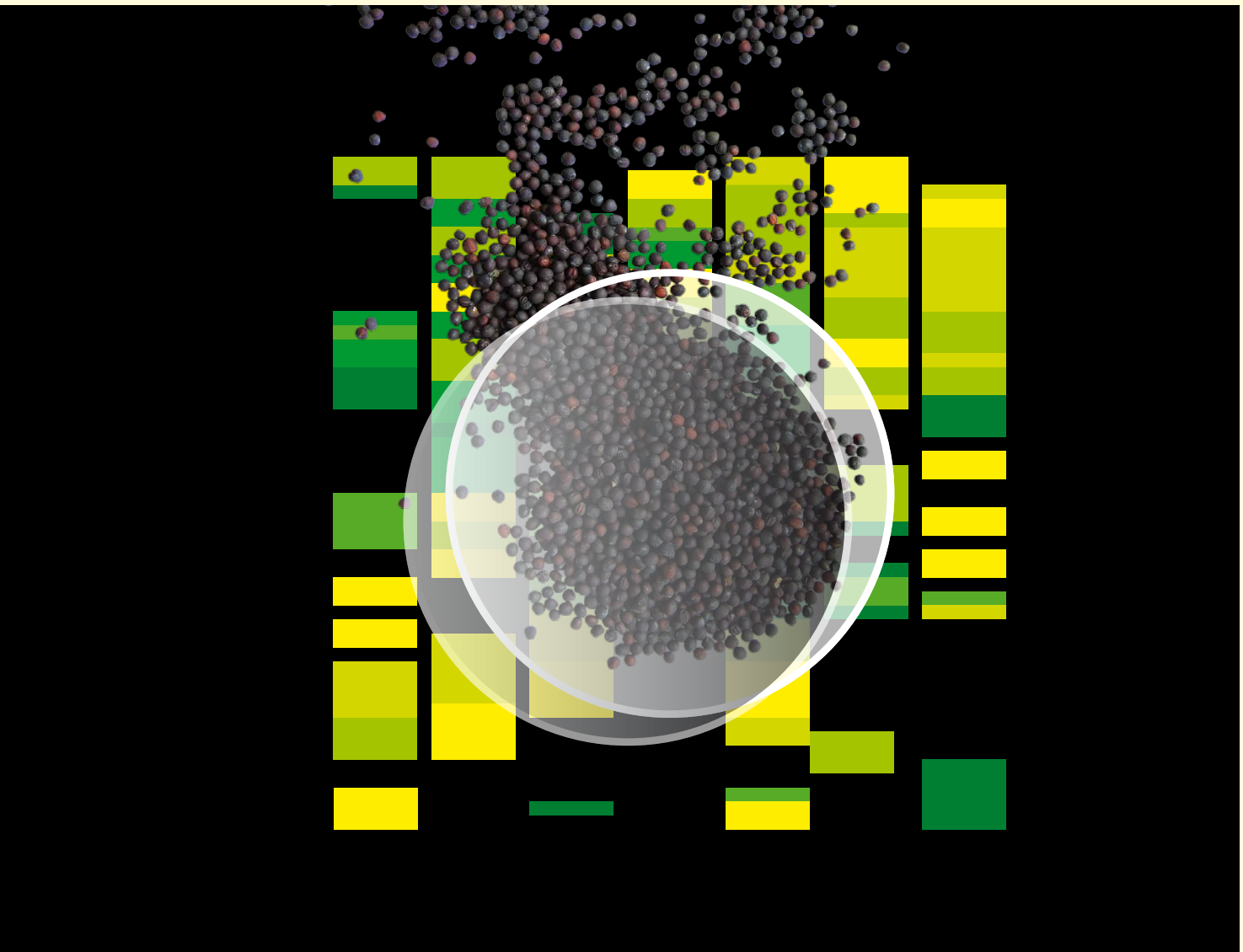
Release of genetically modified plants – ethical requirements

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



Preamble

The EKAH's mandate is to observe developments in non-human gene technology and biotechnology and to assess them from an ethical viewpoint. The Committee advises the federal administration on drawing up and implementing future legislation and specific draft laws. It is also required to provide information about the topics it deals with and to lead the discussion on these issues.

On 12 December 2011 the ECNH presented its statement entitled "Ethical requirements for the experimental and commercial release of genetically modified plants"[1] at a public event in Bern. The statement was well received, although it did evoke some critical reactions. In response to certain aspects of this criticism, and in order to avoid any misunderstanding, the ECNH decided to make its considerations regarding the issues discussed on 12 December 2011 clearer; these are presented in this brochure.

1 See http://www.ekah.admin.ch/en/documentation/statements-by-the-ecnh/statements-on-legislation/index.html

1 Background to the discussion

Moratorium initiative: In November 2005 the Swiss electorate voted in favour of the popular initiative "For foodstuffs from GM-free agriculture". This initiative demanded a transitional provision to article 120 of the Federal Constitution, preventing the cultivation and sale of genetically modified (GM) plants, plant components and seeds for a period of five years, until 28 November 2010. This moratorium did not affect either research into or the experimental release of genetically modified plants. However, the release of GM plants was not permitted on a commercial basis for the duration of the moratorium.

National research programme 59 (NRP 59): On 2 December 2005 the Federal Council decided to commission the Swiss National Science Foundation (SNSF) to conduct a national research programme entitled "Benefits and risks of the deliberate release of genetically modified plants" (NRP 59). The idea was submitted to the State Secretariat for Education and Research during the NRP 2002/2003 evaluation round.[2] Twenty-nine research projects were launched in the autumn of 2007. The research programmes were to run for five years and twelve million Swiss francs was made available for them, the majority of which amount has been spent on experiments into the release of a range of genetically modified wheat lines. In 2009 the SNSF produced an initial interim report for the Department of Home Affairs. The final report on NRP 59 will be published in the summer of 2012.

Moratorium extension until the end of November 2013: In 2009 parliament decided on an amendment to the Gene Technology Act (art. 37*a* GTA) in order to extend the moratorium by a further three years until 27 November 2013. One of the reasons given for extending the moratorium was that the Federal Council wished to await the results of NRP 59, which would then provide a basis for a decision regarding how to proceed with the use of genetically modified plants (GM plants) in Swiss agriculture.

After November 2013: When the moratorium ends, it will again become possible to cultivate GM plants on a commercial basis in Switzerland and to release products resulting from these crops, provided no further decision is made to extend the moratorium. On 28 February 2012, a motion[3] signed by 122 parliamentarians was submitted to the Federal Council calling for a temporary continuation of the moratorium. The motion calls on the Federal Council to create the legal basis to continue the already existing moratorium for agriculture beyond November 2013.

2 See Swiss National Science Foundation, Benefits and risks of the deliberate release of genetically modified plants, Portrait of National Research Programme 59, Bern, November 2007.

3 Motion 12.3026 "Gentechmoratorium befristet weiterführen" (Temporary continuation of gene technology moratorium), submitted by National Councillor Markus Ritter (CVP, Canton St. Gallen); http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch_id=20123028.

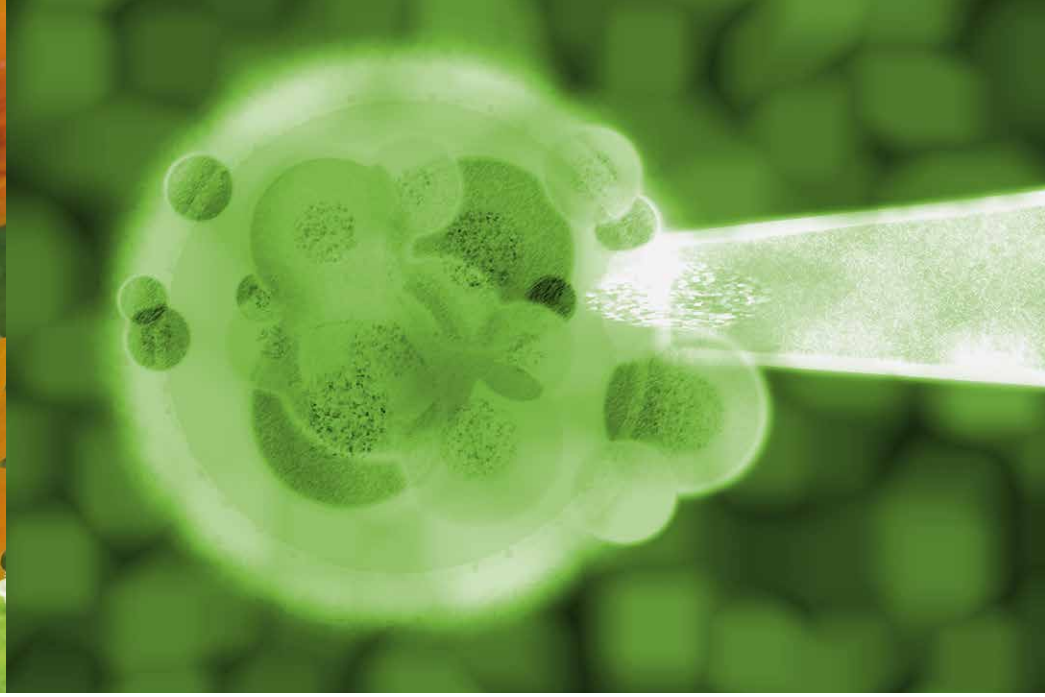
2 Report objective

Parallel to the NRP 59 and in view of the fact that the moratorium on the release of GM plants may expire at the end of November 2013, the ECNH will discuss the ethical requirements to be met when GM plants are released into the environment. It will also consider the significance of field trials on such plants in terms of risk identification and assessment. This report is intended as a contribution of the ethical considerations to the public discussion.[4] It looks solely at the ethical requirements for the release of GM plants. The ECNH is aware that other plant-breeding processes and the release of other organisms such as pathogenic or non-native organisms, as well as other agricultural methods, are also associated with risk. These are intentionally not dealt with in the report. However, it is clear that many of the considerations concerning the release of GM plants also apply to the release of other organisms which involve risk and to other plant-breeding and agricultural processes and methods.

The ECNH is also aware that the concept "GM plant" encompasses very different types of plant[5] and that properties can be added, suppressed or removed using genetic engineering methods. An adequate assessment of these plants and the risks associated with their release must look at these differences in each individual case.

4 See also on this subject ECNH, Gene Technology for Food, Ethical considerations for the marketing of genetically modified foodstuffs and animal feed, 2003 and the ECNH statement on the Identification and Assessment of Risk in the Ordinance of 1 March 2011 on the Contained Use of Organisms (ECNH publications can be found at www.ekah.admin.ch).

5 Currently, a distinction is made between three "generations" of genetically modified plant: The first generation focuses on the production of GM plants with herbicide and insect resistance ("input traits"). The second and third generations are devoted to the development of plants designed to improve the quality and properties of the harvested crop ("output traits"). In the second generation, the focus is on increasing the content of essential nutrients or reducing naturally occurring undesirable substances or allergens. The third generation of GM plants is designed to produce substances such as vaccines, antibodies and pharmaceutical proteins.



3 Epistemological considerations

There is little argument about the fact that releasing genetically modified plants involves risk. Opinion varies when it comes to assessing how high this risk is; this depends to some extent on what we perceive the lack of knowledge and uncertainties with regard to these plants to be, and what the consequences of these might be. At an epistemological level, the ECNH differentiates initially between two positions: the in-principle lack of knowledge position and the incomplete knowledge position.

3.1 The in-principle lack of knowledge position

The in-principle lack of knowledge position argues that genetically modifying a plant is a process whose consequences can, in essence, not be controlled. According to this viewpoint, GM plants are new to the extent that they cannot be described for epistemological reasons. Due to an interaction between a plant's genes with its environment, modifying a plant genetically may lead to unexpected, qualitatively new relationships with unpredictable consequences. We have no experience to learn from, nor do we have the scientific capabilities and methods to make sensible claims about the risks of this interference and its effect on a plant or about the effect such plants may have on the environment. Nor are there any analogies to refer to, as we do not have any basis for analogies. There is no way of assessing the risks involved, not even qualitatively.

This radical in-principle lack of knowledge position **is not taken by any member of the ECNH**.

3.2 Incomplete knowledge position

Two objections can be made to this in-principle lack of knowledge position with regard to GM plants. Firstly, in a position of in-principle lack of knowledge, we do not have any basis upon which to draw a conclusion either way. We cannot conclude that GM plants should be released, or that they should not be released. Secondly, in this context we can argue that although we are confronted with many unknown factors when assessing the risk of GM plants, we do have some sort of

basis upon which to do so. A genetically modified maize plant may be very different from a conventional maize plant, but it *is* still a plant. It may not be possible to determine the probability of occurrence and potential damage it may cause, but based on our previous knowledge, it is possible to establish potential damage scenarios.

When making an assessment of GM plants, if we assume that there are analogies and previous knowledge to which we can refer, we are not in a situation of in-principle lack of knowledge, but of incomplete knowledge. Analogies and experience provide us with an initial basis for assessing the effects of genetic modification on a plant and its environment.

The ECNH **unanimously** supports the position that in the case of GM plants we are not in a situation of total lack of knowledge, but of incomplete knowledge.[6]

6 The term "incomplete knowledge" could lead to misunderstanding, as it might suggest that we are fully aware of what knowledge is relevant to our actions and an assessment of those actions, and therefore of where our knowledge gaps lie. However, this is not the meaning intended here.

4 Genetically modified plants: Two assessment models

Even if we assume that our pre-existing knowledge at least provides a basis upon which to assess the effects of GM plants, opinions still differ over what is required to make this assessment. Determining what is required depends to an extent on the way in which we attempt to describe GM plants. The ECNH distinguishes between two assessment models.

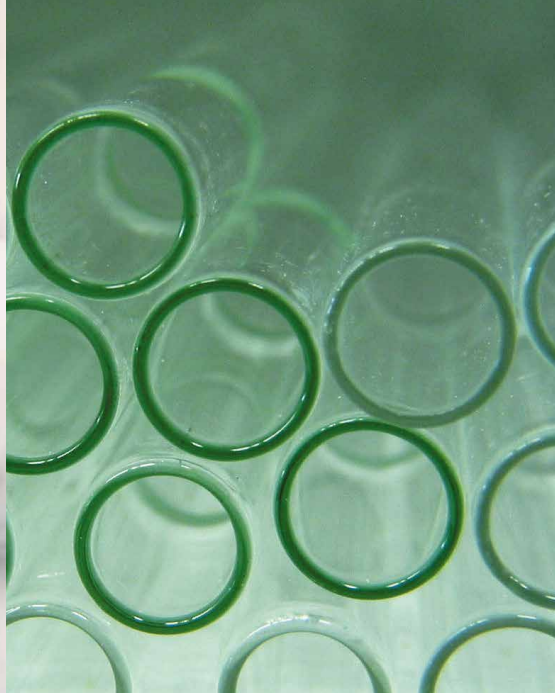
4.1 Causal assessment model (first model)

The first model was reflected in the concept of substantial equivalence, which was originally used to assess the safety of genetically modified foodstuffs for human health. Genetically modified food is considered to be substantially equivalent from a physiological-nutritional point of view when two criteria are met. Firstly, the parameters of the biochemical and toxicological characteristics of a genetically modified foodstuff may not be "substantially" different from those of a conventional, non-genetically modified foodstuff. Secondly, the genetically engineered additional characteristics should not be toxic or allergenic, in as far as this can be determined.[7]

The concept of substantial equivalence is applied in the Swiss authorisation procedure for GM foodstuffs in order to assess the effects of consumption of a given foodstuff on human health.[8] However, it is not applied when assessing the environmental risks. Yet the understanding on which the concept of substantial equivalence is based appears to play a role when the impact of GM plants on the environment is assessed. According to this understanding, GM plants are essentially the sum of the original plant, i. e. the plant which is used as the basis for GM plants, and of the genetically inserted properties. If, due to an inserted property, a substance is produced that is already known, it is assumed that we can draw on empirical data regarding its impact on the environment. According to the understanding of this assessment model, the suppression or removal of a property has no unforeseen effects and therefore does not require further tests to be made.

7 See also the explanation of substantial equivalence in ECNH, Gene Technology for Food, 2003, p. 8 ff

8 The currently accepted view is that testing for substantial equivalence is only a first stage in risk assessment. It is insufficient for a thorough safety assessment.



A similar approach is followed when new plant species are assessed. The natural variations in a species of plant are seen as a kind of "cloud"; as long as the GM plant resembles the variations in this recognised "cloud", according to this model we have the necessary empirical knowledge to be able to say the plant is safe. The characteristics and impact of these plants therefore do not require further investigation.

As the aim of genetic modification is usually, however, to create a GM plant which does not fit into this "cloud", parameters must be tested other than those compared when an assessment of substantial equivalence is made. These parameters are the integration of a new gene into the plant's DNA and the new genetic products (toxins and proteins). The genetic products are tested for biodegradability and for their allergenicity and toxicity for humans and the environment.

The following objections to this assessment model can be made:

As far as is currently known, it is not enough simply to investigate the additional characteristics of a GM plant and their effects. We also need to consider the complex regulatory and physiological interactions within plants. A single gene can affect several characteristics of an organism, and changing a single gene may lead to changes in several phenotypical characteristics in a plant. This is known as a pleiotropic effect. The expression of a foreign gene, e. g. which leads to the production of a new protein, may also alter the physiological condition of a cell or of a whole organism.[9] Besides the primarily desired and expected effect, the genetically engineered mutation may therefore have further effects on the organism as a whole, both unintended and unexpected. Some pleiotropic effects can be investigated in the laboratory. If these effects are undesirable, affected GM plants can be excluded from further development processes.

Despite the huge number of parameters and the many years which can be spent investigating plants and their effects in the laboratory, the first model always assumes that, despite the

9 See ECNH, Gene Technology for Food, 2003, p. 11.

complexity of the factors involved, an overview can always be maintained of cause (a genetic mutation) and effect in the field. The first model is therefore a *causal assessment model*. It is therefore limited to examining a list of parameters in order to then judge whether a GM plant can be considered to be safe or unsafe.[10]

If a GM plant is judged to be safe, advocates of this model consider the possibility of further unintended and unexpected consequences to be so slight that it is meaningless and has no relevance for how we act. If unintended and unexpected effects do become manifest at a later date, they are considered to be beyond the bounds of predictability and thus no responsibility must be borne for them.

4.2 Risk model (second model)

The second model is usually used to evaluate situations in which decisions have to be made on the basis of incomplete knowledge i. e. in risk situations. This also includes decisions in dealing with GM plants, because GM plants can always have unintended and unexpected effects.

The risk model, like the first model, assumes that we live in a causally determined world. When assessing the effects of introducing GM plants into the environment, however, there is the caveat that we are not in a position to assess the full complexity of causes and effects involved due to our limited human cognitive capacity. An exhaustive assessment of the effects of released GM plants is not possible. We can only draw preliminary conclusions on the basis of the knowledge available.[11] The second model therefore leaves the causal assessment level and switches to a probabilistic level.

The complexity of the situation is determined both by the environment in which GM plants are released and by the interactions which take place within a plant and between the plant and its environment. Not only pleiotropic effects, but also epigenetic effects may lead to changes in the characteristics of a plant. Epigenetic effects are changes in phenotypical characteristics that are not due to a change in the genotype yet can still be inherited. Such epigenetic changes can be triggered by the environment. They frequently provide an explanation as to why plants react differently in field trials to laboratory trials.

The possibility that negative effects occur only rarely or in the long term must also always be taken into account. Risks that are associated with infrequent effects or those which only occur in the long term are not always negligible. The level of risk is calculated as the product of the possible extent of damage and the probability of occurrence of the damage. Although the damage may occur only very rarely, if the potential extent of damage is very large then the risk may be high.

Because we do not have exhaustive knowledge and this knowledge cannot be generated in the laboratory, we need to apply a probabilistic rather

10 See Inge Broer, Divergierende naturwissenschaftliche Bewertung der Grünen Gentechnik: Grundlagen der biologischen Risikoanalyse, in: H. Grimm, Schleissing S. (Hrsg.), Grüne Gentechnik: Zwischen Forschungsfreiheit und Anwendungsrisiko, 2012, pp. 81–91, especially diagram 1, p. 87

11 As already noted above, this also applies to the release of other plants which involve risk and to risks involved in agricultural methods of cultivation.

than a causal assessment model when assessing GM plants. The assessment of GM plants *must* be a risk assessment in order to be appropriate to the situation. It is inadequate to think that a causal model of assessment is sufficient for work in the laboratory and we do not need to apply a risk model until the GM plants are released. This idea fails to recognise that even in the laboratory we need to generate knowledge for an assessment regarding release of GM plants if the aim is to release them into the environment at some point in time.

The ECNH **unanimously** supports this second assessment model, according to which GM plants can have unintended and unexpected effects and must therefore be assessed according to a risk model.[12] The first model is considered to be inadequate for assessing the risks of GM plants and is therefore rejected.

Practical consequences of the second assessment model for the experimental and commercial release of GM plants

The ECNH identifies three different positions at a regulatory level:

1 The first position assumes that, due to the considerable complexity of the interaction between genetic modifications and the environment, it is not possible to understand the unintentional and unexpected consequences and these may only become apparent sometime in the distant future. The risks cannot therefore be determined and there are fundamental reasons for not allowing GM plants to be released in the foreseeable future. This position is supported by a **small minority**.

2 The second position determines whether or not GM plants should be released based on an impact assessment of each individual case. Experimental or commercial release is permitted when the opportunities that releasing GM plants may bring outweigh the associated risks. Even if the risks are great, the plants must be released if the opportunities are greater. If the risks are greater, then the plants should not be released. This position is **not supported** by any member of the ECNH.

3 The third position only considers the release of GM plants to be permissible when the associated risks can be generally judged to be acceptable for the third parties who are exposed to the risks. GM plants may therefore only be released on a trial or commercial basis if there is sufficient knowledge available to assess the risks, and if these risks are generally judged to be acceptable for third parties. A **large majority** of ECNH members supports this third position.

12 This second model is also advocated in the context of genetically modified animals; in an assessment of GM animals, it is assumed that we are dealing with new animals in as much as they may have unexpected characteristics. Natural mutants are also judged in the same way as those which, due to a genetic modification, exhibit new characteristics. Pleiotropic effects were observed, for example, in growth hormone-transgenic animals, which demonstrated faster growth as intended, but at the same time also suffered pathological changes to their internal organs.

5 Purpose of release experiments

5.1 Purpose of release experiments in the first assessment model

Under the first model, it is easiest to carry out a scientific study of the effects of GM plants on selected target and non-target organisms under laboratory conditions. All of the key steps which are necessary to ensure biosafety, such as testing the biochemical and toxicological effects of the new characteristics, take place in the laboratory and the necessary data are obtained. This takes place according to a causal model, using dose-response tests. If, on the basis of these standard tests, no negative effects on the tested parameters can be established, the GM plant can be considered to be safe.

The results gained in laboratory tests on the effects of new characteristics can be confirmed under (controlled) field trial conditions in release experiments. If a field trial demonstrates that the plant essentially behaves in the same way as it does under laboratory conditions, then according to this model we can assume that we understand the plant and its effects on target and non-target organisms, and can therefore also sufficiently assess its effect on the environment.

If a GM plant can be considered safe, then pollen dispersal from the GM plant and a potential cross with non-genetically modified plants does not pose any problems in terms of biosafety. Release experiments to establish the pollen dispersal distances of GM plants are only necessary for legal or economic reasons because contamination of GM-free crops is considered to be damage in legal terms and can result in liability claims.

For advocates of this model, the step from field trials to commercial production is a small one. Monitoring GM plants *for reasons of biosafety* is unnecessary. Field trials are not intended to generate data which then provide a basis for statements about the probability of occurrence of damage scenarios, because a causal model, rather than a risk model, is assumed.

5.2 Purpose of release experiments in the second assessment model

In the second model it is assumed that in dealing with GM plants we are faced with a typical risk situation. A GM plant is not simply the sum of the original plant and the additional genetically engineered characteristics. Genetic modifications to the plant have triggered interactions within and outside of the organism which may give rise to characteristics which are not only unintended and undesirable, but may also have unexpected consequences. It is therefore only possible to a limited extent to refer to empirical knowledge gained from the original plant and the new characteristics which arise when genetic sequences are added, suppressed or removed. We are confronted with a state of incomplete knowledge and the uncertainties associated with this. For the risk assessment of GM plants, it therefore follows that damage scenarios must be developed and statements about their probability of occurrence made.

Under the second model, the function of release experiments is not the same as under the first. Release experiments are not simply an attempt to falsify laboratory results under controlled field conditions. Just like laboratory experiments, they serve to generate statements about the probability of occurrence of damage scenarios. In field trials, the parameters which cannot be tested in the laboratory are investigated. The parameters which must be tested in the field include in particular the complex interactions of the plant with its environment and also cumulative effects which may occur due to additional factors present in field trials.

However, this means that it is not possible to make a comprehensive risk assessment of GM plants on the basis of the data collected from the small field trials carried out in Switzerland. These trials provide data on individual cases but are insufficient as a basis for statements about the probability of occurrence of damage scenarios.

Under this second model, the step from the closed system of the laboratory to the open system of the field is a huge one, because of the considerable increase both in the number of GM plants released and the complexity of interactions with the environment. Furthermore, unintended and unexpected effects may only become apparent after some time, because unusual damage scenarios may only arise in the long term. In addition, negative effects on people and the environment resulting from the complex interactions may only be associated with the release of GM plants after some considerable time. Continuous monitoring of the released plants is therefore essential.

6 What does this mean in terms of requirements for the experimental and commercial release of genetically modified plants?

6.1 Requirements for release under the first model

If investigated undesirable effects occur neither in the laboratory nor in field trials, under the first model an assessment of biological safety is considered complete. The GM plant can be considered as safe, and released. For biosafety monitoring it is fundamentally of no use. If new damage *can* be established once a GM plant has been released, this is ascribed to the "black box" of nature and its "imponderability".

There are only abstract reservations about this imponderability. It is assumed with "probability bordering on certainty" that the GM plant will not produce any unwanted side effects. Should such side effects occur nonetheless, in the opinion of the advocates of the first model, the perpetrators cannot be held responsible. This final imponderability lies beyond the realm of our influence. We can therefore only react to such imponderability *ex post* (retrospectively). It could not be considered *ex ante* (prospectively) in a safety assessment.

In the opinion of the ECNH, this view fails to take account of two things:

Firstly, although it speaks of "risk", it excludes the risk-inherent aspect of probability including the factor time, and only considers the extent of the damage. It therefore assumes that damage can be assessed conclusively. Secondly, it overlooks the fact that the question of what qualifies as damage is a normative one, as is the question of whether a risk is acceptable for third parties, and therefore permissible. These are therefore questions that cannot be answered using methods applied in natural sciences.[13]

13 It could be argued that since existing legal requirements for the experimental release of GM plants are very strict, let alone for the commercial release and the associated complex test procedures, we would be justified in declaring those GM plants that make it to the release stage as safe. However, this is impermissible circular reasoning.

6.2 Requirements for release under the second model

Under the second model, the aim of trials is to provide data which allow us to draw definitive conclusions about the probability of occurrence of a negative event, but not about whether a GM plant is safe or not.

What does this mean for the release of GM plants in the field? Because we are not able to make any definitive statements about the safety of GM plants, a decision to approve their release can only ever be made with reservations. Any assessment of the risks involved in releasing approved GM plants must also be continuously updated on the basis of newly acquired data. In addition, requirements for how these plants are handled must be amended where necessary.[14]

Once approval has been given to release a GM plant *on a commercial basis*, the following criteria for handling the plant are therefore also important:

a Application of the precautionary principle

The precautionary principle is applied in situations involving risk. Precautions are taken by limiting at an early stage the hazards and impairments GMOs may cause or eliminating them if they are considered unacceptable. Article 2 of the Gene Technology Act establishes this requirement, thereby reflecting the fact that a risk model is assumed when regulating the release of GMOs. The precautionary principle does not only apply to the production of GM plants, the laboratory test and experimental release phases, but to handling GM plants in any situation, i.e. also when they are commercially released.

b Step-by-step approach

As we only have incomplete knowledge about GM plants and their effects on people and the environment, handling these plants involves risk. If we release such plants into the environment, we expose both ourselves and third parties to risk. Exposing third parties to risk is, however, only permissible if the risk can be considered to be acceptable.

In order to identify the risk that GM plants pose, we must have access to the necessary data regarding damage scenarios and their probability of occurrence. As GM plants are highly complex systems, and the complexity of the environment is far greater, the data required to make an adequate risk assessment can only be acquired gradually. There must be a gradual increase in both the number of elements with which the GM plant is made to interact and the number of GM plants exposed to this interaction.

Each subsequent step may only be taken when the data collected from the previous step provide sufficient knowledge about damage scenarios and probabilities of occurrence upon which to base an adequate risk assessment regarding the next step. And the risk assessment must determine how

14 An updated and adequate risk assessment on the basis of new data may also lead to requirements being relaxed.

far the next step may be, according to whether or not the risks associated with it can be considered acceptable for third parties.

But at which point do we have sufficient data in order to decide whether or not the risks associated with the next step are acceptable for third parties? There are different answers to this question depending on the position held (see Section 4.2). Either it is necessary that in the next step the overall probability that there will be a negative effect is smaller than the probability that there will be a positive effect, or the data are sufficient if it can be shown that the rights and interests of the entities to be considered from a moral perspective[15] are not violated by the planned next step or that a violation of these rights and interests is very unlikely.[16] Both positions require an examination of all plausible hypotheses of damage scenarios and their probability of occurrence.

The Gene Technology Act also assumes, based on prevailing theory,[17] that the data acquired in laboratory tests and greenhouses is insufficient to make an adequate risk assessment about the effects of releasing genetically modified organisms (GMOs) into the environment. In order to reduce the existing uncertainties and generate a sufficient level of knowledge for an assessment, the law therefore requires that GMOs are introduced into the environment gradually, from the closed system of the laboratory via release experiments under controlled conditions to commercial release. These precautionary measures of carefully containing and handling GMOs should only be relaxed gradually and then only when an assessment of the preceding step has shown that the risks involved in the next step are acceptable.[18]

In terms of commercial release, the need for a step-by-step approach may mean that GM plant approval may only be given by degrees and no general release can be permitted. Firstly, the increased number of plants and the lengthy release process mean that unintended, unexpected and unusual effects, or those which only become evident after some time, may occur which influence the risk assessment. Secondly, the environments in which the plants are released are not only complex but also very diverse in terms of geography, topography, climate and other factors. This is a further reason for taking a step-by-step approach when releasing GM plants on a commercial basis.

c Context-related risk research

In order to provide the data necessary to make a risk assessment, the effects of GM plants must be examined on the basis of parameters which are actually relevant in the context of the plants' intended use in the environment. In a further step, these plants should also be tested in the agro-ecological systems in which they are later to be released commercially, so that their effects on and interaction with this environment can be established.

d Independent risk research

Companies wishing to produce and market GM plants are not legally required to make either the GM plant or the control plant available for independent research. Research privilege, which is enshrined both in Swiss as well as in European patent law, does not require companies to release patent-protected genetically modified material. Companies are free to decide whether, to whom and under what conditions they pass on their material and for what purposes.

In order for authorities to be able to make an adequate risk assessment of the release of GM plants, they require the appropriate scientific data. A risk assessment based solely on data derived from the company interested in the release itself, or from data produced on its behalf, is insufficient. Research which is independent from the interests of the company is only possible if access to the necessary plant material is guaranteed. From the perspective of the ECNH, taking into account the legitimate interests of the companies that produce GM plants, it is therefore necessary to find ways to ensure this access. Otherwise, from an ethical point of view, it would not be possible to approve releases of these GM plants, because no adequate risk assessment can be made.

e Continuous monitoring

One of the aims of monitoring is to observe whether unintentional but *expected* undesirable effects occur, i.e. to take note of damage scenarios which have been envisaged and which have been considered *ex ante* in the risk assessment. The question is whether what is observed corresponds to the expectations which have formed part of the risk assessment, or whether this risk assessment must be adapted.

Furthermore, monitoring must also be able to establish as early as possible any *unexpected* effects which may arise as the result of an interaction between the plant and its environment. These unexpected effects may also mean that the risk assessment must be adapted after a decision regarding authorisation has been made.

Continuous monitoring is also necessary following authorisation for commercial production. Firstly, this is the only way in which the effects which become evident at a later stage can be identified. Secondly, the more plants that are released, the more likely it is that effects with minor probability will arise. Only continuous monitoring makes it possible to recognise and react to these at an early stage.

In order to establish and conduct an adequate monitoring programme, an efficient observation method must be developed. This observation method must identify the critical events as early as possible. The ECNH is of the opinion that further research is required into the procedure and the detailed listing of the monitoring criteria. For example, it must be established how and by which methods reliable and meaningful data regarding long-term effects on people and the environment can be obtained. Also to be addressed in this respect is the question of how long feeding trials must be conducted in order to obtain adequate data for a risk assessment.

It is also essential to consider data collected from around the world on the unexpected effects of GM plants and to establish in each case to what extent and under what conditions these data can be applied to the Swiss situation.

f Guarantee of freedom of choice: the liberty right to refuse

Freedom of choice can be understood as the right to claim or the liberty right to refuse something. Having the right to claim is understood in this context as the right to choose between several options. In contrast, the right to refuse means that nobody can be forced to accept a particular choice. In 2003 the ECNH published a report entitled "Gene Technology for Food – ethical considerations for the marketing of genetically modified foodstuffs and animal feed" in which it considered the issue of freedom of choice.[19] The overwhelming majority of the ECNH argued that when dealing with foodstuffs, precedence should be given to an interpretation of freedom of

15 On the issue of which living beings should be considered from a moral perspective, see ECNH, The dignity of animals (2001), Research on Primates (2006), The dignity of living beings with regard to plants (2008)

16 Article 6 paragraph 1 of the Gene Technology Act states that genetically modified organisms may only be handled in such a way that they, their metabolites and waste products do not endanger humans, animals or the environment.

17 See also Christoph Errass, Öffentliches Recht der Gentechnologie im Ausserhumanbereich, 2006, p. 170 ff. and Astrid Epiney et al., Die Ausscheidung von gentechnikfreien Gebieten in der Schweiz de lege lata et de lege ferenda, 2011, p. 112 f.

18 If the step-by-step principle were weakened, it would not be possible to respond adequately to the risks associated with the release of GM crops. Such a requirement would run counter to the fact that here decisions are being made about *risk* situations.

19 ECNH, Gene Technology for Food, Bern 2003. See also ECNH, statement on the popular initiative "For foodstuffs from GM-free agriculture".

choice as a right to refuse, because what we eat is to a large degree linked to how we decide to lead our lives. In the ECNH's view, being forced to eat something we do not want to eat, for whatever personal reason, is more difficult to justify than being forced to go without something for which there is an alternative. Article 7 of the Gene Technology Act states that GMOs must be handled in such a way that their metabolic and waste products do not compromise consumers' freedom of choice; in the ECNH's view, this is to be understood, from an ethical viewpoint, as the right to refuse. In this case the state has the duty to ensure that GM-free plants remain available, even if GM plants are released. However, it is not required to guarantee access to GM plants.

g. Coexistence: guarantee of GM-free production

Protecting GM-free production, including seed production, is, in addition to protecting personal property, a prerequisite for guaranteeing freedom of choice for consumers and economic freedom for producers. GM plants may therefore only be released on an experimental and commercial basis if GM-free production is not affected by this. It follows that guaranteeing GM-free production is a condition when regulating the coexistence of GM plants and GM-free production. If and how GM-free production can be protected within Switzerland's small-scale agriculture system and given the topographical peculiarities of the Swiss countryside has been investigated in the NRP 59 and in other projects.

If, having taken into account the need to protect GM-free production, coexistence is considered possible, the state can impose to a proportionate degree the associated costs on the producers of GM plants (e.g. restrictions on use based on regulations on separation distances and separation in flow of goods). The state is justified in doing this on the grounds of its duty to protect the public.

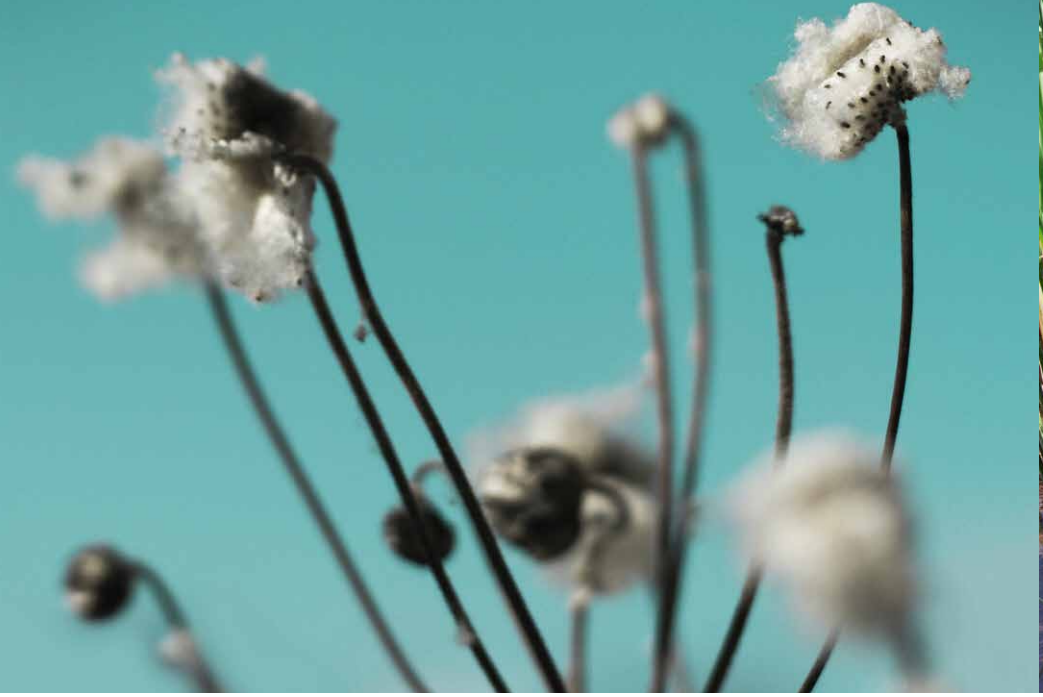
7 Overall ethical assessment

The ECNH members are **unanimous** in their opinion that, when dealing with GM plants, we are not confronted with in-principle lack of knowledge, but with a situation of incomplete knowledge. This means that even in situations in which we have just a small amount of knowledge, it is permissible to refer to analogies and experience. This knowledge can provide an initial basis for estimating the risks that the effects of a genetic modification on a plant and its environment might involve, which in turn can generate further data for a risk assessment.

Which data are necessary to adequately perform a risk assessment of GM plants depends on the way in which we try to explain GM plants. The ECNH differentiates between two assessment models. According to the first model, GM plants are essentially the sum of the original plant plus the additional genetic characteristics. Although certain pleiotropic effects are also considered when assessing GM plants, this model is based in the main on the concept of substantial equivalence. The ECNH considers this causal assessment model to be insufficient and therefore rejects it as a basis for a thorough risk assessment.

The ECNH is **unanimous** in its support of a different, second assessment model for GM plants, according to which it is essentially possible that GM plants may have unintended and unexpected effects, either as the result of pleiotropic or epigenetic effects or from cumulative effects. A decision must be made based on incomplete knowledge, and we are thus confronted with a typical situation of risk. Consequently, we cannot definitively claim that a GM plant is "safe" or "unsafe". We can only make statements about the risk involved, i. e. about the probability of occurrence of damage scenarios.

The consequences of the second assessment model for determining whether or not the experimental and commercial release of GM plants is permissible depend on the degree to which knowledge is considered to be incomplete; furthermore, they depend on whether this situation of incomplete knowledge can be overcome, at least step by step, despite the complexity of the factors involved.



A **small minority** on the Committee believes that, due to the complexity of the interaction of the factors involved, we are unable to comprehend the effects a genetic modification may have on a plant and its environment now and perhaps in the foreseeable future. It is therefore not possible to assess the risks, and this constitutes a fundamental reason why GM plants should not be released for the foreseeable future.

The **large majority** of the ECNH believes that it is fundamentally possible to assess risk adequately, in a step-by-step process. The regulatory concept underlying the assessment process determines when it is possible to move onto the next step in each given case:

– Taking the approach which assesses the moral value of a particular action according to its possible consequences, the opportunities which releasing a GM plant may bring are weighed up against the risks involved; this allows us to determine if this action is morally right. According to this approach, higher risks for third parties can be justified if the benefits outweigh the risks. If, in a particular case, the risks involved in releasing GM plants on an experimental or commercial basis outweigh the opportunities this may bring, then it is not permissible to release them. If, however, the opportunities outweigh the risks, then they must be released. **The members of the ECNH do not advocate** this approach.

– By contrast, taking the second approach, certain types of action are judged to be either ethically right (permitted) or wrong (not permitted), independent of the consequences which may occur in each individual case. As applying a principle of non-maleficence would make it impossible to act at all, instead a general duty of care and general threshold levels are imposed. With regard to GM plants, this means that it is only permissible to release plants in as far as the associated risks for third parties can be judged to be acceptable. This approach is advocated by the **overwhelming majority**.

8 Recommendations

On the basis of the above considerations, the members of the ECNH unanimously propose the following recommendations for an ethically justified approach to the experimental and commercial release of GM plants:[20]

1 In assessing the release of GM plants, the **risk model** must be consistently applied.

This leads to the following further recommendations:

2 **Precautionary principle.** The precautionary principle must be applied when GM plants are created and handled in the laboratory and in the field.

3 **Step-by-step approach.** Each step may only be taken when and to the extent that sufficient knowledge is available about damage scenarios and their probability of occurrence. This allows us to assess whether or not the risks (for third parties) involved in the next step are acceptable. This step-by-step approach should also be taken when authorising the commercial release of GM plants. Firstly, environmental conditions vary considerably. Secondly, the higher number of GM plants released and the longer periods over which they are released mean that effects occur which are rare or which do not become evident until later on. For these reasons, there should be no general authorisation for the release of GM plants, but rather authorisation should be granted gradually. If current legislation does not allow for this approach, it will require amendment.

4 **Context-related risk research.** Context-related data must be made available for an adequate risk assessment to be made. Applicants should be required to provide this.

5 **Independent risk research.** Independent research data are necessary in order for a proper risk assessment of GM plants to be made. Ways must therefore be found of guaranteeing and establishing in law access to genetic material for independent research – while at the same time safeguarding legitimate interests in protecting intellectual property.[21]

20 These recommendations were approved unanimously. They are also supported by the minority which is essentially opposed to the release of GM plants for the time being should their basic objections to the release not be shared.

6 **Monitoring.** In order to detect the unintentional, undesirable and unexpected effects of GM plants as early as possible and adapt the risk assessment accordingly, it is necessary to develop an efficient observation method. In the ECNH's view there is still need for further research and reflection regarding the way in which reliable and meaningful data on long-term effects and unusual occurrences can be obtained. Using data from other countries may play an important role but the transferability of data to the specific context should always be carefully examined.

7 **Freedom of choice and protection of GM-free production.** In order to ensure consumers' freedom of choice and specifically their (liberty) right to refuse (and in order to protect genetic diversity), GM-free production including seed production must be protected. Coexistence regulations should be formulated in such a way as to guarantee this protection. Any additional production costs which arise should be passed onto the producers of GM plants to a proportionate degree, as the duty to protect the public is weighted higher than the interests of the GM producers, who can also reasonably be expected not to produce GM plants.

8 **Publicly funded research.** If public funding of research in the applied field is too focused on the promotion of a particular technology (in this case of genetic engineering), there is a risk that other promising technology or methods suffer a disadvantage. The ECNH therefore attaches priority to ensuring that public funds are not applied in one area only and not only for technology, but also in response to the needs of society.

21 The issue of who is responsible for ensuring that these independent data are made available for risk assessment and who should bear the costs of generating these data has yet to be resolved.

Pictures:

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