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Report of the Swiss Ethics Committee for Non-human Gene Technology

Ethical Evaluation of "Terminator" Technology

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The Ethics Committee's mandate

The Swiss Ethics Committee on Non-human Gene Technology (ECNH) advises the Federal Council and the secondary authorities on ethical questions associated with non-human gene technology and biotechnology, taking into consideration aspects of the dignity of creation, the safety of humans and the environment, sustainability, and the conservation of biological diversity. Since gene technological interventions in the non-human sector always have an impact on humans as well, the ECNH also includes the social and economic impact in its ethical evaluation.

1. Principles and starting point

1.1. Brief description of "Terminator" technology

The "Terminator" and similar technologies modify organisms in such a way that the expression of traits can be regulated and controlled from outside. The goals of this include preventing the re-use and unauthorised repeated cropping of seed, and also reducing the possibility of the undesired spread of the transgenic genome in the environment.

The basic concept was introduced under the phrase *control of plant gene expression*. It is also described as *genetic use restriction technology* (GURT) or *technology protection system*. These technologies are used to integrate mechanisms into the plant, which reproduction (e.g. germination of seeds) can be prevented ("v-GURTs") or the expression of specific traits can be suppressed ("t-GURTs"). The name "Terminator" technology has become associated with the use of v-GURTs in the seed sector.

1.2. Patenting

In its Statement, the ENCH separates the ethical evaluation of *patenting* from the ethical evaluation of the *use* of the technology. The content of the examination will be, whether the possibility of patenting might exacerbate any potential impact of using "Terminator" technology.

1.3. State of knowledge

"Terminator" technology remains a laboratory technique. There are still no data about the concrete impact of this technology. The ECNH therefore bases its considerations on the possible uses and risks of this technology that can be predicted. The ECNH's evaluation is thus a prospective and temporary one.

1.4. State of the international debate (Convention on Biodiversity)

On 24 May 2000 in Nairobi, the "Conference of the Parties to the Convention on Biological Diversity" approved a Recommendation on *genetic use restriction technologies*: "in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, inter alia, their ecological and socioeconomic impact and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated."¹

¹ Convention on Biological Diversity, Addendum to draft decision, 5th meeting, Nairobi, 15–26 Mai 2000, 24.

2. Elements of the ethical evaluation

Seeds form the basis of the food supply, and a gene technological procedure that permits the external control of seed is accordingly of existential significance. "Terminator" technology touches on basic ethical problems of the international community in economic, ecological and social terms and in terms of the relationships between countries, north-south relationships in particular. Because of this existential significance, the technology must be examined both for its possible positive consequences and for its possible adverse effects.

In what follows, the ECNH is concerned first with the elements of the ethical evaluation of the technology. Light is shed on problematic areas and arguments for and against permitting "Terminator" technology from various points of view are collected. Then, on the basis of the arguments considered by the ECNH to be important, an assessment is carried out. The final section contains the ECNH's recommendations.

2.1. Research and economic aspects

a) Problem areas

"Terminator" technology allows plants to be genetically modified so that their seeds are sterile. The sterility of the seed prevents farmers from reusing part of the harvest as seed. They thus lose their "farmers' privilege". The economic aspects of this loss of privilege must be clarified, and the extent to which "Terminator" technology promotes a trend towards monopolisation in the seed market must be examined.

The costs involved in the development of genetic procedures are high. The commercial interest of the companies in protecting these procedures by means of the additional integration of "Terminator" technology is correspondingly great. If the protection of these commercial interests is considered to be legitimate in principle, alternative ways of protecting the high development costs, to avoid any potential adverse effects, should be explored.

b) Arguments in favour of permitting the technology

"Terminator" technology has a versatile and interesting application potential, from both the research and the economic perspectives. Since the technology represents a possibly important commercial factor, the economic evaluation should be given particular weight. Essentially, commercial considerations do not indicate the need to ban the technology, since the market itself will regulate its use, according to whether it is accompanied by economic advantages or disadvantages.

Farmer's privilege plays a particularly important role in developing countries. "Terminator" technology is however designed for the highly industrialised agriculture of the developed nations. In these countries, seed is usually bought anew each year. Selling seed with "Terminator" technology does not yet

restrict the farmers' freedom. Dependence arises only when the product is not available in any other form. Any possible trend towards monopolisation can be countered by other means than prohibiting the technology.

The application of the technology cannot be reversed on a global level. Its spread cannot be prevented. A ban could indeed lead to the opportunities offered by the technology being missed.

c) Arguments against permitting the technology

The loss of farmer's privilege primarily affects small farmers in developing countries. Repeated cropping of seed from the harvest is of great commercial significance for these farmers, but use of the technology leads to the destruction of economic and production forms of the local culture.

From an economic point of view, the technology has the same impact as a patent, except that the protection the technology offers is not subject to a time limit. "Terminator" technology and GURTs enable seed firms to control farmers. If farmers buy transgenic seed, they are also obliged to buy the chemicals that go with it from the same supplier. Because of the significance of seed for food, there is already a general trend towards monopolisation and therefore also the risk of abusing this monopoly. The trend towards monopolisation is promoted still further as the technology itself becomes a product through the issuing of licences.

Commercial interests should be considered as legitimate interests of the companies in the ethical evaluation. "Terminator" technology is, however, not considered a suitable instrument with which to protect the high development costs associated with the seed containing this technology, since the necessary conditions with which the adverse economic effects of the technology's application can be offset are lacking.

2.2. Social aspects of the technology

a) Problem areas

An ethical evaluation must consider the social impact of the technology. The consequences of a possible monopoly for the individuals concerned and for society as a whole should be examined. In particular, the loss of farmer's privilege should be examined for its social impact. Further, whether the application of the technology threatens social rights, and what the implications are for development policy, should also be explored.

b) Arguments in favour of permitting the technology

The freedom and self-determination of the individual are not limited by the "Terminator" technology as such, but only through a possible increase in monopolisation. The increasing dependence of farmers on individual seed producers is not a problem specific to "Terminator" technology, which could be countered by banning the technology.

An economically promising application of the technology could have a positive impact on the economy and food supply of a country, and therefore lead to an overall improvement in the social situation.

c) Arguments against permitting the technology

The increased trend towards monopolisation in the seed market may result in making not just individual farmers but also a whole country dependent on a type of seed and the corresponding chemicals. Thus, the hypothetical control of the seed of a whole country through refusing to grant a licence also arises. Economic heteronomy not only leads to the destruction of traditional forms of production, but also contains a particularly high potential for social conflict.

It is assumed that the technology will be applied particularly to crops that are of great economic value and where the breeding of hybrids, which also requires the annual new purchase of seed, is difficult. Examples of such crops are rice, wheat, soy and millet. Together with maize and potatoes, these crops form the basis of the global food supply. A monopoly on these crops would represent a serious threat to food security.

Every dependency reduces individual freedom of choice. This is in contradiction to the understanding of development aid, which is based on the principle of help for self-help. Monopolisation and heteronomy thus touch on human dignity and the right of each person and community to earn their own living.

2.3. Ecological aspects

a) Problem areas

Considering the ecological aspects, the impact of the technology on species diversity and genetic diversity through the crossing-out of transgenic traits should be examined. The possibility that the application of the technology will lead to a reduction in seed diversity needs to be clarified. The technology should also be evaluated in terms of sustainability and the precautionary principle.

b) Arguments in favour of permitting the technology

Through the sterility of the seed, "Terminator" technology can prevent genetically modified seed from crossing out: thus, plants with transgenic traits may be released while at the same time their crossing out in the wild population is prevented.

If it is advantageous to the farmers, every type of seed suppresses other, less advantageous types, whether they have been bred using traditional or gene technological methods. The reduction in seed diversity is a problem that is neither specific to technology in general, nor to "Terminator" technology in particular. A potential reduction in species diversity therefore cannot be countered by a ban on the technology, but rather requires other appropriate measures that promote biodiversity.

c) Arguments against permitting the technology

From an economic point of view it is sufficient for the "Terminator" technology to achieve the sterility of a particular part of the seed, in order to make its re-use economically uninteresting for the farmer

and the annual new purchase of seed necessary. Therefore despite the use of the "Terminator" technology, the possibility that the non-sterile part of the seed will cross out in wild populations cannot be excluded.

Furthermore, despite the sterility of the *seeds* there is a possibility that the transgenic *pollen* will cross out in wild populations or other crop fields. For wind-pollinated plants in particular, it should be borne in mind that pollen can be transported over wide distances. There also remains the possibility of horizontal gene transfer, the transfer of the transgenic traits of a plant through soil organisms.

Equipping a type of plant with the "Terminator" technology or other GURTs is expensive. It can therefore be assumed that for economic reasons only a few types will be genetically modified. As a result of the trend towards concentration of the seed market, in addition to the suppression of the local types, there also exists the danger of an additional reduction of biodiversity among crop plants.

2.4. Aspects of the dignity of creation²

a) Problem areas

"Terminator" technology prevents or limits the natural reproductive potential. The extent and manner to which this limitation touches on the dignity of creation should be clarified. Whether individual plants have such a dignity at all needs to be examined, and if so, how this dignity is affected by using "Terminator" technology.

b) Arguments in favour of permitting the technology

Human control of plants through gene technology is not differentiated from the general instrumentalisation of plants by humans. The concept of respecting the dignity of creation cannot be equated with a total absence of intervention.

The addition and insertion of new material does not necessarily influence the plant's ability to react to its environment. The plant is still capable of adaptation. A genetically modified plant therefore does not a priori have less "freedom" than a non-genetically modified plant.

The *t*-*GURTs* make it possible to add traits to plants that increase their value – in contrast to "Terminator" technology (*v*-*GURT*), in which the sterility of the seed and thus the vitality of the plant is a foremost consideration. In *t*-*GURTs*, limiting the reproductive potential is not an issue.

² Article 120 of the Swiss Federal Constitution requires the dignity of creation to be taken into account in the handling of seed and the genomes of animals, plants and other organisms. In its Decree of 27 April 1998 the Federal Council mandated the ECNH to monitor the developments and applications of biotechnology and gene technology in the non-human sector and to evaluate them from an ethical point of view. The ECNH should express its opinion on adherence to the principle of the dignity of creation.

c) Arguments against permitting the technology

The term dignity of creation is based on a biocentric standpoint. Even individual plants have their own worth, the importance and damage to which must be justified. Since its "own worth" also includes the drive towards growth and reproduction, the systematic limitation or prevention of the ability to reproduce represents damage to the dignity of creation.

A significant characteristic of life forms is the ability to react flexibly to their surroundings and various environmental influences. The goal of the "Terminator" technology and other GURTs is however to eliminate precisely this "independence" of the plants and to place them under external control. This leads to an unacceptable level of instrumentalisation of the plants.³

2.5. Impact of patenting "Terminator" technology

a) Problem areas

Patenting the "Terminator" technology must be evaluated to see whether patenting would lead to an additional intensification of any adverse effects of its use. The extent to which claim to a patent leads to an increased dependency of the farmer's options as breeders and producers must be clarified. Furthermore, there should be a clarification of how any adverse effects of the patenting could be halted.

b) Arguments in favour of permitting the patenting of the technology

The development of such a technology is intensive in terms of time and costs. There exists a justified claim, to protect the high development costs through the possibility of patenting. The possibility of patenting offers companies an incentive to invest in the expensive and cost-intensive development of technologies. Patenting thus contributes to promoting innovative research. The patenting also brings an advantage to society, of creating transparency about the technology, because knowledge about the procedure must be declared as a prerequisite of patenting.

Patenting the technology in Switzerland prevents Swiss industry being at a disadvantage in this sector of the globalised market. A ban on patenting that was only nationally applicable would be completely out of proportion in the global economy.

c) Arguments against permitting the patenting of the technology

The juxtaposition of gene technology and traditional agriculture is proving to be difficult. Gene technology is developing the tendency to suppress other forms of production. Because of the dynamics of power, patented plants are able to suppress indigenous types. Patenting leads to a dependence of the farmers and to a further reduction in biological diversity. Because of different agricultural conditions in the industrialised and developing countries, it is feared that patenting crop plants will cause a further intensification of the north-south conflict.

³ The plant becomes purely a means to an end. Protection of the plant for its own sake is not recognised.

There is a trend towards the formation of monopolies and seed control through patenting. However, it is a fundamental principle that rights of ownership that prevent advantageous characteristics of plants from being used in solidarity and in the sense of general human wellbeing should not be protected. Ownership rights of seed mean here not just any ownership rights, but rights to a global food supply.

3. Prerequisites for an ethical assessment

"Terminator" technology and other GURTs have diverse potentials. At the same time these technologies have a high potential for abuse because of their intrinsic control function. An ethical assessment of the benefits and risks of "Terminator" technology requires that data on the impact of the technology are available. "Terminator" technology is however still a purely laboratory technology. There are as yet no concrete data on of the technology's impact. The starting point for an assessment is therefore judged to be inadequate. Nevertheless, individual statements towards an ethical evaluation of the technology can be made.

Because of the fundamental ethical questions touched upon, and the lack of data, the discussion of the "Terminator" technology is held on a complex and abstract level. Thus, for example, seed signifies goods that are necessary for survival. Consequently, the regulation of access to seed touches upon an existential human interest. The ethical assessment of the benefits and risks of the technology and its application should be carried out in a correspondingly scrupulous way. Furthermore, any assessment should remember that in the industrialised nations very little of farmers' own seed is used, since they are accustomed to buying new seed. The dominating question to be clarified is therefore the ecological impact of a possible crossing out of transgenic traits. In the developing countries, on the other hand, the factors to be evaluated should be weighted differently. In these countries the socioethical and development policy aspects of the technology play the predominant part in the evaluation. Lack of access to seed with particularly advantageous traits is, however, not a problem specific to "Terminator" technology. For farmers in the developing countries the access to seed in general, and to seed associated with expensive technology in particular, is difficult.

3.1. Technology assessment

In order for an ethical assessment of "Terminator" technology and other GURTs to be undertaken, a comprehensive technology assessment (TA) is necessary. A comprehensive TA goes beyond the natural scientific safety and risk research and clarifies the economic, ecological, social and ethical impact of the application of the technology in an overall context. The open questions of the release of genetically modified organisms in general should also be included.

Among the <u>economic</u> aspects, for example, the possibly differential impact of permitting use of the technology in industrialised and developing countries, and ways of preventing possible problems from resulting should be clarified.

In relation to the <u>ecological</u> impact of the technology, many deficits still clearly exist. For example, the long-term impact on biodiversity of using the technology must urgently be clarified. Furthermore, the stability and expression of the genetic material should be examined and the possibilities of horizontal (via soil organisms) or vertical (e.g. via pollen) gene transfer should be considered.

With regard to the <u>social</u> impact, a comprehensive TA will include the impact on the social structure. Thus, the social impact of a possible increased dependence of farmers on seed producers, together with an increased trend towards monopolisation, should be clarified. The of a reduction in biodiversity on the traditional crop structures of a community must also be examined. Evaluation of the potential for social tensions and conflicts should be included.

Within the <u>ethical</u> impact, the extent to which permitting "Terminator" technology and other GURTs influences the values held by a society, and what effect this could have, should be examined. For example, the impact of the technology on the relationship between the individual or community and the non-human environment should be considered.

The overall research plan should therefore be drawn up in an accordingly interdisciplinary way. A systematic safety and risk evaluation is of fundamental importance, as are the development of concepts and methodologies for recording and evaluating the risk and benefit potential associated with use of the technology. In particular, methods of long-term monitoring are needed.

3.2. Taking into consideration the precautionary principle and sustainability

While a comprehensive TA determines the economic, ecological, social and ethical impact of a technology, the actual evaluation of these concepts only takes place as part of an assessment. As a general principle, the Swiss Federal Constitution requires adherence to the precautionary principle⁴ and to sustainability,⁵ and thereby anticipates an evaluation. In other words, these principles must be taken into account in any assessment. The clarification of these two principles requires a deeper engagement with the terms "caution" and "sustainability", which cannot be undertaken here.

For "Terminator" technology and other GURTs, the question of <u>how to weight a lack of knowledge</u> must be answered when making an ethical assessment of precaution. What might be the consequences of such ignorance? What may we, or should we, do or not do because of our ignorance? Dealing with lack of knowledge responsibly includes being clear about its nature, i.e. whether it is a fundamental lack of knowledge, a "not-yet-knowing", or a lack of experience in dealing with the individual case. It must also be explicitly stated <u>that</u> we do not (yet) know.

Lack of knowledge, and its consequences, are fundamental problems, not solely with regard to new technologies. Attempts to deal with lack of knowledge or not-yet-knowing fall in the tension between absolute caution and absolute risk. It is up to the individual or the community to find a position within this diversity, although taking either a cautionary stance or an adventurous one should be <u>justifiable</u>

⁴ Article 74 Para. 2 of the new Federal Constitution; see also Article 1 Para. 2 of the Law relating to the Protection of the Environment.

⁵ Article 3 Para. 2 and Article 73 of the Federal Constitution

according to the risks or opportunities associated with the technology. The justification will necessarily differ according to the nature of the lack of knowledge.

4. Recommendations of the ECNH

On the basis of the above considerations, the ECNH issues the following recommendations for dealing with "Terminator" technology:

4.1. Technology assessment

The ECNH unanimously (with two abstentions) recommends that a comprehensive technology assessment of "Terminator" technology be carried out, taking into consideration the economic, ecological, social and ethical impact of the technology.

4.2. On using the "Terminator" technology:

The members of the ECNH (with one abstention) have issued the following recommendation:

The ECNH recommends, by a small <u>majority</u>, to permit the use of "Terminator" technology only under defined conditions. For example, no applications that lead to abuse should be permitted, and there should be obligatory follow-up monitoring of the economic, ecological and social impact. The conditions should be so defined that they can be fulfilled and cannot be equated with a hidden ban on the technology.

A significant <u>minority</u> expresses its opposition to permitting the use of "Terminator" technology at this time. Within this minority, most ask for a <u>prohibition at the present time</u>. The remaining representatives of the minority recommend a <u>moratorium</u> on using the technology. The moratorium should be used to fill in the gaps in knowledge, for example in the form of a comprehensive technology assessment. On the basis of such a technology assessment, the situation should then be evaluated anew.

4.3. On patenting "Terminator" technology

An ethical evaluation of patenting "Terminator" technology poses questions of a fundamentally different nature than those associated with its use. The ECNH is of the view that these questions deserve a more profound reflection. We therefore direct you to a future Statement, in which the ECNH will consider basic ethical questions of the patenting of living organisms.

6 October 2000