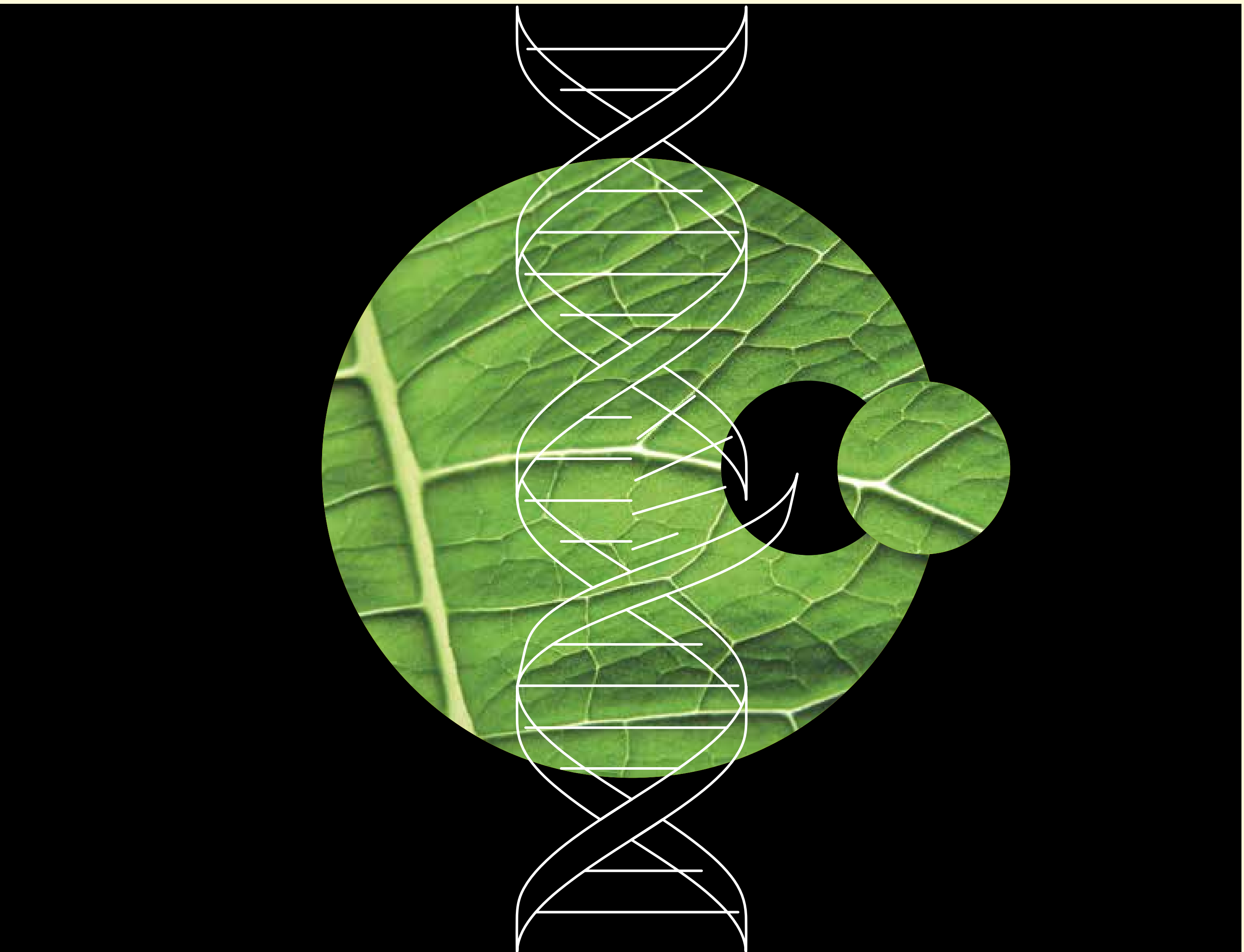
New Plant Breeding Techniques – Ethical Considerations

Report of the Federal
Ethics Committee on Non-Human
Biotechnology (ECNH)



1 Introduction and processes

1.1 Object and context of the discussion

In recent years technologies have been developed or employed in plant breeding which have replaced genetic and conventional techniques, and combinations of the two; these are known collectively as (NPBTs). As with methods in genetic engineering, NPBTs can also be used to modify the genome of a plant. This means new characteristics can be created; for example, a plant's components can be altered to generate resistance to disease, infestation by insects or weed killer. NPBTs have become increasingly important in crop research and development.

Like other methods in breeding technology, NPBTs do not cover the whole of the breeding process. They are used in the laboratory at the beginning of the process. A large part of the work in plant breeding takes place outdoors in the field, where the plant reacts to its environment, and new characteristics must be tested for biological stability in a "real-life" situation.

Currently there is much discussion about which NPBTs count as genetic engineering processes and so fall under current legislation on genetic engineering. Genetic engineering is a feature of almost all NPBTs, in one form or another.[1] These techniques therefore all currently fall under the applicable Gene Technology Act. However, it is being suggested in both Europe and Switzerland that some NPBTs or their products should not be subject to the legislation on genetic engineering.[2] If this were the case, users of NPBTs would be spared complicated assessment and approval procedures that have to be gone through before genetically engineered organisms can be released into the environment. As crops that have been developed using NPBTs are already being introduced onto the market, the central question dominating the current national and international debate on NPBTs is which techniques fall under the legal definition of genetic engineering and which should in future be covered by this definition.[3]

1 Genetic engineering is used, for example, to spark or accelerate a process in a plant or to trigger a change in a genome. One example of an NPBT not involving genetic engineering is marker-assisted selection, which looks for new characteristics of a plant without altering the plant's genome (e.g. by deactivating a gene).

2 For example, breeding techniques involving oligonucleotides are not considered to be genetic engineering techniques, but rather a form of conventional mutation breeding; see the statement by the German Central Committee on Biological Safety (ZKBS): http://www.bvl.bund.de/SharedDocs/Downloads/06_Gentechnik/ZKBS/01_Allgemeine_Stellungnahmen_deutsch/04_Pflanzen/Neue_Techniken_Pflanzenzuechtung.pdf?__blob=publicationFile&v=3 (referred to 27.04.2015). Others suggest that techniques that result in products in which no genetically engineered alterations can be detected should no longer be subject to the Gene Technology Act, regardless of whether genetic engineering techniques were used.

3 See e.g. Benno Vogel, Neue Pflanzenzuchtverfahren, Grundlagen für die Klärung offener Fragen bei der rechtlichen Regulierung neuer Pflanzenzuchtverfahren, December 2012, report commissioned by the Federal Office for the Environment FOEN.

From an ethical viewpoint, the main problem is not how to legally class these techniques. Regardless of hether NPBTs should be legally defined as genetic engineering techniques, we should first of all ask ourselves what ethical issues arise in connection with NPBTs and their applications. Only then can the relevant official bodies discuss and decide how NPBTs are to be legally classified so that they can be used in an ethically defensible manner.[4]

1.2 Ethical issues

Many of the ethical considerations pertaining to the legal classification of NPBTs have already been discussed in depth by the ECNH in its statements on genetic plant breeding techniques. Of particular relevance here are considerations of risk ethics and freedom of choice. The ECNH will address these considerations to the extent that they are of particular relevance to the NPBT discussion, or look at them in more detail if the discussion differs to any relevant degree from that on genetic engineering, or if the Commission has developed its considerations. Otherwise, for further explanations, it will refer to its previous statements and reports on genetic engineering or, where appropriate, give a short summary of their contents.

This report addresses a whole series of issues, of which an overview is given below.

Categorisation of NPBTs

In the current debate on regulating NPBTs, different ways of categorising the techniques are proposed. For the purposes of legal assessment, they are grouped according to specific criteria. The scientific publications currently available suggest that different authors apply different criteria to differentiate between the techniques and to place them into categories, the reason for this being that the categorisation criteria cannot easily be determined empirically. Furthermore, the decision as to which categorisation criteria should be considered relevant is a normative one. Categorisation is necessary in order to assess techniques and their products. From an ethical viewpoint, however, we need to ask how these categories are formed and what the basis of the applied criteria is. We also need to ask if they serve or are designed to serve any other purposes and interests. Such purposes and interests are not neutral, and must be openly discussed and justified in the decision-making process.

Differentiation between "natural" and "artificial"

Even before the advent of modern genetic engineering, to many people it was important whether a plant was created "naturally" (usually understood as "using conventional cross-breeding techniques") or "artificially" (usually understood as "genetically engineered or altered in a non-natural way"). Put simplistically, "natural" is associated with "better" and "artificial" with "worse", or vice versa, depending on the viewpoint. Regardless of the connotations given to "natural" and "artificial", these notions involve moral evaluations. Although often implicit only, such evaluations have an influence on the risk assessment

of NPBTs. The ECNH therefore critically considers this differentiation and its implicit effect on the discussion of risk in Section 3.1.

New plant breeding techniques and the dignity of living beings

When methods in genetic engineering started to be used in breeding techniques, there was considerable controversy over whether the genome of animals, plants and other living beings could be interfered with and modified in such a way as had not previously been possible. In Switzerland this led in 1992 to the adoption of Art. 120[5] of the Federal Constitution: in the use of reproductive and genetic material from animals, plants and other organisms, the dignity of living beings should be taken account of and the genetic diversity of animal and plant species protected. The ECNH was deployed in 1998 to provide, inter alia, advice and support in implementing this constitutional provision. It is therefore appropriate to assess any objections to the development and use of NPBTs in the light of the mandate given by Art. 120 of the Constitution (Section 3.2).

Considerations on risk ethics

In Section 3.3 the ECNH addresses questions of risk ethics involved in the use of NPBTs. Here the ECNH reiterates some important fundamental considerations on risk ethics, which it first discussed in detail in its 2012 report on the release of genetically modified plants.[6] These are also of importance when assessing the risk of NPBTs; any special aspects of risk assessment with relation to NPBTs need to be considered.

Nutrition and self-determination

Besides the debate on risk ethics, self-determination is a further aspect that is of moral significance. Self-determination is the ability to decide how one wishes to live one's own life. The right to self-determination, understood as a liberty right, is to be seen primarily as the right to be protected against encroachment on this right to self-determination. This does not yet result in obligations for third parties, apart from the obligation not to infringe on this right to self-determination. In Section 3.4,

4 Arguably, this investigation would also need to consider conventional, non-genetic plant-breeding techniques from a new perspective.

5 Art. 120 of the new Federal Constitution of 1999 corresponds to Art. 24 novies para. 3 submitted to popular vote in 1992.

6 ECNH, Release of genetically modified plants – ethical requirements, 2012.

the ECNH discusses the issue of food and the extent to which this liberty right can justify claims against others above and beyond this right to self-determination, and what consequences this could have for the regulation of NPBTs.

Impact on research

In the discussion on NPBTs, one of the fears expressed is that these new techniques could have a range of negative impacts on research into and development of other breeding techniques and objectives. The ECNH addresses these reservations in Section 3.5.

NPBTs and intellectual property issues

In this report, the ECNH will not address the ethical questions involved in the intellectual property issues relating to NPBTs and their products, e. g. what objections are made to awarding intellectual property rights and how are they justified? Is it possible to respond to justified objections and find an ethically acceptable solution to conflicting interests concerning the protection of intellectual achievements on the one hand and access to genetic material for breeding techniques on the other? Here reference is made to a study commissioned by the ECNH.[7]

7 Eva Gelinsky, Geistige Eigentumsrechte im Bereich der neuen Pflanzenzuchtverfahren, Literaturübersicht und Einschätzungen, November 2013, commissioned by the ECNH, published on www.ekah.ch (in German).

2 “New Plant Breeding Techniques” (NPBTs)

The term “new plant breeding techniques” encompasses a wide range of different processes. Many of them cannot be easily differentiated from either genetic techniques or conventional techniques, or at least not entirely. NPBTs use the latest technical developments in genetic engineering, combining them with classical crossing techniques or other conventional processes to modify the plant’s genetic makeup. However, they can also involve methods which, like current techniques in genetic engineering, intervene directly in the genome of the plant and change it by introducing either foreign or endogenous genetic material.

The ECNH believes that the discussion should not focus on the statutory classification of individual techniques, but on assessing the risks associated with these techniques. In order to gain an idea of the issues, the ECNH commissioned a specialist report from the Austrian Environment Agency (UBA).[8] One of the Commission’s concerns was to learn about the NPBTs at the centre of the current regulation discussion. It also wanted the authors to draw up specific criteria upon which the risks associated with the application of the techniques can be assessed.

In this report, the ECNH refrains from listing and explaining the techniques discussed, referring instead in particular to the UBA report and that by Benno Vogel. Here we concentrate on highlighting the challenges involved in drawing up and suitably defining and categorising the new techniques.

2.1 Definitions and categorisation: Challenges

The UBA report investigates the damage situations associated with the various NPBTs and draws up criteria on which the probability of these scenarios occurring can be assessed quantitatively and qualitatively. As there is such a wide range of techniques which fall under the term NPBTs, the authors divide them into eight categories. To do this, they assessed to what extent experiences from conventional breeding on the one hand and approaches currently used in genetic engineering techniques on the other can be used to assess the risks. Benno Vogel’s study

8 Michael Eckerstorfer, Marianne Miklau, Helmut Gaugitsch, New Plant Breeding Techniques and Risks Associated with their Application, Umweltbundesamt Wien (Austrian Environment Agency), Specialist report commissioned by the ECNH, March 2014, published on www.ekah.ch.

categorises the new techniques according to whether and to what extent they fall under the legal definition of gene technology, dividing them into 22 categories. The aim of the two reports is to provide a basis for deciding how NPBTs should be used. They both make reference in one way or another to definitions, criteria and assessment standards applicable to current techniques in genetic engineering and their products.

Both reports assume that the relevant standards currently applied in genetic techniques and their products provide a sufficient basis for risk assessment. Some considerations from risk theory and their practical application must first be considered in order to determine the validity of this assumption. This is the first challenge, which the ECNH addresses in Section 3.3.

A second challenge lies in showing to what extent the assessment methods referred to may actually be applied in the case of NPBTs. In view of the myriad new techniques and the different ways of combining them with conventional and genetic techniques, criteria need to be developed which differentiate the former from the two latter plant breeding methods.

Plant breeding techniques can in fact be categorised according to very different viewpoints – depending on what is considered relevant to the particular NPBT: research objectives, field of application, risk associated with the technique or the characteristics of the resulting product. However, the categorisation of the techniques is never merely descriptive. In selecting the criteria and differentiating between the techniques based on these criteria, the legal implications of particular techniques and their products are also established. Categorisation is also always associated with evaluations, either implicit or explicit. If these evaluations serve to legitimise the way NPBTs are used, we need to look closely at the reasons for them and whether they are justifiable? Furthermore, they must be transparent and comprehensible. From an ethical viewpoint, the criteria for categorising NPBTs must be selected in such a way that NPBTs can be used in an ethically acceptable manner. In Section 3 the ECNH discusses the aspects that need to be considered in this respect.

2.2 Three examples

In the current discussion on regulation, an attempt is made to divide NPBTs into two categories: genetic engineering techniques and non-genetic engineering techniques. The following three examples, on which the current debate on regulation of NPBTs focuses, serve to illustrate the value criteria upon which this division is based. The ECNH does not attempt to propose its own categorisation. It simply aims to raise awareness of the fact that the viewpoints considered in categorising NPBTs should be formulated in a transparent and clear manner, so that the consequences of any regulations drawn up on this basis can be openly discussed.

2.2.1 Accelerated breeding

Accelerated breeding involves combining genetic techniques with the technique of crossing different parent plants. The genetically transferred genes that

induce early flowering can be taken from other plants of the same species, from related wild species or from species which cannot be crossed naturally. For example, in accelerated apple breeding, birch tree genes are added to apple plants to preserve the characteristic of early flowering. The apple tree therefore flowers in the first year, rather than the fifth or sixth, as is usually the case. The transgenetic early flowering apple trees are then used in a conventional breeding process. Fifty percent of the progenies are then transgenetic, and so will flower early. If a resistance gene, e.g. from a wild apple variety, is crossed in, once again fifty percent of the progenies possess the resistance gene. A quarter of the progenies have the early-flowering characteristic and the resistance gene. A seedling is selected from this quarter and used to "backcross" with varieties that display good fruiting qualities. This backcrossing process is repeated several times until the desired fruiting quality of the seedlings is reached. At the end of the breeding process, those seedlings which are resistant and have good fruiting qualities, but which no longer contain the birch gene, continue to be used.

Depending on whether it is considered necessary to take into account solely the product or both the process and the product in order to make an appropriate assessment, different results will be arrived at in categorising the accelerated breeding technique. If only the final product of the accelerated breeding process is considered, e.g. the apple variety, and if it can be shown that this variety contains no genetically modified DNA, then it could be concluded that this NPBT does not fall into the "genetic engineering" category, but could be regarded as a conventional breeding technique. However, if it is maintained that an appropriate assessment should also involve consideration of the process, then accelerated breeding fits into the "genetic engineering" category, as genetic engineering techniques are applied in the process.

2.2.2 RNA interference

The RNA interference (RNAi) process is used to "switch off" certain genes. Short ribonucleic acids (RNA)[9] bind with mRNA, which conveys genetic information,[10] and cleave the

9 RNA (ribonucleic acid) molecules are present in large numbers in plant cells. Some RNAs can control the production of several different proteins. They therefore play an important role in regulating the reading of genes in plants.

10 mRNA (messenger RNA) is the RNA transcript of a fragment of DNA.

mRNA into fragments. This prevents the mRNA from producing a protein, thereby inhibiting gene expression. This process can be used to modify plants genetically so that they can synthesise insect-specific RNA. When insect pests consume this RNA, the RNA molecules switch off vital genes in the insects and they die. The use of RNAi in curing human disease has yet to produce significant results, as it has proven difficult to introduce RNA into human cells. Insects, however – and in particular their larvae, which are which typically are voracious eaters – absorb RNA easily via the midgut, from where the RNA can spread throughout the whole of the insect's body. New RNA insecticides are designed to be so specific that even insect species that are closely related to the targeted pests are not supposed to be affected. Seed that has been genetically modified by means of RNAi to produce plants resistant to the western corn rootworm is currently being tested in the USA. The RNA applied switches off a specific gene (Snf7) that transports proteins to the correct place in the cell. Without this function, the insect larvae die within a few days.[11]

Before the RNAi process can be categorised, the exactness (target-orientaton) of the technique needs to be discussed in detail. When compared with genetic engineering processes, it can be argued that RNAi, by virtue of being a more precise process, is safer than more imprecise genetic modification technologies. A risk assessment, however, will highlight the fact that neither the precision aspect nor a comparison between two techniques tell us anything about the safety of a given technique. Instead, it will take the associated risks as the basis for assessing and categorising the technique. For the RNAi method to have the desired effect, the plants must produce specific RNAi molecules, which are then eaten by the insect pests attacking the plants. These RNAi molecules must then cause the insects to die. A small mutation in the genome could mean that the insects develop resistance to the RNAi molecules. A genome mutation in the insect may already occur in laboratory tests, but such a change may also first occur in the field, when the modified plants interact with their environment. This example clearly shows that the

11 Critics claim that the consequences of the RNAi process are currently unclear, as very little (independent) research into the risks has been carried out. In particular they question whether it can be guaranteed that the RNA which switches off this Snf7 gene does not also pose a risk to other animals and possibly also for humans. They refer, for example, to the scientific paper by Zhang, L. et al., 2012 (Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. In: Cell Research 22, pp. 107–126). This demonstrates that RNA material from edible plants can also be detected in the blood of mice and humans.

discussion on categorising NPBTs centres on which assessment model is applied (for a detailed discussion of this issue, see Section 3.3).

2.2.3 Oligonucleotide-directed mutagenesis

Oligonucleotide-directed mutagenesis (ODM) operates with short DNA fragments that can be produced in the laboratory from natural examples. The DNA is engineered at a specific point, for example to create resistance to a herbicide. These short synthetic DNA fragments (oligonucleotides) are implanted into the cells in such a way that they do not become part of the cell's genome. The aim is for the cell to adapt its own DNA to the foreign synthesised fragment. In this way, the plant's DNA is modified at the desired position.

Using current methods, no genetic difference can be identified between plants which have been bred using ODM and those bred conventionally. The ODM method is one of the new techniques in plant breeding for which no definitive legal status has yet been established in the EU. Using the so-called *Rapid Trait Development System* (RTDS™), an ODM technique, a herbicide-resistant rape variety has been developed which the company *Cibus Europe* plans to test in field trials in Germany. In February 2015, at the request of Cibus, Germany's Federal Office of Consumer Protection and Food Safety (BVL) officially stated that it did not classify the herbicide-resistant rape produced using the ODM technique as a genetically modified organism within the meaning of the Genetic Engineering Act.[12] As a result of this decision on categorisation of the rape variety, the latter is not subject to licensing regulations governing the release of genetically modified organisms.

12 This decision by the German Federal Office of Consumer Protection and Food Safety (BVL) applies until such time as the EU Commission makes an alternative assessment. The BVL based its decision on a statement by the German Central Committee on Biological Safety (ZKBS). Several organisations and associations appealed against this decision, expressing the same concerns about the Cibus rapeseed technique as are raised about classical genetic engineering techniques. They also criticised the BVL for taking this decision before the technique had been tested by the EU Commission. The BVL rejected this objection on 3 June 2015. In response, on 3 July 2015, two affected companies and Friends of the Earth Germany (Bund für Umwelt und Naturschutz Deutschland, BUND), supported by an alliance of other organisations, filed a suit against the BVL.

3 Ethical considerations

3.1 Differentiation between "natural" and "artificial"

The differentiation between "natural" and "artificial" has been of importance not just since the advent of modern genetic engineering. It is an aspect of many debates on the ethical assessment of new technologies and regularly influences judgements made in many different areas of life, not only with regard to medicine, animals or the environment. The more technical an intervention in natural processes appears, the more artificial the result of the intervention is considered to be. The difference between "natural" and "artificially modified" organisms is also the implicit basis upon which genetic engineering is defined. Because it also plays a role in the debate about definitions and categorisation of NPBTs, it needs to be addressed here and attention drawn to the implicit impact of such a distinction.

In the context of NPBTs, plants which are the product of conventional breeding techniques, as can also occur in nature, are termed "natural". Plants which are the product of new techniques are, in this process of differentiation, regarded as "artificial". Between the two ends of the scale there is a gradation between naturalness and artificiality, depending how far the techniques or their products resemble or differ from conventional processes. The assessment of NPBTs can be influenced by this process of differentiation between "natural" and "artificial" on two levels.

3.1.1 Influence of differentiation on the moral status of a plant

Some believe that the way in which a plant comes into being determines its moral status. Naturalness is an aspect to which particular value is ascribed. This position holds that artificially manufactured plants therefore have no moral status or a lesser one than plants created by a natural process.

The ECNH members are of the **unanimous opinion** that a being's moral status, and therefore whether and how it should be considered morally, does not depend on the way in which it arises but on whether it possesses characteristics which are relevant from a

moral viewpoint. Depending on the ethical position taken, these characteristics are e. g. the ability to feel pain, to be sentient, or the mere fact of being alive (even when artificially created). In the opinion of the ECNH, the criterion "naturalness" is not enough to determine the moral status of a being.[13]

3.1.2 Influence of differentiation on risk assessment

The differentiation between "natural" and "artificial" can – independent of the debate about the moral status of plants – have an influence on risk assessment.

Many people believe that the greater the similarity between an "artificial" process – i. e. one involving a technical intervention – and a natural process, the smaller the risk involved in the technique and its products. And the greater the differences between an NPBT and a conventional technique, or the profounder a technical intervention, the higher the associated risk is usually considered to be. Others view the connection between the level of technical intervention and risk assessment from exactly the opposite angle: the more technical the intervention appears, the greater the level of control over the risks associated with the intervention and the resulting product is considered to be.

There is a broad understanding of what constitutes the level of intervention, for example the extent of modification (e. g. the number of modified genes), the extent to which natural processes are reduced, the precision of an intervention or the length of time it remains effective. The ability of a plant to reproduce or adapt may also be a factor in assessing the intensity or level of intervention.

Most people intuitively adopt the notion that there is a correlation in one or other of the above-mentioned ways between the level of intervention (the extent of the technical impact and therefore the "artificiality" of the product) and the risk involved, and this influences many of their everyday judgements.

A **minority** of ECNH members however, believe there is no basic correlation between level of intervention and

13 On this issue, see Bernard Baertschi, Artificial life. The moral status of artificial living beings, publ. ECNH, 2009; see also ECNH, Synthetic Biology – Ethical Considerations, 2010, p. 15.

risk for any of the above-mentioned aspects. The **majority** also hold the view that there is no essential relationship between the level of intervention and the associated risks. However, this majority believe that an indirect link between level of intervention and risk is plausible inasmuch as the greater the disparity between a given technique and a natural process, the less reliable the findings about the effects of the NPBT and the new plants in the field. In view of the negative experiences with other technological applications in the environment, e. g. earthquakes following geothermal drilling, and the speed of developments in plant breeding, it therefore makes sense to attribute a certain weight to the notion of artificiality as an indicator in risk assessment and to consider very carefully the use of artificial processes in the environment. The ECNH members **all agree** that lack of experience with new plant breeding techniques and their products is an important factor in risk assessment.

3.2 New plant breeding techniques and the dignity of living beings

Article 120 of the Federal Constitution states that the dignity of living beings should be taken account of in the treatment of animals, plants and other organisms. Before discussing what requirements must be met for an adequate risk assessment of NPBTs and their applications, we must look at whether objections can be raised to creating plants using NPBTs on the basis of the notion of the dignity of living beings, which was adopted in the Constitution in 1992 following a referendum.

In its 2008 report "The dignity of living beings with regard to plants – Moral consideration of plants for their own sake", the ECNH was commissioned by the Federal Administration to consider how to define the dignity of living beings in the context of the ethically justified treatment of plants. The ECNH is of the opinion that it is possible to subject the constitutional concept of the dignity of living beings to a weighing up of interests. The interests of plants need to be weighed against the interests of other living beings. This understanding also corresponds to the legal explanation of the constitutional concept with regard to animals. The ECNH further considers that the concept of the dignity of living beings refers to individual beings. In the case of plants it is difficult to determine what the morally relevant entity is which, in itself, has interests. Is it the parts of the plant which are capable of surviving independently, the individual plants or the network of plants? Or is it impossible to answer this question, because we do not know anything about the pertinent issues, and perhaps cannot know anything about them? And finally, we need to ask which ethical fundamental positions allow us to consider plants for their own sake. A more detailed discussion of the stages in the debate can be found in the 2008 report. Here the ECNH will confine itself to explaining the main positions held by


the members and to examining their significance in terms of the dignity of living beings and the permissibility of NPBTs.

In 2008, the majority of the then ECNH members adopted a biocentric ethical approach: the key relevant moral characteristic of this position is that plants are living beings. In connection with a hierarchical position,[14] this majority considered that any human interest in intervening in a plant's genetic makeup should, from a moral viewpoint, be weighted higher than the interests of plants. The only exception to this are inventions that occur arbitrarily, i.e. *without any reason*, such as the gratuitous destruction of plants. Gratuitous destruction, which is a purely arbitrary action, is not an interest that can be weighed and so be used to justify interference with a plant. As NPBT interventions on plants do not occur arbitrarily, according to this position no objection can be made to creating plants using NPBTs based on the dignity of living beings.

A minority of the ECNH in its composition in 2008 held a pathocentric position. According to this position, sentience is the morally relevant characteristic upon which interests should be weighed. The minority held that there is no scientifically plausible basis for assuming that plants are in any way sentient. Accordingly, plants cannot perceive interventions as being damaging to themselves. In terms of the dignity of living beings, interventions on plants are therefore essentially permissible, and do not require justification.

Neither the majority nor the minority position, as stated in the 2008 report, would raise objections to the production of plants using NPBTs on the basis of the dignity of living beings. The **majority** of the current ECNH members also hold this opinion. However, it should be made clear that within this majority, a minority of members only support this conclusion because they already have doubts about the theoretical justification of applying the constitutional concept of the dignity of living beings to plants. With regard to plants, this minority believe that the concept of dignity is linked to characteristics which plants – based on what we know – do not have (e.g. self-referentiality, autonomy, sentience). This opinion is to some extent similar to the minority position held in 2008, which links the intrinsic value of a living being to the characteristic of sentience, and does not consider it plausible that plants have this characteristic.

A **minority** in the current committee conclude, however – for instance from a hierarchical biocentric position, which bestows intrinsic value on all living beings – that care must be taken in the case of plants: humans never have the right to do with them totally as they please. However, this does not mean that we may not instrumentalise them at all. But before plants are instrumentalised in such a way that they lose their fertility and adaptability, good and relevant reasons must be given.

None of the majority or minority positions held within the ECNH exclude the possibility of formulating other

14 The same morally relevant interest is weighted higher for humans than for animals, and for animals higher than for plants.

ethical objections to breeding and using plants created using NPBTs, quite apart from the dignity of living beings. The reasons for these objections are not found in the moral value of plants, but rather in the legitimate interests of humans or other morally relevant living beings. In the following paragraphs we will look at the exact nature of these objections, the arguments raised to defend them and the positions held by the members of the ECNH.

3.3 Considerations on risk ethics

As explained in Section 2.1, the process of defining and categorising NPBTs is linked directly to evaluative aspects. The choice of criteria to differentiate between NPBTs, genetic engineering and conventional techniques has ethically normative consequences and may also have an impact on legal regulations. When assessing the risks of techniques used in conventional breeding processes, reference is usually made to experiential knowledge. Special authorisation procedures are in place for the use of genetically engineered plants and their products. We must therefore clarify the extent to which an assessment of the risks associated with NPBTs can be made based on experiential knowledge from conventional breeding on the one hand, and by applying means of assessment which have so far been used for genetically modified plants on the other.

In its 2012 report entitled "Release of genetically modified plants – ethical requirements", the ECNH looked closely at the ethical requirements for making an adequate risk assessment of new plants in the field. The considerations set out in the report can essentially be applied to all new plant breeding techniques when there is doubt over the extent to which experiential knowledge can be relied on. A brief overview of the main considerations in this report is therefore given here.

3.3.1 Two assessment models

In its 2012 report, the ECNH distinguishes between two assessment models:

Model 1:
new plant = parent plant + added or modified characteristic(s)

Model 2:
new plant > parent plant + added or modified characteristic(s)

The *first model* assumes that the new plant is the sum of the parent plant (the unmodified reference plant) and a new characteristic or several new characteristics. These new characteristics can be created by adding, removing or repressing genes or genetic sequences. If the parent plant and the new characteristic(s) are each considered safe in their own right, the first assessment model comes to the conclusion that the new plant is safe. A *safety assessment* is carried out. A **small majority** find this assessment model sufficient and therefore adequate.

The *second model* looks at the new plant not as a sum but rather as something more than the parent plant and

the newly added characteristics. It is not just these characteristics which are new; the whole plant is new, and as such is an unknown entity. If the plant is conceived of in this way, simply examining the new characteristics in isolation does not allow us to predict the consequences of making a modification within the plant and of releasing the plant into the environment. Our knowledge is incomplete. It is not possible to make a definitive assessment of the safety of the plant, and so *a risk assessment* must be conducted. The risks posed by the new plant can be identified by looking at the products of the various damage scenarios and their probability of occurrence.

A **large majority of the ECNH members** are of the opinion that an adequate assessment of genetically modified plants can only be based on an understanding of the plant according to this second model, and that a risk assessment must therefore be made. NPBTs can also lead to unintentional and unexpected changes in the plant, besides the intended genetic modifications. Epigenetic effects, which may be desirable, may also result.

Such unintentional and unpredicted changes and effects lie in the nature of all breeding processes. Theoretically, all plant breeding techniques and their products should therefore be assessed according to the risk model.[15] The crucial question is to what extent it is legitimate, when conducting a risk assessment, to rely on experiential knowledge in order to assess the risks associated with such changes and effects. The basis of this experiential knowledge also needs to be made clear. According to the second assessment model, a definitive assessment cannot be based on experiential knowledge of the parent plant and of the modified characteristics alone. There must be experiential knowledge of the whole of the new plant. In conventional plant breeding, the assumption is made (whether always legitimately is open to debate) that the extent of experiential knowledge is such that self-control and monitoring suffice. In the case of NPBTs and their products, in the Model 2 concept, such experiential knowledge does not exist. This does not mean that in these cases experiential knowledge of the components “parent plant” and “new characteristics” cannot be used *as a basis for developing risk-relevant knowledge*. In this case, it may also be necessary to establish the extent to which such a basis varies for the different categories of NPBTs.

A **small minority of the ECNH**, although supporting the second assessment model, i.e. taking the opinion that the new plant should be seen as more than just the sum of the parent plant and the added or removed gene sequences, are not entirely in agreement with the understanding of risk outlined above, arguing that all parameters relevant to the risk assessment can be found in the product. Only the product need therefore be submitted to a risk assessment. According to this position, the technique has no significance in the risk assessment.

15 This applies not only to genetic engineering and NPBTs, but basically also to all techniques which interfere in the genetic structure of plants, therefore also to products resulting from classic mutagenesis, in vitro reproduction and conventional crossing techniques. The latter are not discussed in this report. However, it would also be worth considering if considerations regarding NPBTs also apply to conventional processes. For when considering new breeding techniques, it is not enough to refer to experiential knowledge about the parent plant, as there may always be unintended and unexpected effects.

A **large majority of the ECNH** counter the argument that *all* parameters for the risk assessment can be found in the product and that an assessment can therefore be restricted to the product, raising the following considerations. Firstly, we must ask what is meant exactly by the phrase "everything can be found in the product". If this simply means that all the effects of a product can be causally ascribed to the product itself and so arise from the product, the statement is a trivial one. For a risk assessment of organisms released into the environment, this statement becomes meaningless. Secondly, a full understanding of the causal effects of a product can only be achieved in ideal laboratory conditions.[16] In this context, however, we are not looking at a risk assessment in the laboratory, but at the risks of plants released into the environment that have been produced using new plant breeding techniques. It is clear that, as a result of the biological processes and the interactions taking place between biological organisms and their environment, the number of parameters relevant to a risk assessment rises considerably. These parameters not only involve the released product; as the plants interact with their surroundings, the environment is also affected, and this in turn may result in new changes in the original plant. A plant is not a static product, but rather an organism that constantly interacts with its environment, which itself is not static. Therefore, the product alone does not provide all the relevant parameters necessary for an adequate risk assessment.[17] Of course, this position also holds that product assessment is a key component of the risk assessment, but because there is incomplete knowledge about the effects of a technique on the product and its environment, this risk assessment should not be made independently of the technique used to generate the product.

3.3.2 Principles of appropriate risk assessment

It is in the nature of risk situations that one has only incomplete knowledge, be it incomplete causal and therefore predictive knowledge, or an incomplete knowledge of the risk. In the case of NPBTs, the lack of complete knowledge results partly from unforeseen changes that may take place within the plant as a result of the NPBT. Secondly, because of the unknown number of parameters, we can only have an incomplete understanding of the possible interactions of plants with their environment.[18] The uncertainties regarding long-term and cumulative impacts are also an element in the incompleteness of knowledge.

When risk situations are handled reasonably, the aim is not generally to exclude all risks. To want to eliminate all risk would mean it would no longer be possible to act. Making a reasonable decision in situations of incomplete knowledge therefore means restricting options for action only as far as necessary. In dealing with risky procedures and their products in the environment, one exposes both oneself and others to risk. Exposing others to

16 It must also be borne in mind that adequate ways of identifying risk-relevant parameters are often only developed and refined at a later stage.

17 Moreover, if it is argued that the risks arising from release do not exceed those assessed in the laboratory, then it is assumed that "nature" in no way increases risks; it may in fact reduce them. According to this conception of nature, the only risk of a plant produced by an NPBT would be that it did not "function" in the environment as expected. It would therefore have to be assumed that the only risks associated with a particular plant are those already anticipated in the laboratory. The ECNH considers this view to be laden with assumptions and implausible. For the sake of completeness, a further conception of nature which is frequently put forward in the risk discussion should be mentioned here. This views nature as a "black box". We cannot predict what will happen in nature. Possible risks cannot therefore be included in an assessment. This view fails to recognise that the need to decide despite not being able to predict all the consequences of that decision is precisely the essence of a risk situation. Furthermore, in order to make an adequate risk assessment, it is not necessary to have thought of all the possible or conceivable consequences. However, plausible consequences must play a role in the risk assessment. Interactions with the environment are among such plausible risks. One of the tasks of risk assessment is to investigate the plausible risks and not to conceal them in the concept of the "black box". If nature really were a "black box" as understood by this position, then it would essentially be impossible to determine probabilities and therefore risks. The only rational consequence would therefore have to be that organisms should not be released.

18 In a closed system, the safety of new plants can, under some circumstances, be conclusively determined if the parameters used in the assessment are limited to a reasonable and "manageable" number. However, a safety assessment can only

risk is acceptable when the risks are generally reasonable. However, the risks must be identified and assessed before it can be decided whether the risks for third parties are reasonable.

The concept of risk is characterised by two variables: “extent of damage” and “probability of occurrence”. A risk exists if damage occurs with a certain probability. In order to assess the risk posed by NPBTs and their products, the plausible damage scenarios and the related data on probability of occurrence must first be known.

In order for risks to be assessed, in principle they need to be quantified. The quantification of new techniques in particular often involves a large amount of effort or, indeed, is not even possible. Under these circumstances, qualitative information may also be sufficient. However, it must be possible to compare this information with other known risks and assess it on that basis.

If there is little or no quantitative data or qualitative information upon which to make an appropriate risk assessment with regard to the release of a plant in the environment, such data must be gathered gradually. In its report on the risk assessment of the release of genetically modified plants, the majority of the ECNH argued that, even when there is still little scientific data regarding the new plants, there is no need to start from square one. Some reference can at least be made to a certain experiential knowledge. There are initial elements upon which the knowledge necessary for an adequate risk assessment can be incrementally developed. Firstly, this requires a step-by-step increase in the factors with which the plants interact. Secondly, the number of plants that are exposed to this interaction needs be increased gradually. Each next step must only occur when enough data has been gathered from the previous step to provide sufficient knowledge regarding the damage scenarios and probabilities of occurrence necessary for an appropriate risk assessment. Moreover, the risks associated with this step must be considered acceptable for third parties.

There is still no clear answer to when sufficient knowledge has been gathered to evaluate appropriately the risks associated with the next stage. The ECNH restricts itself to naming a few criteria that, in its view, must definitely be met, as well as to setting out some methodological considerations.

In order to generate the knowledge necessary for an adequate risk assessment, the relevant questions regarding plausible damage scenarios and probability of occurrence must first be asked. Risk data must be based on suitable research work, information sources and publications. To this end, where appropriate, the ECNH encourages the development and establishment of quality criteria that allow us to adduce and assess research and study findings, in plant breeding research just as in medical authorisation procedures. Among other things, it must be ensured that the research data and information referred to are readily understood. This

relate to the effects a plant may have within this closed system, and not to its effects in another (i.e. open) system. However, the time factor is often not considered: the fact that some effects may not manifest themselves until after some considerable time is frequently forgotten.

means providing access to the plant material so that the results of third parties can be checked. Furthermore, it should be examined how access to unpublished studies and studies with negative research findings can be ensured.

3.3.3 Peculiarities in assessing the risk of NPBTs

To what extent does the quality of new plant breeding technique assessments differ from that of assessments of genetic engineering procedures, and which risk aspects of NPBTs should we pay particular attention to?

NPBT: a laboratory technique. The term "new plant breeding technique" should not obscure the fact that these procedures – just like genetic engineering techniques – are used in the laboratory. Classical selection procedures to adapt the products of these techniques to circumstances in the environment are not actually applied until the plants are released in the field. Whereas the isolated plant can be tested in the laboratory under defined and controllable conditions, outdoors it may interact in a highly complex manner with multitudinous environmental parameters. Neither, therefore, is the restricted assessment that can be made in laboratory conditions and that is sufficient for investigating the functions of plants in a closed system sufficient to assess the risk of plants produced using NPBTs. Experiments done in the laboratory have no link with external, ecological parameters. For this reason, any results they produce lack external validity to a high degree. First we must ask if the plant with its new characteristics also "functions" in conditions outdoors, and secondly, what its impact on the environment is. As the situation outdoors is more complex, the approach to research in the field differs from that in the laboratory.

Lack of data on effects in the environment. The main focus of the discussion on risk assessment of NPBTs is not their application in the laboratory but the release of the products of these techniques in the environment. To date, according to a report by the UBA,[19] there is little scientific data about the effects of such plants. The scientific debate on this issue has only just begun. Research into the risks is complicated by the fact that many of the techniques discussed are still at the basic research stage, and as yet there is little or no material with which to investigate the impact on the environment. Unlike in genetic engineering, however, in view of the very different techniques which fall under the term NBPTs, it is may be reasonable to draw on experiential knowledge, to differing extents, in order to establish damage scenarios and probability of occurrence.

Speed factor. A **large majority of ECNH members** believes there is one little-considered factor which may have an influence on the risks of NPBTs, namely the increasing speed with which new plants can enter the environment as the result of new breeding techniques, whether used individually or in combination with each other and with other – genetic engineering or traditional – breeding

19 See footnote 8.

techniques. One reason for this is that NPBTs are increasingly based on information technologies. This link between NPBTs and new information technologies means that the development processes in plant breeding are becoming much faster. This majority in the ECNH fear that this will increase the likelihood of damage occurring, as neither the capacity to clarify the risks nor the introduction of adequate authorisation procedures can keep pace with the rate of production and release. In particular it is feared that releasing new plants into the environment at a rapid rate will make it difficult for existing species to adapt, as well as threatening biodiversity and so bringing further risks. Although it is true that little scientific data is generally available on damage scenarios and probability of occurrence for conventionally bred plants, it is assumed that, unlike for NPBTs and genetic engineering techniques, experiential knowledge gathered over an extended period of time is available, and so statements about damage scenarios and probability of occurrence for similarly bred new varieties can be made. For new plants that have been bred using NPBTs there is no comparable quality of long-term experience.

3.3.4 Precautionary principle versus "evidence-based approach"

In the discussion surrounding the risks involved in releasing genetically modified organisms into the environment, very specific objections are regularly made to the application of the precautionary principle.[20] It is therefore worth looking briefly at this principle and these objections in relation to NPBTs as well.

The precautionary principle

It is generally recognised that the precautionary principle should be applied when there are indications that serious and unacceptable damage may occur, but the probability of occurrence can only be assessed very roughly. In such serious cases, the precautionary principle entitles and obliges the authorities to encroach on the freedoms of individuals and businesses – albeit while respecting their fundamental rights – and to restrict their actions in order to prevent potential extensive damage.

The evidence-based approach

Advocates of the evidence-based approach believe that there is no proof so far that genetically modified organisms (GMOs) have caused serious damage to health or the environment. There is therefore no scientific basis for applying the precautionary principle when dealing with GMOs; the reasons are solely politically motivated. They claim that resorting to the precautionary principle hinders scientific and technical innovation, as under some circumstances the state must restrict technological applications despite the lack of certain knowledge about their negative impact. They therefore argue that the precautionary principle should be countered with an evidence-based approach, according to which state-imposed restrictions on such technological applications

20 See e.g. studies carried out in the EU research project "Precautionary Expertise for GM crops" (results published on http://technology.open.ac.uk/cts/peg/index.htm).

in the environment would only be acceptable *if there is scientific evidence* that massive negative effects resulted from the use of genetic engineering.

Advocates of this approach therefore make completely different demands on legislators. They claim that, as there is no evidence of damage, it must be assumed that the technology is safe. There is therefore no (longer) need for special regulation of the technologies. Only the products must still be assessed, not the techniques. However, before the use of products is prohibited, there must be clear evidence of their negative impact on health or the environment.

Objections to the "evidence-based approach" and its conclusions

In this "evidence-based approach", only empirical proof of damage can be judged to provide evidence. Proof of damage can only be brought ex post. However, in risk situations – and the application of NPBTs in the environment creates such a situation – decisions must be made in advance. Predictions must be made even when there is no available evidence of damage. The precautionary principle applies only when there is a r*easonable* suspicion that *serious* damage could occur. Plausible damage scenarios must exist; the mere possibility of damage occurring is insufficient. As it is only possible to talk of probability in risk situations, the argument that no damage has as yet occurred basically leads nowhere.

There are several further arguments to the objection that there are currently no indications for considerable damage caused by NPBTs. As they are relatively new, there is as yet no long-term data about the effects of NPBT products on health and the environment. Furthermore, the general lack of access to these techniques and their products means it is not possible to gather such data in independent risk research studies. Since it is not possible to collect conclusive data about NPBTs in the environment because of the myriad complex factors involved, a systematic monitoring process would need to be developed to record the relevant effects at an early stage, clearly correlate them and react to them, i. e. using proper risk assessment methodologies. Only few and partial attempts have been made to perform this kind of monitoring to date.

A **large majority of the ECNH** feel that there are two plausible reasons for applying the precautionary principle: damage scenarios such as NPBT-produced plants developing resistance or allergenic and toxic properties on the one hand, and past experience with other technologies and products posing serious damage over the long-term or cumulatively (e. g. bovine spongiform encephalopathy [BSE] or damages caused by asbestos, hormone-active substances, or antibiotic-resistant germs).

Moreover, the ECNH rejects by a **large majority** the criticism that the precautionary principle essentially poses a barrier to technology and innovation. Authorisation procedures and regula-

tion of technologies associated with risk do in fact encourage innovation, as research must be carried out into alternative technologies and solutions to problems found.

3.4 Nutrition and self-determination

In addition to the debate on risk ethics, the aspect of self-determination is of moral significance for assessing NPBTs. Self-determination is the ability to freely decide how to live one's life. The right to self-determination in terms of civil rights and liberties is primarily understood as the right to be protected against encroachment on this freedom. This imposes no obligations on others, other than prohibiting them from preventing a person from living an autonomous life (insofar as this self-determination does not unacceptably limit the freedom of other persons).

What rights arise in relation to this demand for self-determination in terms of food? Can we find an ethical justification for these rights? Who can claim legitimate rights in relation to food in the context of self-determination, and which ones? What do these rights involve in relation to NPBTs, and what obligations arise from them, and for whom?[21]

The discussion about self-determination and food often involves a number of stakeholders:

– Individuals, who claim the right to decide independently about the food they eat;

– Producers (seed producers, breeders and farmers), who claim the right to make their own decisions about their methods of production and marketing of their products;

– The political community, which wants to determine the way in which plants are bred, grown and produced for food, and therefore the nutrition of its members.

3.4.1 Self-determination of individuals

For someone to be able to exercise their right of self-determination, some basic requirements must be met.[22] From this follows the obligation for others to ensure that everyone has access to sufficient amounts of safe food.[23] What does this mean for the discussion on NPBTs?

Before a foodstuff that has been produced using NPBTs can be approved on the Swiss market, an adequate risk assessment must first conclude that the risks associated with the release of the product are acceptable, both for a person's health and for the environment. The members of the public must be able to trust that this is so. Given the lack of independent research and the dearth of risk data, however, a certain mistrust in the investigations concerned may be warranted. Where there is insufficient risk data, no adequate risk assessment can be made. Accordingly, in such a case it is not possible to assess whether a risk is acceptable. Furthermore, it must be remembered that a particular product

21 See also ECNH, Gene Technology for Food, 2003. In this report the ECNH looked at individual aspects of freedom of choice in relation to genetically modified foodstuffs.

22 What these are exactly is a matter of debate. Generally, however, safe shelter, access to adequate and safe food and to enough clean water are considered a minimum. Everyone has a right to having these minimum basic requirements met.

23 Who should meet these rights is also a controversial issue, and depends on who is considered to bear responsibility. In this text we focus on the national level, because of the ECNH's mandate. However, from an international viewpoint these obligations may be considered to fall into the realm of universal human rights.

may pose an unacceptable risk for an individual as the result of a particular constellation (e. g. because of an allergy or intolerance), although the risk has been deemed reasonable by the licensing authority. Certainly, an adequate risk assessment will also consider the risks involved for vulnerable people. However, in risk research, which provides the assessment criteria, these risks are neglected to a certain degree, just as they are in actual assessment practices, in which politics and pragmatics play a significant role. This raises the question of whether the right to safe food is sufficiently met in relation to NPBTs.

If, however, a correctly conducted risk assessment concludes that the risk is acceptable, this right may also be met by products that have been produced using NPBTs.

Besides the right to an adequate amount of safe food, there is also the issue of whether further rights, e. g. to a particular kind of food, can be claimed based on the individual's right to self-determination. It is broadly felt that food is a key aspect of our lives, one which determines our understanding of ourselves and forms a major aspect of our identity, and is therefore seen as morally relevant. Considering the controversial debate surrounding NPBTs, the **ECNH unanimously concludes** that the moral issue is of significance in the case of NPBTs.

One expression of a person's self-determination in those areas of life which are important to that person is freedom of choice. By freedom of choice we mean the right to choose between several options. Depending on what it relates to, this right may be seen as a *right to claim* or a *right to defend.*

Since food can be seen as a central element in self-concept, no-one may be forced to eat something that they do not want to eat.[24] However, beyond the right to adequate and safe food, we cannot claim the right to have specific foodstuffs made available to us. On the other hand, we do have the right to avoid certain foodstuffs, i. e. the right to defend. As a result of this right, we can insist that products should be marked so as provide information about their contents and production methods,[25] giving consumers the opportunity to avoid these products.

This raises a whole range of further questions. What should be done when there is no alternative product available for those who wish to or have to avoid a certain product? How far does the right to alternatives extend? Whereas the general public cannot prevent the sale of products that adhere to ideational or religious rules under current legislation, the right to self-determination does not entitle us to demand from the state that such products should be made available. This does not exclude the possibility that there may be other reasons – for example in order to protect minorities and ensure peaceful cohabitation – for taking account of special dietary requirements of an ideational or religious nature and possibly for supporting access to such products.

24 The controversy over whether it is permissible to force feed a person *in an exceptional situation* has no bearing on the arguments put forward in this context for a number of reasons, but these will not be discussed further here.

25 No validity can be given to the objection that genetic intervention in some products is no longer detectable at a later stage and therefore does not need to be indicated. The risk assessment position espoused by the ECNH (Model 2) makes it clear that the risks posed by a plant that has been produced using NPBTs cannot be established solely by examining the composition of the plant (see detailed explanations under Section 3.3). Furthermore, appropriate detection methods are often not developed or refined until later.

The questions relating to the right to claim alternatives are relevant insofar as non-NPBT products, as a result of developments and applications in NPBTs, may effectively become unavailable over the longer term. A claim to the provision of appropriate alternatives to food produced using NPBTs can probably only be justified on the basis of the right to self-determination in the event that the provision of adequate and safe food produced without NPBTs could no longer be guaranteed. The extent to which developments and applications in NPBTs affect, over a longer period, the requirements to protect legitimate claims to alternatives to food produced using NPBTs needs to be examined. If self-determination could potentially be restricted or if the risk that it may be restricted is too high, the necessary measures must be taken when dealing with NPBTs.

3.4.2 Self-determination and production

Seed producers, breeders and farmers have the right to freely choose seeds, breeding methods and farming techniques. In their capacity as producers, they select these primarily for economic reasons, with a view to the needs and interests of the market and the consumers. The right to self-determination does not entitle the seed producers, breeders and farmers to make claims on the state to access certain seeds, breeding techniques or farming methods.

However, the production of seeds and the production and cultivation of crops are a *prerequisite for ensuring individual self-determination* with regard to food. In order to secure the right of every person to adequate and safe food, this first has to be produced. To secure this right in the long term, the bases of food production must be protected; these include biodiversity in general and agrobiodiversity in particular, the preservation of arable land and sufficient water. The knowledge of how to use these bases expediently and sustainably must also be cultivated; this includes both preserving traditional methods and encouraging innovation. Accordingly, we do not only need to ensure access to the bases of production, but also to the appropriate knowledge.

While this does not automatically give producers a direct claim, it does mean that the state has obligations with regard to seed production, breeding and cultivation. The state authorities must ensure that the biodiversity and agricultural biodiversity necessary for food production are also protected long-term. If certain processes and products in fact result in the displacement and restriction of diversified seed production and therefore of agricultural biodiversity, then the state is morally obliged to take all necessary measures to preserve the foundations of diverse and sustainable food production.[26] Such measures could involve not only preserving, but also developing and maintaining varieties with the greatest possible biological diversity. Measures that support access to and the preservation of technical and cultural knowledge on seed handling could also help to maintain seed variety and agrobiodiversity. In particular, if private-sector seed production and

26 The breeding of hybrids also restricts biodiversity. The ECNH is of the view that the same considerations should apply to hybrids. However, they are not discussed in this report.

breeding can be shown to threaten the bases of food production in the long term, the state should become directly involved in plant breeding, seed production and seed conservation. This might mean considering measures to restrict intellectual property rights over seed varieties, if such intellectual property rights pose a serious threat to agrobiodiversity as the basis of food production.

3.4.3 Self-determination and communities

In the context of food, we can also talk of the right to self-determination of communities (political communities, states). With regard to states the primary concept is sovereignty. This generally means the right of a community to organise itself and therefore to shape specific areas of life, including food production and consumption.[27] As a result, we need to ask how a community should use its food sovereignty in relation to NPBTs.

Assuming that each member of a community has the right to adequate and safe food, then a community (i. e. a political community: states or international communities) clearly has an obligation to its members. The community has a duty to create and preserve conditions under which those rights can be protected in the long term. In addition, it must ensure it guarantees its members the right to defend their interests.

In order to preserve social harmony, and considering the threat not only to the preservation of human rights but also to the bases of production in a society when this harmony is disrupted, it may be necessary to take into account specific nutritional needs with a cultural, ideational or religious basis, and in some circumstances to ensure access to the appropriate products. The members of the ECNH have differing views on whether or not NPBTs will in future restrict access to these products.

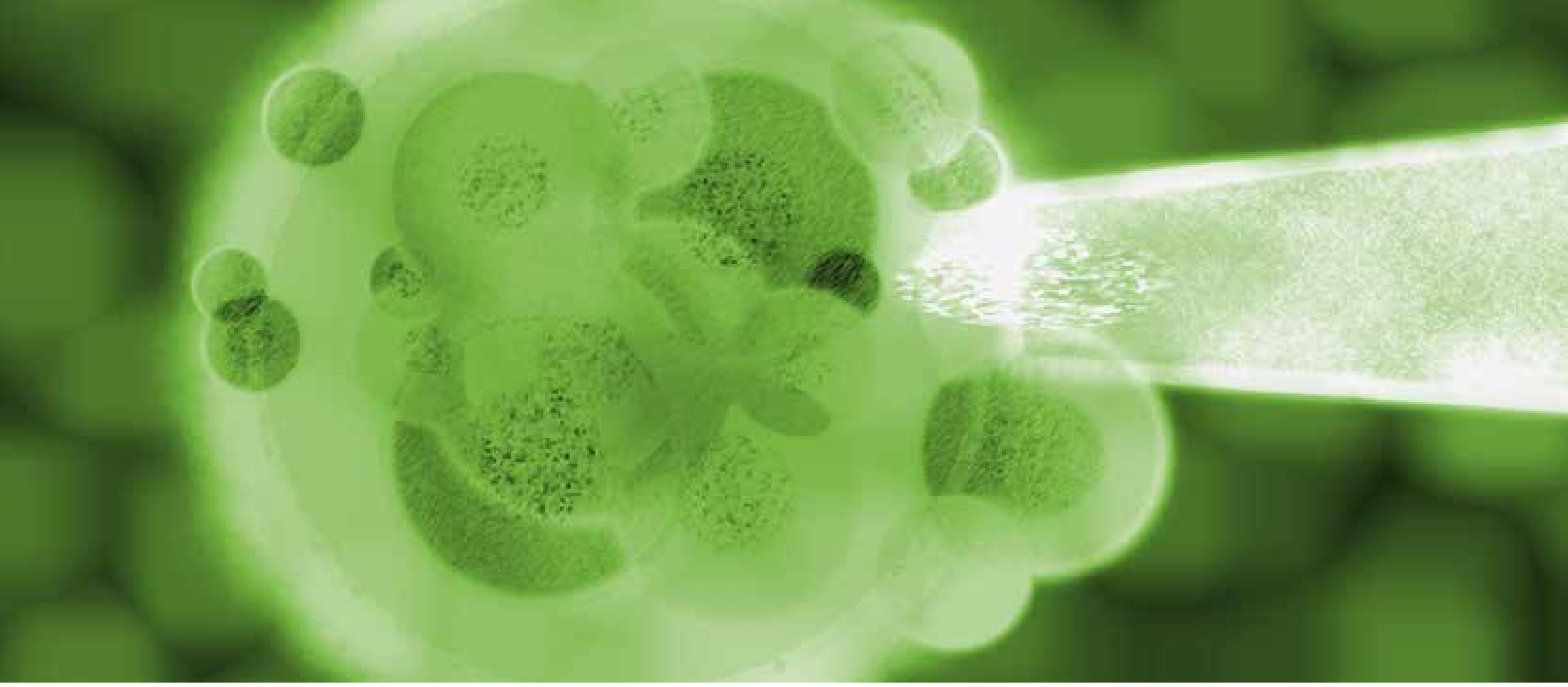
The question of whether rights and obligations arise *between communities*, and what these might be, is not discussed here.

Security of supply and the associated aspect of agrobiodiversity should in particular be considered when NPBTs are regulated at international level. The debate must focus on how to ensure that the less- and under-privileged can feed themselves in a world in which NPBTs are applied. The extent to which dietary habits and traditions should be considered when assessing the right to adequate nutrition also needs to be clarified. For example, under certain circumstances, in order to preserve its right to defend, a community could claim the right to refuse to import NPBTs and their products from another community if this meant that native plants would be suppressed and so a lack of alternative products would ensue.

3.5 Impact on research

In the discussion on NPBTs, one of the fears expressed is that the development and application of these techniques could have a negative impact on research and development of other breeding techniques and objectives.

27 See also ECNH, Gene technology and developing countries, 2004.



Linking NPBTs with information technologies means that huge and complex amounts of data are collected on the genetic composition of plants. It is true that we are as yet unable to analyse and use this vast volume of data to any extent. Yet large companies such as seed and breeding companies nevertheless collect such data because it is, or could become, relevant to the granting of patents on new processes and plant varieties. Although the intellectual property of NPBTs is not discussed in this report, the impact of this development should be borne in mind. Patent claims should not be allowed to impede research. This development in plant breeding may restrict access to seed to such an extent that the bases of sustainable food production could be seriously threatened in the long term.

It is also feared that the breeding of new plants using information technology and the collection and hoarding of data is changing the understanding of what a plant is. The image of the plant as an organism embedded in an environment and network is being replaced by one in which the plant is simply an aggregate of information. Critics argue that the impact of such a change in perception is reflected in breeding activities. Increasingly, plant observation and assessment is based on individual and isolated parameters. The complexity of the network of which the plant forms a part is forgotten. Restricting the way in which the plant is perceived also narrows the way it is assessed. This affects and restricts breeding objectives, so that when the plant is released into the environment, it does not "function" as expected on the basis of the parameters tested in the laboratory. Furthermore, this restriction has an impact on risk research, which focuses on selected individual parameters and ignores the risks that may arise through connection and interaction with the environment.

When this restricted view of plants is combined with biased research promotion, research into plant breeding may concentrate primarily on technological approaches, and so plants are created that – having specific resistance characteristics bred into them – sooner or later will result in undesirable resistance in weeds or pests. A **large majority of the ECNH** believe that this resistance could worsen the problem of weeds and pests, and therefore result in considerably poorer harvests. In view of the problems facing agriculture (and therefore food supply), the majority of the ECNH members believe that research which seeks to solve these problems should consider to a greater extent the complex interactions involved (including in actual cultivation and in the environment) instead of pursuing isolated approaches. For a **small minority**, the most serious consequence of resistance formation is merely that certain transgenetic plants could no longer be used.

4 Recommendations from an ethical viewpoint

Categorisation of NPBTs

– Categorisation are not based on descriptions alone but on implicit assessments. These in turn may affect risk assessment, declaration regulations etc. To enable an open debate on how to deal with NPBTs and their products, the relevant interests and assessments inherent in the categorisation proposals and their effects should be made transparent.

Risk assessment

– It should be ensured that assessments of NPBTs and their products are conducted according to the principles of a risk assessment (assessment model 2) rather than of a safety assessment (assessment model 1).

– For a **large majority of the ECNH members** this also means that it is unacceptable to restrict an assessment of risk to the product alone, disregarding the technique by which it is produced.

– In risk situations, it is only possible to make statements about probability based on statistics. A decision to allow the release and use of plants that originate from NPBTs can only ever be made subject to reservations. A proper risk assessment requires regular updates of risk data on authorised plants, and if necessary adjusting the way these plants are handled. The ECNH therefore recommends developing a monitoring plan for plants produced by NPBTs early on, and setting up systematic accompanying research.

– In view of the considerations on risk ethics, the ECNH sees no reason to reduce the requirements placed on new plant breeding techniques involving genetic engineering, nor on the products which demonstrate genetically engineered modifications. In those cases in which no genetically engineered modifications can be detected in the products (possibly only due to current detecting methods), the ECNH also recommends that a risk assessment should not be carried out on the products alone. A proper

risk assessment of the products can only take place when the techniques used to produce them are also considered.

– The ECNH further recommends that a close eye should be kept on the risks from NPBTs which do not currently fall under the Gene Technology Act, and that the techniques, where necessary, should be adequately regulated.

– Precedents should not be created at national level, such as in the case of the rapeseed produced by the company Cibus using the *Rapid Trait Development System* (RTDS)[28], which in early 2015 was classified in Germany as "not genetically modified". So long as the European Union is still examining whether a technique is subject to genetic engineering regulations or not, individual European countries, including Switzerland, should not make any preemptive decisions which then restrict the decision-making options of other European countries. This is particularly important in the case of plants such as rape, which can spread very rapidly.

– Systematic monitoring should be required and conducted for all NPBTs and their products that are subject to self-regulation.

Ensuring self-determination

– In order to guarantee self-determination, the ECNH recommends introducing suitable declaration requirements for products generated using NPBTs. These should give comprehensive information about the contents of the product and about the techniques used in its production. New detection techniques should be taken into account.

– In order to be able to guarantee long-term individuals' legitimate liberty and claim rights, as well as food security, the bases of production, i. e. biodiversity in general and agrobiodiversity in particular, must be protected.

– In order to protect agricultural biodiversity, precautionary measures may need to be taken with respect to seed development, breeding and cultivation – not only in Switzerland

28 See also Section 2.2.3 on the example of Cibus rape.

but also through international cooperation. Specifically, the following aspects should be considered:

- Ensuring access to seed.
- Ensuring and maintaining access to knowledge about the handling of seeds.
- In addition to maintaining existing gene banks, it should be examined whether further public-sector involvement in breeding is needed, not only to preserve seed, but also to develop it in view of changes to the environment.
- If the intellectual property rights to seeds and their use leads to unacceptable restrictions on the right to self-determination of individuals, statutory regulations regarding intellectual property should be corrected accordingly.
- Under certain circumstances, measures should be taken to promote the development of knowledge about seeds and how to handle them.
- Efforts should be made at international level to maintain and encourage self-sufficiency in food production in order to protect the legitimate rights of all people to self-determination in relation to their food.

Research

– There is a close connection between the need to preserve and foster agrobiodiversity and research into plant breeding. If the type of research pursued by the private sector seems to be leading to a narrowing of the scope of the research objectives and so longer term to a reduction in agrobiodiversity, public funding of plant breeding research must create a balance and ensure greater diversification in the research.

– Developments in intellectual property and its impact on research and objectives in plant breeding should be carefully monitored. If the developments have impacts on agrobiodiversity and the respect for self-determination that cannot be justified, intellectual property rights in plant breeding should be restricted.

– If risk assessment is to be adequate, proper risk research needs to be conducted. This means determining how access to plant material can be guaranteed so that results can be assessed by independent third parties. It should also be asked how access to unpublished studies and studies with negative research results can be ensured.

The public debate

– So far the debate in Switzerland on NPBTs has mainly taken place in academic circles. However, these technologies and their applications affect the whole population. In view of the rapid developments in new techniques and the considerable interest in their use, and also of the objections to the (overly precipitate) introduction of these techniques into the environment, the ECNH feels it is vital to include the wider public in the debate to a greater extent than has been the case so far. In promoting the public debate, it should be ensured that the discussion is as transparent and balanced as possible.

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March 2016

Publisher: Federal Ethics Committee on Non-Human Biotechnology ECNH

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Translation: Philippa Hurni-Bainbridge, Jens

Graphic design: Atelier Bundi AG, Boll

Printing: Ackermanndruck AG, Köniz

This brochure is available in printed form in English, German and French. It is also available in electronic form in these languages and in Italian, at www.ekah.admin.ch.

Printed on chlorine-free paper.

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