MON 88017 due to the expression of the Cry3Bb1 protein to non-target terrestrial (plant- and ground-dwelling), soil and aquatic arthropods are expected to be negligible in the context of its proposed uses." "If subjected to appropriate management measures, the cultivation management of maize MON 88017 is unlikely to raise safety concerns for the environment." "Moreover, scientific uncertainty related to the appropriateness of the 'high dose/refuge strategy' in delaying resistance evolution in Western corn rootworm remains."

48) Insect resistance means that the plant releases an insect-killing poison, while herbicide resistance means that the plant is insensitive to some noxious substances.

## 10.3 Coexistence of genetically modified crops with GMO-free farming

Although they do not necessarily constitute a direct health and environmental hazard, genetically modified organisms released into the environment can cause economic damage when transgenes – i. e. genes taken from other species – are transferred by pollination to neighbouring fields cultivated with the same crops. When this happens, farmers from the neighbouring fields are no longer able to market their crops as GMO-free, and if the modified crop variety has not been approved yet, they can find themselves in the position of having to apply for a marketing authorisation pursuant to the Genetic Engineering Act because of the presence of genetically modified units in the harvest.[49] Some countries have tried to address the issue with coexistence regulations. Generally, these regulations prescribe that a certain distance must be maintained between GMO fields and fields cultivated with standard crops. The coexistence regulations are also discussed in Switzerland.[50] However, this solution relies on reconcilement between diverging individual farmers and may give rise to conflicts at a local level.[51] These conflicts could be reduced minimized by determination of whole areas with or without GMOs, whereby the determination could be achieved through voluntary agreements or spatial planning regulations, such as Landscape plans, space planning instructions or future agronomic plans.

**The conclusion of voluntary agreements for the coexistence of GMO and GMO-free farming through the creation of GMO-free areas should be encouraged. Additionally, we recommend considering spatial planning solutions.**

Such planning instruments raise some concerns with respect to their compatibility with the free-trade principles of EU and WTO regulations. Ultimately, such objections can be set aside, because planning does not interfere with the marketing of genetically modified products; it merely regulates their use and is objectively required to ensure coexistence between opposite farming methods (Epiney 2011).

The strategy of coexistence could prove a way to prevent the economic disadvantages of genetic engineering from impacting on GMO-free farmers. However, this strategy cannot be ecologically effective in the long term for two reasons: first, organisms obviously do not comply with crop separation rules and second, coexistence entails significant costs for GMO farming both during cultivation and in the processing and supply chain. In other words, there is no way out of the fundamental dilemma on whether and how the release and marketing of GMOs should be authorized. The recommendation above is thus further corroborated: besides considering risk minimisation, a motivation illustrating the advantages derived from GMOs should also be provided and a "soft" version of genetic engineering should be adopted (Winter 2011).

Since the coexistence of GMO and GMO-free farming has proven to be ineffective and economically unsustainable, the question arises as to what criteria should be used to judge whether and how the release of GMOs should be authorized.

49) According to the case law of German courts, see VG Augsburg, sentence of 29.3.2011 (Az. Au 1 K 10.947).

50) Cf. draft of an Ordinance considering measures in the agriculture sector for coexistence of genetically modified plants and non-modified plants (Gentechnik-Koexistenz-Verordnung, KoexV, 30.1.2013). During the consultation process, a large majority of the involved stakeholders generally argued against GMO farming in Switzerland. On the basis of this feedback, the Federal Offices for the Environment and Agriculture developed new options that were discussed with the involved parties during workshops held in June and July 2014.

51) See also the draft proposal for an amendment to the Genetic Engineering Act of 30.1.2013, which provides two models for the establishment of "GMO-free farming areas": either the cantonal authority designates an area as GMO-free upon request of a voluntarily established entity, or the designation is made upon the Canton's own motion and the cantonal authority also appoints a competent body (cf. Art. 19e of the draft proposal). Also this draft proposal was included in the mentioned consultation.

## 10.4 Should foreign investments be subject to control?

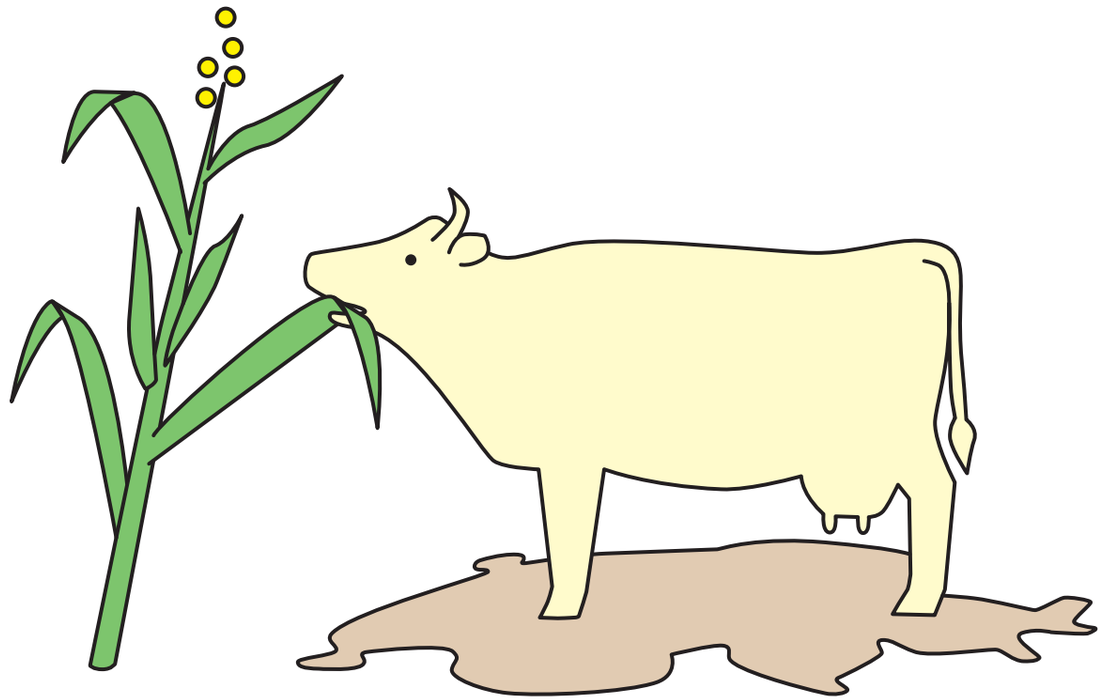
Looking at Switzerland, if one adds up to the domestic use of genetic programmes their use on the part of Swiss enterprises globally, the resulting potential is huge in comparison to the size of the country. The leading sectors are seed production and the pharmaceutical industry. Swiss corporations operating in these sectors have set up a broad global network of foreign subsidiaries that are responsible for R&D and the production of marketable products. For example, Syngenta controls 9 % of the global commercial seeds market, ranking third behind Monsanto (27 %) and Du Pont (Pioneer) (17 %).[52] Markets are supplied both through exports and through direct foreign investments.

The foreign but Swiss-controlled production of genetically modified organisms can result in paradoxical situations. For instance, Syngenta has applied to the European Commission for authorisation to import and market a maize variety for food and feed uses containing five genetic modifications.[53] However, Syngenta did not apply for a cultivation permit. The most likely explanation is that Syngenta is aware that the cultivation of GMOs in the EU and in Switzerland meets with public opposition because of the potential environmental risks (e. g. damage to non-target organisms) or contamination of other maize fields cultivated with conventional or organic methods. Hence, Syngenta prefers to apply for and obtain cultivation permits in other countries, where no such public concerns are expressed.[54] As a result, the modified maize variety will be cultivated in countries that impose less strict conditions for its subsequent importation into the EU – and Switzerland, if Swiss authorities lean their market authorisation on that of the EU. The question is whether Switzerland should oblige companies based in its territory to comply with Swiss regulations in their direct foreign investments.

Genetically modified seeds can be cultivated in countries that impose less strict conditions and are then imported into the EU – and Switzerland, if Swiss authorities lean their market authorisation on that of the EU.

This could be legally objectionable and contrary to the principle of territoriality,[55] according to which the laws of the recipient country govern direct investments. However, territoriality is no longer understood as an absolute principle; it is not considered to be violated if activities abroad have effects on the home country (Müller/Wildhaber 2001, p. 398 et seqq). Its relativity is especially apparent in environmental law and in its scope, which is acquiring an increasingly transnational dimension because natural processes abroad are interrelated with national ones and because environmental impacts in one country can have repercussions in another country. Let us suppose, by way of example, that traditional farming in Latin America were replaced by large plantations of soya beans, eucalyptus and the like because of cultivation of GM plants: the resulting effects on the global climate would backfire against the investor countries. These effects would also affect Switzerland and therefore allow introducing counteractive measures.

Seed production and pharma multinationals seated in Switzerland have set up a broad global network of foreign subsidiaries that are responsible for the development and the production of marketable products.



52) Berne Declaration (2014a)

53) Application for authorization of genetically modified Bt11 x 59122 x MIR604 x 1507 x GA21 maize for food and feed uses, import and processing submitted under Regulation (EC) N° 1829/2003 by Syngenta (EFSA-GMO-DE-2011-99).

54) Cf. Berne Declaration (2014b) p. 22 et seqq.

55) According to the territoriality principle, the jurisdiction of a State (including its legislation, administration and case law) only extends over that country's territory.

## 10.5 Should the production of imported products be subject to controls?

A related question is whether Swiss law should also regulate the production methods for imported products even when Swiss companies do not control their production. To that end, a control could be exerted through the domestic pull of demand for such products (so-called process and production measures or ppm, in the terminology of international trade law). Controls may include verifying whether imported products obtained with the use of biotechnologies have caused environmental damage in the country of origin during the production phase. A less obtrusive control would consist in verifying whether the imported item was produced in the exporting country in compliance with the locally valid regulations. The EU regulation on timber imports sets an example here.[56] From the legal point of view, a compliance control can be conducted on the importer's obligation of due diligence. In practice, the lawfulness of the tree harvesting activity is not actually verified. Alternatively, the importing country could impose its own standards, making up for any substandard requirements in force in the exporting country. An example of this is the EU regulation on biomass imports.[57]

When importing biotechnical products, their production process in the country of origin could be verified in order to see if it has caused any environmental damage or at least if the legal provisions in force have been observed.

Another example is provided by the case of hormones in meat. The EU import ban on beef from animals treated with growth-promoting hormones was judged in the WTO dispute settlement procedure only in relation to the possible presence of hormone residues in meat that is liable to pose a health risk for consumers.[58] The underlying issue is that the breeding method used for the cattle is inappropriate for the species. Interestingly, this consideration was not made in the settlement procedure, although it would have been appropriate to address this aspect as well.

We suggest starting a political debate on this topic and exploring through studies whether it would be advisable to incorporate production standards in import regulations for biotechnical products.

56) EU regulation no. 995/2010 of the European Parliament and of the Council of 20.10.2010 laying down the obligations of operators who place timber and timber products on the market, OJ L 295 p. 23, articles 4–6.

57) Directive 2009/28/EC of the European Parliament and of the Council of 23.4.2009 on the promotion of the use of energy from renewable sources, OJ 2009 L 140, p. 16, Art. 17. No import bans are imposed on the basis of this directive. Rather, its aim is to exclude imported products from the calculation of each Member State's target of energy generation from renewable sources.

58) WTO Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R and WT/DS48/AB/R.

# 11

# Cultural factors

Traditionally, risk regulation has concentrated on the protection of human health and the environment. Animal welfare has been considered too. The discussion on genetic engineering shows that citizens also have other concerns linked to what can be described collectively as "cultural typifications" or "cultural patterns" (Schütz 1972). These concerns originate from a number of assumptions that may vary significantly from country to country as they depend essentially on the historical development of each civilisation. Concerns are expressed about five aspects in particular:

- Doubts about the usefulness of technology, based on the belief that nature already contains all desirable organisms.
- Heightened apprehension for health and environmental hazards.
- Trust in the long experience of evolution compared to the partial and limited time horizon of biotechnological tests.
- Beliefs about the integrity of living beings.
- Ethical and religious concerns for a man-made hybrid versus Nature and Creation.[59]

Probably, cultural typifications will also extend to synthetic biology and highly artificial breeding, as soon as the public becomes more aware of their existence.

Cultural typifications play a significant role in democracies. They can trigger political demonstrations, e. g. against the release of genetically modified organisms (GMOs) into the environment, and influence the preferences of consumers, who tend to choose non-modified products. Despite their undeniable importance, they are totally disregarded in risk regulations. Only a few States have attempted to take this factor into account. Reasons of public morality are usually recognised, as in art. 4 para. 4 of the Swiss Law on technical barriers to trade.[60] In article 8 of the Swiss Genetic Engineering Act, the dignity of the living being is set as a standard: "Engineered modifications of the genetic material of animals and plants must not violate the dignity of the living being. Their dignity is deemed to have been violated when characteristics, functions or ways of living that are specific to that species are significantly compromised if this is not justifiable by preponderant interests worthy of protection. The damage caused to animals and the damage caused to plants must be assessed differently from each other."

Traditionally, risk regulation has concentrated on the protection of human health and the environment.

Genetic engineering issues show that citizens have – besides the protection of health and environment – further concerns that are influenced by what can be described collectively as "cultural typifications".

This clause is clearly limited to the ethical aspect. Moreover, it leaves the door open to trade-offs that are contrary to the deontological[61] concept of dignity. A more comprehensive definition is provided in art. 10 of the Norwegian Genetic Engineering Act: "In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development."

So far, this declaration of principle has however had no practical effects. Decisions are usually based on the assessment of health and environmental risks (Spök 2012). Since such risks have been assumed in Switzerland, the need has not yet arisen to resort to the cultural factor.

Concerningly, the WTO system has proven to be completely insensitive to the cultural factor, especially in the agreements on Sanitary and Phytosanitary Measures (SPS) und Technical Barriers to Trade (TBT) that are relevant in the present context. The case law that applies to these agreements recognises health and environmental protection as legitimate reasons to limit trade. In the case "EC – Measures Affecting the Approval and Marketing of Biotech Products",[62] the panel did not mention once in its about 1000-page deliberations that the EU moratorium was essentially motivated by cultural typifications.

Despite their practical importance, cultural typifications are totally disregarded in risk regulations.

We recommend that Switzerland examine the role of cultural typifications more closely and include them in its regulatory framework on the use of genetic programmes in biotechnologies.

59) For a detailed analysis of these concerns see the report of the Federal Ethics Committee on Non-Human Biotechnology (2010).

60) See also art. XX GATT.

61) Deontology or value ethics judges actions on the basis of values. In this respect, it differs from consequential ethics (ethics of responsibility), which judges actions on the basis of their effects (for example in terms of costs and benefits). Cf. Federal Ethics Committee on Non-Human Biotechnology (2010).

62) European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Panel Report WT/DS 291, 292, 293/R 29, 19.9.2006.

Cultural typifications could be taken into account through product identification rather than through binding regulations. Both Switzerland and the EU have opted for the mandatory labelling of genetically modified foods. However, identification requirements apply only to foodstuffs that contain genetically modified cells or are produced from GMOs, such as milk obtained from genetically modified cows.[63] No labelling obligations exist for foods containing or consisting of organisms fed with genetically modified feeds, e. g. pigs fed with genetically modified soya. In theory, genetically modified feeds can be imported[64] to be used in industrial animal fattening processes. As long as farmers in Switzerland abstain from genetically modified feeds they are in concurrence with imported products that may produce at a lower price without this restriction. The freedom of choice for consumers is limited if the conditions of feeding are not subject of labels.

Instead of using regulations, product labelling could be a way of taking cultural typifications into account.

We propose that Switzerland also prescribe the identification of foods obtained from the processing of animals fed with genetically modified feeds.[65]

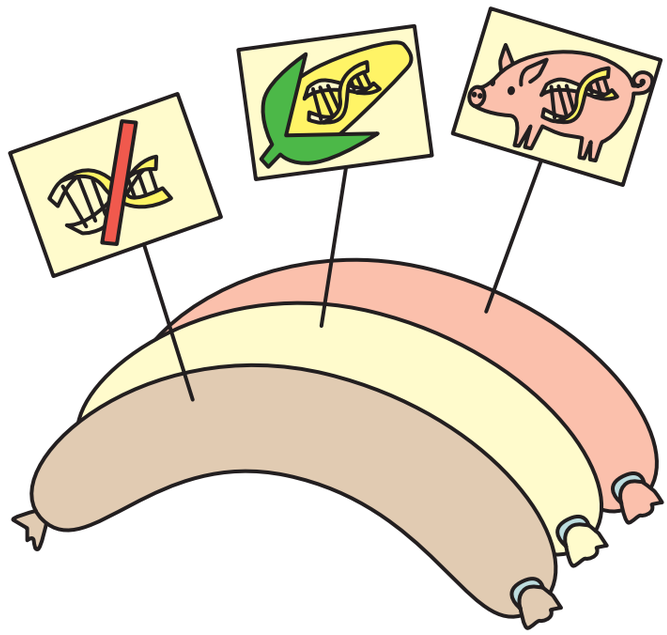
The indication of opposite characteristics, i. e. the absence of genetic modifications in a product, is also a topic open for discussion. The EU does not have any such label. However, the absence of genetic modifications is implied through other labels, in particular those provided on organic products. Unlike the EU, Switzerland has introduced provisions for the labelling of products "containing no genetic modifications" with very strict evidence-based requirements that have limited its use in practice.[66]

63) Art. 7 FDHA Ordinance on genetically modified foodstuffs (Verordnung des EDI vom 23.11.2005 über gentechnisch veränderte Lebensmittel); Art. 12 EC Reg. 1829/03.

64) The commercialization needs a permission, cf. Art. 12 Swiss Law on genetic engineering. In the EU modified feeds must be indicated in labels, see art. 24 EC Reg. 1829/03.

65) The Ordinance on genetically modified foodstuffs is currently being revised to cover also this aspect. The consultation on the revised wording of the law was concluded on 31.3.2014.

66) Cf. Art. 7 para. 8 Ordinance for genetically modified food.



# 12

# Sharing the benefits arising from the utilisation of genetic programmes

The benefits obtained from the utilisation of genetic programmes developed by R&D activities are essentially reaped by the subjects entitled to claim exclusive rights on them. In the chapter on sovereignty and property rights, we explained that all genetic programmes available in Switzerland whether in situ (i. e. in natural habitats), ex-situ (i. e. in botanical gardens and other plant collections), or created in laboratories, fall under the Swiss jurisdiction. Under the current Swiss legislation, these genetic programmes are considered to be non-ownable by the national law. Foreign and Swiss researchers can use, modify and re-combine this genetic material at will. The benefits arising from this need not be shared with the Swiss State. If intellectual property rights are established for this material, however, its genetic modification or recombination may be subject to the approval of the right-owner, who may, under certain conditions, be entitled to a share of the benefits.

The benefits arising from the utilisation of genetic programmes developed by R&D activities are essentially reaped by the subjects entitled to claim exclusive rights on them.

Swiss law does not prescribe a regime controlling the access to genetic material, but the Federal Council has the power to introduce access restrictions if it so decides.[67] Out of all industrialised countries, only Australia and Norway have implemented access policies. The EU provides no harmonisation on this matter, which is therefore individually ruled by each single Member State. For instance, no regulation is planned to be introduced in Germany. In fact, several arguments speak against an access regime that could end up imposing a huge administrative burden on the otherwise unhampered research and development activities. Switzerland itself would have to survey in its own country but also abroad the whole process from drawing the sample over different steps of R&D until the marketable product or intellectual property rights. Furthermore, the potential financial return would probably be minimal. Although monetary compensations have been envisaged since the implementation of the CBD in 1993, they have hardly ever been paid anywhere in the world. In any case, the transaction costs would probably be higher than the potential returns in the long term. Benefits deriving from cooperation in research and development would be more meaningful than monetary benefits. To reap such non-monetary benefits is currently at the centre of the international debate on benefit sharing (Kamau/Winter 2013).

A regime controlling the access to the genetic material would impose huge administrative burdens and stifle research and development activities. Furthermore, the potential financial return would probably be minimal.

Following these considerations, we discourage the Federal Council from using its legislative powers to introduce provisions regulating the access to genetic resources.

67) Art. 23 q para. 1 of the Federal Act of 1.7.1966 on the Protection of Nature and Cultural Heritage: "The Federal Council has the power to subordinate the access to domestic genetic resources to a notification or permit, as well as to an arrangement on the use of genetic resources and the distribution of the ensuing benefits."

The issue of benefit distribution does not apply solely to the domestic genetic programmes, but also to the genetic resources that have been transferred to Switzerland, where they are subject to R&D.

The issue of benefit distribution does not apply solely to the benefits of genetic programmes available in Switzerland, but also to the genetic resources that originate from another country and have been transferred to Switzerland, where they are used in R&D activities. Provided that these are genetic resources under the CBD and that they have been found and taken in situ and ex situ, the Provider State is authorised, as mentioned in the chapter on ownership, to impose access regulations and to demand a share of the benefits.[68] On the side of the User States, specific controls envisaged in the Nagoya Protocol must be introduced. User States have the obligation to ensure that the genetic resources used in their territory for R&D processes have been extracted and exported in compliance with the access regulations of the Provider States and that mutually agreed terms (MATs) are in force to ensure sharing of benefits.[69] Furthermore, User States must provide access to justice and other institutions to ensure the enforcement of the agreed terms.[70] In the law transposing the Nagoya Protocol, Switzerland formulated the following provisions:[71]

"Art. 23 n Due diligence requirement

(1) Any person who – according to the Nagoya Protocol – utilises genetic resources or directly benefits from their utilisation (Users) shall apply due diligence appropriate to the circumstances to ensure that:

a. the resources have been accessed lawfully; and
b. mutually agreed terms are in force for the purpose of achieving a fair and equitable sharing of the benefits obtained.

Art. 23 o Notification requirement

Compliance with the due diligence requirement must be notified to the Federal Office for the Environment FOEN before market authorisation has been obtained or, if such authorisation is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

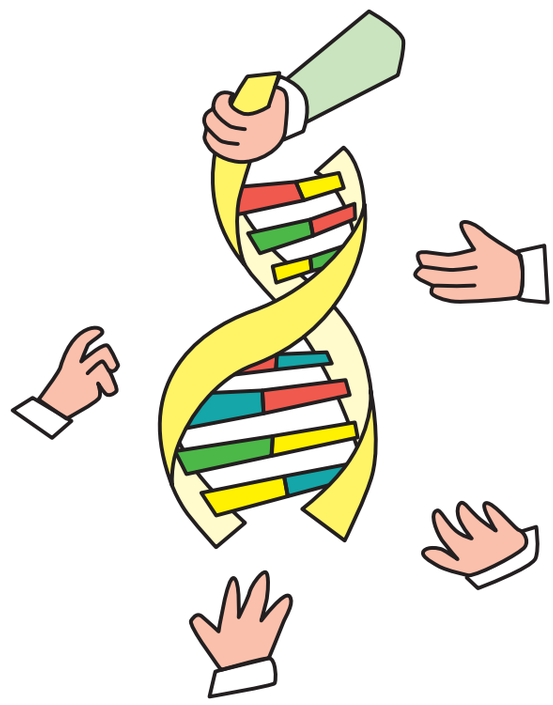
Art. 24 a

(1) …

(2) Any person who intentionally fails to provide information or provides false information under article 23 o shall be liable to a fine of up to CHF 100 000; if the offender acts through negligence, the fine shall be up to CHF 40 000."

The obligation of the researcher or developer ("User") is thus limited to compliance with the access requirements of the Provider State. A self-standing benefit sharing requirement had been proposed in the draft version of the law,[72] but no mention of it is contained in the final text. This omission is regrettable, because Switzerland could have gone beyond a minimalist interpretation of the Nagoya Protocol, setting a good example and winning over the trust of the Provider States.

Under the Nagoya Protocol, anyone using genetic resources or deriving direct benefits from their utilisation must ensure that such genetic resources have been accessed lawfully.



68) Art. 15 CBD and art. 5 and 6 Nagoya Protocol. The latter has been ratified and enforced by 50 States. Switzerland ratified the Nagoya Protocol on 11.7.2014 and transposed its provisions in the Nature and Cultural Heritage Protection Act.

69) Art. 15 Nagoya Protocol.

70) Art. 18 Nagoya Protocol.

71) Art. 23 n and 23 o of the Federal Act on the Protection of Nature and Cultural Heritage. Useful guidelines for researchers are provided in: "Access and Benefit Sharing. Good practice for academic research on genetic resources" Swiss Academy of Sciences, 2006 (by S. Biber-Klemm and S. Martinez). See also the template of the "Agreement on Access and Benefit Sharing for Non-Commercial Research. Sector specific approach containing Model Clauses", Swiss Academy of Sciences, 2010 (by S. Biber-Klemm, S. Marinez, A. Jacob, A. Jevtic).

72) Under article 23 n of the draft version, Users shall "apply due diligence appropriate to the circumstances to ensure that […] b. these benefits are shared in a fair and equitable way." The draft version is available in English under www.cbd.int/abs/doc/SwissRatification_of_the_NP-Draft_legal_measures-10_April_2013.pdf

It is also questionable, that the authorities are required to be notified of compliance with the due diligence requirement rather late, when the product based on genetic resources is marketed, and that only the violation of the notification requirement is sanctioned with a fine. This implies that the entire research and development process on genetic resources is devoid of controls. This cannot be possibly reconciled with the Nagoya Protocol. Art. 15 para. 1 and art. 18 of the Protocol demand that the User States must monitor the utilisation of genetic resources for their research and further development in order to make sure that the requirements set by the Provider States are met. A critical issue is to establish how the "benefits resulting from the utilisation of genetic resources"[73] can be determined. A very long time can elapse before a genetic programme is valorised. In the valorisation process, there might be steps between the access to the biological material and the marketing of the final product, in which the information on the genetic resource becomes public domain (e. g. is available in databases accessible to the public). Public domain information can thus be used for privately held knowledge and products.

The authorities are required to be notified of compliance with the due diligence requirement only at the marketing stage. This implies that the entire research and development process on genetic resources is devoid of controls.

73) Art. 1 d[bis] of the Federal Act on the Protection of Nature and Cultural Heritage.

We recommend examining more closely whether Switzerland as a User State is obliged and in a position to prescribe that the databases domiciled in its territory should ensure traceability of information to the State that has provided the source organism and comply with the access conditions valid in that State.

When determining the benefits, another aspect to consider is that the Provider State's sovereign rights may volatilise during the valorisation process. This may happen, for instance, when the genetic programme is used only for comparison with another programme in order to better identify the latter and in the end the latter and not the former is used for product development.

We recommend studying in greater detail how the entitlement to the sharing of benefits obtained from genetic resources may be exhausted in the R&D process.

Given the difficulty in determining the benefits obtained from the use of genetic resources (Kamau/Winter 2013), more thorough reflection is needed on the possible alternatives to the "benefit-sharing in exchange for access" approach proposed in the Nagoya Protocol.

We suggest considering a number of multilateral approaches to the sharing of benefits from the utilisation of genetic resources – from cooperation on research to material and data pools through to financial funds. Switzerland could give its original contribution to the forthcoming international negotiations, thus taking its pioneering role in the development of bilateral contractual solutions one step further.

# 13

# Summary

Most of the time, the different biotechnical utilisations of genetic programmes are discussed in separate fora, and so is their legal regulation. An overall view is needed here to consider systematically both the different utilisations and their various legal implications. This overview should help finding common denominators in the developments and challenges in the field of utilisations in order to set the goals for a sustainable management of genetic resources.

## Conclusions and recommendations

A change in perspective from phenotype to genotype can be observed in science, technology, economics and law. The implications of this change for Switzerland have not been thoroughly elaborated yet. Our suggestion is to research its effects more accurately and to analyse its political impact.

The term “genetic resources”, introduced by the Convention on Biological Diversity, is not sufficient in this context because it does not include artificial sequences. We suggest using the broader term “genetic programmes”, so that the products of synthetic biology are also included. The following definition of genetic programmes is provided: a genetic programme is made of DNA and RNA sequences that have been either generated naturally or assembled artificially. It is normally found in cells or incorporated into them, but can also be produced and used separately at a subcellular level.

Modern breeding methods have such a depth of intervention that they cast doubts on the validity of the legal demarcation between breeding and genetic engineering. We therefore recommend rethinking the boundaries between the two. The same applies to synthetic biology: since synthetic biology radically redesigns existing organisms, it also needs to be demarcated and differentiated from genetic engineering. Furthermore, we also recommend examining in detail the current lines of research in biotechnology that are being followed in Switzerland in order to verify whether they really provide the best opportunities for the acquisition of knowledge and its utilisation, or whether other lines of research should be developed.

The political debate and decision-making on the utilisation of genetic programmes in Switzerland should be based on a clear idea of the extent to which the development of genetic programmes should be privatised and research activities should make their findings available to the public domain. We recommend making the results of basic research on genetic programmes available, to the maximum extent possible, to the public domain. Still, provisions should be taken to make sure that the costs for the unbiased and lasting storage and availability of such information are covered.

We suggest that national and cross-border collections, exchange networks, and research and development activities concerning genetic programmes in Switzerland be included in a separate study and evaluated in terms of their performance and costs.

Our opinion is that discoveries about genetic programmes should be understood as improvements to the common knowledge of society. We therefore recommend that Switzerland should vote against the patentability of discoveries in international negotiations. Patents are admissible only in the later stages of the valorisation process of genetic programmes.

Intellectual property rights owners are progressively taking possession of living nature, thereby accelerating an ongoing industrialisaton of farming with critical social and environmental consequences. We recommend exploring ways of limiting patentability in the plant and animal domains.

Funding for research activities on genetic programmes should be objectively linked to the benefits that can be derived from these projects and programmes. Money should be assigned only to research projects that also explore the side-effects on health and the environment. In the selection stage, we recommend that funding programmes should make collective decisions that take environmental concerns into consideration as well. In addition to planned research, also freely selected research topics should deserve funding. State and private priorities should not interfere with the principle of self-determination of research during selection and conduction of research and development activities.

For the benefit of society, we recommend investigating the ecological and agronomic impact of the Swiss variety testing method more closely. As a preferred option, a comparative study should be conducted with selected EU countries. Since the majority of farmers tend to follow informal cultivation recommendations, we further suggest reconsidering the actual purposefulness of the mandatory catalogues of varieties. It might well be that their role as quality guarantors has been superseded by informal but more concrete cultivation recommendations. We suggest examining in greater detail whether the niche approval for native breeds is serving its purpose or whether more approval opportunities should be provided for small-scale farming.

With a view to limiting health and environmental hazards, we recommend extending the scope of the Genetic Engineering Act to specific highly invasive breeding methods. Alternatively, regulations on environmental protection and variety approval should be amended to envisage also a risk assessment procedure for these breeding methods. The risk assessment

procedures should be tailored to the specificities of selective breeding methods. A more detailed study is required on the state, benefits and risks of the new breeding methods that radically modify the genome.

We call for new studies on the lines of research in synthetic biology that are most likely to pose a serious threat to human beings or the environment, in order to have them included in the scope of the Genetic Engineering Act. We also recommend developing new risk assessment methods that are specific to synthetic biology. Such methods should identify appropriate tests to be conducted on the produced organisms.

The risk assessment of genetically modified organisms should be oriented towards "soft" genetic engineering procedures. When the risk analysis comes to the conclusion that the marginal risk is uncertain, unlikely or negligible, we recommend that also the benefits provided by the organism should be described in detail and motivated.

We welcome the conclusion of voluntary agreements for the coexistence of GMO and GMO-free farming through the creation of GMO-free areas. Additionally, we recommend considering also ad-hoc spatial planning solutions.

With respect to trade regulations, we suggest starting a political discussion and examining on the basis of surveys if specific production-related investment and import regulations should be introduced for biotechnical products.

Since the modification of organisms evokes a politically sensitive response in the community, we believe that the role of cultural typifications should be studied in greater detail in relation to the regulation of the biotechnical utilisation of genetic programmes in Switzerland and taken into account in the relevant regulatory frameworks. We further propose that Switzerland should also enforce the labeling of foods obtained from animals fed with genetically modified feeds.

With reference to sharing the benefits deriving from the exploitation of genetic programmes located in Switzerland, we discourage the Federal Council from using its legislative powers to introduce provisions regulating the access to genetic resources. Rather, we suggest examining more closely whether Switzerland as a User State is obliged and in the position to force its local databases to ensure traceability of information to the State of origin and compliance with its conditions for access. We also recommend studying in greater detail how the entitlement to the sharing of benefits obtained from genetic resources may get lost in the research and development process.

In our view, it would be desirable to have a variety of multilateral arrangements for the sharing of benefits obtained from the utilisation of genetic resources. They could be based on a number of instruments, ranging from research cooperation to material and data pools through to financial funds. Switzerland could give its original contribution to the forthcoming international negotiations, thus taking its pioneering role in the development of bilateral contractual solutions one step further.

## In a nutshell, the authors make the following recommendations

- Targeted breeding, genetic engineering and synthetic biology should not be seen in isolation but considered, examined and regulated as alternative types of biotechnical utilisation of genetic resources.
- In the regulation of property rights over genetic resources, genetic information and genetically modified organisms, lawmakers should opt primarily for public rather than private ownership.
- Funding for the biotechnical utilisation of genetic resources should not be influenced by irrational fashion hypes that promote one or the other type of research.
- The health and environmental hazards should be regulated so as to take into account the specific risks of the three mentioned biotechnologies. Furthermore, risk regulations should be more oriented towards a "soft biotechnology" and require that not only risk minimisation, but also the social benefits be demonstrated.
- Cultural typifications of biotechnically modified or created organisms should be described more in detail and considered more thoughtfully in the regulatory framework.
- Switzerland should also maintain freedom of access to its genetic resources and unvaried provisions on the sharing of the ensuing benefits.

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