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CONSULTATION ON EMERGING BIOTECHNOLOGIES – SWISS RESPONSE

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Introduction

This report gives an overview of responses of Swiss society and policy makers to emerging biotechnologies. The first part is an outline of general issues that are applicable to all emerging biotech areas. I obtained most information via the internet. However, representatives of organizations mentioned here below also addressed some of the consultation questions in a two hour discussion round. In the second part of this report I will give an overview per technology field.

I have used information from the following four Swiss organizations:

- The Swiss National Science Foundation, SNSF, funds fundamental research and launches National Research Programma`s (NRP) focusing on a specific scientific area.
- The Federal Ethics Committee on Non-Human Biotechnology, ECNH, is appointed by the Federal Council to advise the authorities from an ethical perspective, in the field of non-human biotechnology and gene technology. ECNH has published reports on among others GMO's, Nanotechnology, Xenotransplantation and Synthetic Biology.
  Ariane Willemsen ariane.willemsen@bafu.admin.ch
- The Swiss Centre for Technology Assessment, TA-SWISS (counterpart of UK POST) encourages the dialogue between science, industry and society, by doing studies and organising so-called PubliForums, for which citizens are invited to discuss topic like GM crops or xenotransplantation.
  Sergio Bellucci Sergio.bellucci@ta-swiss.ch
- The National Advisory Commission on Biomedical Ethics, NEK-CNE, monitors the development of sciences relating to human health and disease, and their practical applications. It comments from an ethical perspective - in an advisory capacity - on social, scientific and legal issues arising in this area.
  Jean-Daniel Strub Jean-daniel.strub@bag.admin.ch

General /main issues for all technology areas

1. What are emerging biotechnologies? (based on comments of the discussion group)

First things that come to mind are new technologies with new methods, but also older technologies but with new concepts or a new system or new applications.

We can also ask “emerging for whom”:

- For science: the “emerging” part can be part of the research: new aspects of medical assisted reproduction.
- But also emerging attention of the public or media or other target groups
- Or emerging on in technology transfer or on the market, since in this area we are confronted with uncertainties regarding the possibility of transfer between research and commercial use.

Emerging can also be looked at in the sense of emerging risks or emerging chances, or emerging *awareness* of risks / chances.
How to label an emerging biotechnology highly influences the funding and innovation progress.

Important properties in the discussion:

- **Risks versus chances**:
  - Risk versus chances discussions from different angles: medical, economics, practical
  - The difference between the individual risks/chances and group risks
  - One should only start to look at chances, once a level of risk has been reached that is acceptable and where one can justify this decision (regulators). So chances only play a role in rest risks.
  - Important to find the balance: Acceptance of risks are linked to benefits.
  - The use of the Utilitarian approach (sacrificing one part of the population to save the other) to risk taking is within Switzerland not acceptable, however globally this is sometimes the case.
  - If one sees emerging as positive progress and the focus is merely on chances, one might look at these technologies too positively. This may lead to the fact that one loses the momentum to look at alternatives: GM crops, xenotransplantation, (nuclear energy).
- **The value of innovation**: Switzerland is a society highly dependent on its capacity to innovate, so weighing risks vs chances is important. A discussion on **the value of innovation**, in public opinion, is needed. What is the social value of innovation.
- **Intuition**: Issues for which you don`t intuitively have an ethical opinion, for example with plants or fish, since intuition is the starting point in ethics discussion.
- **What is life and what is non-life**: This is important in synthetic biology, but also in robotics.
  To define what is life and what not with regards to Sentient **Synthetic/artificial** versus **natural** living organisms, there is no clear cut definition. It is therefore important to look at the gradual development of sentient beings.

2. The precautionary principle (comment of discussion group in *italics*)

The principle of precaution is applied in almost all emerging biotechnologies. Not being particularly risk-taking people, the Swiss seem to be rather safe than sorry.

This principle deals with the question of how to take responsibility, it suggests that one should go step by step and look at what risks there might be. This is contrary to the pro-actionary principle, where one would deal with new risks when encountered. However there is the problem of defining what is new, for example in synthetic biology or nanotechnology.

At the beginning of research little precaution is applied. Creative minds don't think about risks. Researchers often seem to have lost contact with the outside world, there are not enough interdisciplinary activities, scientists are too specialised. They are not aware of what risks might exist and what ethical questions to ask. Science fiction visions are apparently very important.

3. Economic factors

Not only do emerging biotechnologies arouse concerns about health and safety issues and about ecological impacts, but for Switzerland they are an important key to economic competitiveness and growth. Switzerland does not have natural resources and depends strongly on its human capital. With the pharmaceutical and chemical tradition, Switzerland is globally one of the leading countries in biotechnology and the country will not let go of this position easily.

4. The role of politics (including comments from the discussion group)

Politics often follow the recommendations of the ethics committees and of the public opinion (referendum). The chosen policies can have a strong limiting influence on R&D in these areas, f.e. GM Crops.

There is a specific legal framework for GM crops, Xenotransplantations and regenerative medicine. Legal aspects for the other 3 technology areas are integrated in other laws since the knowledge base on risks is still very poor to develop a separate law, eg nanotechnology is integrated in a law on chemicals.

In the discussion group two issues were addressed:

- ***Justification of decisions****: where as the public can just say yes or no to a certain technology, the regulators have to justify their decisions. They can therefore not rely on their intuition, but have to be well informed.*
- ***Majority****: All decisions have to be taken within the legal framework and conform the constitution, so even when the majority is in favor, the question should be asked if this condition applies. When there is a gap, majority decisions can be highly questionable.*

5. Public involvement (comment of the discussion group in *italics*)

The Swiss actively participate in the legal, social and ethical discussion around emerging biotechnologies i.e. GM crops, xenotransplantation and regenerative medicine:

- Through the consultation of a proposed new law sent to all relevant stakeholders
- Through voluntary, but binding, referenda to obtain approval from the Swiss public for the introduction of this new law.
- Or through other forms of public participation, for example the Publiforum of the TA-Swiss, with forums on GM Crops or xenotransplantation.

The role of ethical and other organisations in the public debate

The public has very clear attitudes and opinions, but it has an incoherent way of dealing with risks: depending on the situation they change their ethical position.

Importance of DIALOGUE: a sensibilisation of the public ánd an open debate is needed:
Since people often haven`t learned to think about certain moral issues, you have to present them with various options of thinking. So ethical committees can play a big role in advising public opinion and raising awareness, therefore allowing everyone to decide for themselves: how can an issue be dealt with ethically, how can a decision be ethically justified or defended.

But it is also important to listen to the public, how is an issue considered by public and experts, and to find out where the limits of acceptance are and what the reasons are for this. This is done by organisations like TA-Swiss in its Publiforum

6. **Ethical and social issues of the technology are often integrated in the Swiss National Research Programmes**, launched by SNSF, for example in the NRP63 Regenerative Medicine, NRP64 Opportunities and risks of nanotechnology and NRP59 GM Crops

7. Swiss characteristics (comments of the discussion group in italics)

Switzerland does not seem to take a leading role in the European community in legally approving emerging biotechnologies. This is especially the case with xenotransplantation, stem cell research and GM Crops, where the country takes a relatively conservative position.

Sergio Bellucci: Typical Swiss is that one only looks at risks, not chances! It is a negative approach when one only looks at risks and not at the opportunities that new technologies could bring.
However Jean-Daniel Strub sees a move towards a more liberal approach. This might be linked more to a cultural change, rather than ethical, in a more permissive society, laws etc.

There is a gap between the German speaking Swiss and the French and Italian speaking Swiss:
The German speakers are less liberal, and environmental, non-human issues are more important. For example there are no experts from the French speaking part on the topic of Ethics for non-human living beings. And although catholic, the canton Tessin (Italian) is very liberal versus in-vitro fertilisation.

However there is even a bigger cultural difference on ethical questions, between rural and urban people. The challenge is to integrate these 3 language areas and rural vs urban

Comments per technology field

Genetically Modified Crops

In Switzerland GM crops are controversial, both through government regulation and public opposition. In 2005 the Swiss public voted by referendum for a moratorium of 5 years on the commercial use of GM plants. This means that marketing and import is allowed but not commercial cultivation. This moratorium has recently been extended until 2013. Research regarding the opportunities and risks of GM plants are under stringent conditions allowed.

The position of the ECNH:

- **Strong advocates of the precautionary principle** when placing genetically modified products on the market, as long as the long term effects of GMOs are not clear.
- Freedom of choice should be ensured: consumers should always be able to purchase GMO-free products; declaration is therefore a must (more than 1% in the food)
- Gene technology free as in organic farming and traditional agriculture should be protected by avoiding vertical gene transfer from gmcrops, to ensure the access to gm free products

(Gene technology for food: http://www.ekah.admin.ch/en/topics/genetically-modified-food-and-animal-feed/index.html)

The NRP59 "Benefits and risks of the deliberate release of genetically modified plants", (www.nrp59.ch), launched by the SNSF, examines the benefits and risks of genetically modified (GM) plants under the ecological, social, economic, legal and political conditions of Switzerland. Despite high expectations, it is unlikely that NRP 59 will be able to definitively answer whether GM plants should be authorized for crops in Switzerland or banned. Its role will rather be to provide the scientific basis for a more rational discussion that will contribute to the political decision-making process.
As part of this research programme field trials with GM crops were done. However the high costs for protecting the trial field against destruction by public opposition groups, measures to prevent influences of this field for the environment are actually higher than the research project as such. These high costs will discourage future research in this area and testing of new plants in Switzerland (*however Ariane Willemsen of ECNH was quite skeptical and commented that this argument is strategically used to obtain extra funding).*

A study by **TA-Swiss with other European partners**, among others POST UK on

- Regulatory challenges for the European system in the next years
- public debate in the future
- Approaches for technology assessment to handle future issues

www.ta-swiss.ch/?uid=28)

Human Enhancement Technologies

This technology does not yet seem to be subject of a broad public or political debate in Switzerland. A certain range of products is for sale in Swiss shops or via the Internet (partially legal). Nestlé invests heavily in R&D of individualized food to enhance human mental and physical performance.

TA-Swiss is currently conducting a study which aims to provide answers to the following questions:

- How widespread is Human Enhancement today – internationally and in Switzerland?
- What prospects are emerging for the future technical development of biomedical enhancement?
- Which major actors exist in the field of Human Enhancement, and what motives are they pursuing?
- What is the legal framework for Human Enhancement?
- What central ethical issues arise with Human Enhancement?
- What economic interests and consequences are associated with Human Enhancement?
- Which social developments promote or inhibit the realisation of Human Enhancement?
- How can the future development of Human Enhancement be controlled?
- Results will be published before the summer of 2011.

www.ta-swiss.ch/en/projects/biotechnology-medicine/human-enhancement

Nanotechnology

Nanotechnology R&D in Switzerland does not seem to have been under the influence of ethical, public acceptance or safety issues yet. However, recently the Swiss government launched two interrelated programmes which address the issue of safety and risk for the environment and human health. One is the Action Plan on Synthetic Materials of the Swiss Government, the other the NRP on Opportunity and Risks of Nanomaterials. Both aim to build a knowledge base for a regulatory framework around the use of nanotechnology in the various technological areas.

Action plan Synthetic Nanomaterials *http://www.bafu.admin.ch/publikationen/publikation/00574/index.html?lang=en*
This Action Plan responds to the discussion of risks of synthetic nanomaterials used in nanotechnology. It intends to create the basis for the safe use of such materials and nanotechnology. Self-supervision in the area of synthetic nanomaterials will be defined and voluntary measures by the industry will be supported. Also the need for regulation, taking into account international developments, particularly in the EU, will be assessed.

NRP 64 "Opportunities and risks of nanomaterials" *www.nrp64.ch*
This NRP should provide data to develop tools to monitor the behaviour of nanomaterials and their potential impact at all stages of their life cycle on humans, the environment and flora and fauna within different media (air, soil, water) to maximise benefits and minimise human health risks and environmental risks. It should provide data to support the development and implementation of safe and effective applications of nanomaterial-based technologies and information needed to define working practices and regulations. Finally it also aims to enhance and strengthen Swiss expertise and competence in the development of innovative nanomaterials as well as in risk assessment.

A study by TA-Swiss on risks, future prospects and applications in Nanofood (2009) http://www.ta-swiss.ch/?uid=26 with the following results and recommendations:

Results

- The analysis of the Swiss market showed that so far only few nanoscale food additives as well as food supplied with such components are available. These additives are already in use and have been toxicologically reviewed for many years.
- On the Swiss marketing food packaging with composite films and PET bottles with nano-technologically improved barrier features can be found.
- At present, the contribution of nanotechnology to an environmentally friendly, constitutional and ethically responsible nutrition is estimated marginal in Switzerland.
- A requirement for this is the human and eco-toxicological harmlessness of the applied nanomaterials. Food packaging with nanocomponents, however, already offer advantages for consumers at present and therefore hold a bigger potential for the future, especially because it also includes environmental impact reduction potential.

Recommendations

- The challenge for the future consists in not precluding the achievable benefit through possible existing human and eco-toxicological risks of the applied nanomaterials. At this level, for instance, the migration of toxicologically critical nano-materials of food packaging into food has to be mentioned.
- Therefore, the development of nanomaterials in the food sector and the design of the scope of regulation should be conducted by the precautionary principle. **It is recommended to integrate the precautionary principle explicitly into Swiss food law.**
- When implementing the principle, the current regulations to food law, which generally also include nanomaterials, should be adjusted to nanospecific demands. Concrete public guidelines for risk management for producers and importers are recommended.
- Furthermore, **specific labelling of nanomaterials in ingredients and in packaging materials is recommended**. The labelling shall facilitate traceability in the production chain of specific food and governmental food monitoring, as well as offering the freedom of choice to consumers. However, the enaction of **a specific "nanofood law" is not recommended**.
- Finally, it should be surveyed if and to what extent the regulations for traceability along the production chain for synthetic nanomaterials that ist already followed by producers, have to be adapted and how they are applied in practice.
- Regulatory measures have to be accompanied by an intensification of risk research as well as a consequent assuming of product responsibility by the producers. This especially involves increased information, transparency and willingness to communicate with stakeholders and the public.
- As is also recommended within the action plan "Synthetic nanomaterials" by the Federal Council, **dialogue platforms about chances and risks** as well as a corporative agreement process for the handling of nano-materials in the food sector **should form an integral element of the further development process.**

Regenerative medicine

The legal position taken by Switzerland on research on human embryonic stems cell (hESC) can be considered mid-way within Europe. It is the only country where the use of embryonic stem cells was approved by direct popular vote in 2005 with the outcome being the approval for the use of embryonic stem cells that are unused and would otherwise be discarded following in vitro fertilization for research purposes. However, therapeutic cloning, resulting from the transfer of an adult human cell nuclei belonging to a patient into an enucleated oocyte from a woman donor, to provide new tissue for the patient, is not allowed. The production of developing human embryos for reproductive cloning is forbidden and scientifically proscribed.
The recent development of induced pluripotent stems cells or iPSCs has been called a bypass of the legal controversy. Although Switzerland engages in iPSCs it seems that research is not yet well coordinated and there is a need for standardization in procedures.

Since the legal situation for research in this area was unclear until 2005, this may have discouraged Swiss scientists to embark on this type of research and might be the cause that at present, Swiss stem cell research as a whole is weakly visible in an international context. There are no obvious other clues why Swiss science, which has an excellent reputation in the fields of cell and development biology, has been less competitive in the field of stem cell research

The SNSF, launched in 2010 NRP63 "Stem Cells and Regenerative Medicine" (www.nrp63.ch) to give a boost to basic research in this area. The aim is to better understand the molecular mechanisms, and therefore obtain a better estimate of application risks and interpretation of results.
This NRP also looks at the legal and ethical aspects, in order to develop recommendations and guidelines for all parties involved. On the one hand the donor needs to be protected against abuse, on the other hand research should not be restricted unnecessarily.

Synthetic Biology

The discussion on risks and challenges of synthetic biology has only begun in the last few years. TA-Swiss published the “Brochure on Synthetic Biology – the development of a new engineering science” only in April 2011. It is stated that the discussion about synthetic biology is currently still very much under academics and hardly among the wider public. However, it is important to start the discussion now when the technology is still in the phase of fundamental research.
www.ta-swiss.ch/publikationen/schriften/SATW_Synthetische_Biologie.pdf (German only)

Another aspect of the discussion is the potential of synthetic biology in relation to the risks: the opportunities for Swiss industry and commercialization are particularly promising. Its development should therefore not be stopped by ethical or safety considerations.

The ECHN published the report “Synthetic biology - Ethical considerations” in May 2010

http://www.ekah.admin.ch/en/topics/synthetic-biology/index.html
http://www.ekah.admin.ch/en/documentation/publications/index.html

- The ethical discussion is regarding the question to what extent it is possible or impossible in principle to produce living beings in a controlled manner.
- "what we call life relates to purely physical / chemical properties of living beings. It leaves open the possibility that the vision of synthetic biology may be successful, with living beings arising as products of its methods."
- When concentrating on microorganism, ECHN adopts the view that microorganisms have something that may be called an inherent value or "dignity", and that they therefore deserve moral consideration in their own right, because they are living beings. However, the weight attached to their inherent value in an ethical evaluation of interests is negligible. Therefore, no ethical obstacles exist in practice to projects involving microorganisms.
- Another aspect is the controllability of the process and products of synthetic biology. These in turn affect the discussion of questions concerning the ethics of responsibility. According to ECNH concerns expressed do not at present justify a veto on synthetic biology projects. It is not possible – given the lack of data – to judge whether the legal provisions already existing for the handling of genetically modified organisms are also sufficient to regulate the handling of synthetic organisms.
- The empirical data is inadequate to allow an appropriate risk evaluation to be undertaken. Therefore the application of the precautionary principle is recommended.

Xenotransplantation

Switzerland is one of the last countries in Europe to approve of a transplantation law, to regulate under which conditions transplantation is allowed. A draft of the Transplantation Act entered the consultation phase in December 1999. After detailed debates in Parliament the Act came into force in July 2007. No referendum was called for by the Swiss public.

The Transplantation Act also defines under what conditions xenotransplantation could be allowed. Permission should always be obtained by the Swiss Federal Office for Health, BAG. A division is made between clinical trials and standard procedures. Clinical trials will be allowed when the risk of infection for the population can be excluded with a high certitude and when therapeutic gain can be expected. Standard procedures will only be allowed when risk of infection is totally excluded and therapeutic gain is guaranteed.

However, Xenotransplantation in Switzerland is still in the early stages of fundamental research and a lot more research is needed before clinical trials can be started. There are still many questions regarding:

- the risks through rejection and xenozoonosis, which are still expected to be higher than the gains
- the high risk of infection for the environment and population
- regulars tests until the end of the person's life.

- The economic aspects regarding the balance of costs - gains and liability risks
- psychological problems of the receiver of the transplants
- animal ethics: genetic modification and the living conditions in a bacteria-free environment

The ECNH concentrated on the ethical aspects of transferring animal organs or cells to human beings, and particularly on the animal-ethical aspects such as protection from harm and other damage to the dignity of living beings. So far the ethical discussion had only focused on protecting human beings.
On basis of the lack of scientific basis of positive results with xenotransplantion, the ECHN would have favoured a moratorium on xenotransplantation of organs and tissues and demanded that preclinical research should not be performed, for the moment, on either humans or apes. They advised to consider first the availability of alternatives.
www.ekah.admin.ch/en/topics/xenotransplantation/index.html
Statement on the draft bill of the Transplantation Law, 2000 (pdf, 33 KB)