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Federal Ethics Committee on Non Human Biotechnology ECNH

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Ethical requirements for the experimental and commercial release of genetically modified plants

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).[1] 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 is due in 2012.

Moratorium extension: In 2009 the Federal Council 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 28 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.

When the moratorium ends in November 2013, it will again become possible to cultivate genetically modified 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.

[1] The idea was submitted during the NRP 2002/2003 evaluation round to the State Secretariat for Education and Research, 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.

2. Statement objective

In view of the imminent conclusion of NRP 59 and the probable end of the moratorium on the release of GM plants, the ECNH will discuss the ethical requirements to be met when genetically modified 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 statement is intended as a contribution of the ethical considerations to the public discussion.[2] It concentrates on the ethical requirements on the release of genetically modified plants. The ECNH is aware that the release of other organisms such as pathogenic or non-native organisms, as well as other agricultural methods, is also associated with risk.

3. Different understandings of the term 'genetically modified plant'

There is little argument about the fact that releasing genetically modified plants involves risk. However, there are varying opinions about the lack of understanding and uncertainties with regard to these plants, and what the consequences of these might be. The reason for the varying opinions lies in the different understandings of what a genetically modified plant is, in contrast to a non-genetically modified one. Depending on the interpretation, different data are required to show that a GM plant is sufficiently safe.

3.1 Epistemological considerations

3.1.1 The in-principle lack of knowledge position

The in-principle lack of knowledge position argues that genetically modifying a plant is a process over which there is essentially no control. 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 such interference and the effects such plants may have. 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**.

3.1.2 Incomplete knowledge position

There are two objections to the in-principle lack of knowledge position with regard to GM plants. Firstly, in having no knowledge of GM plants, we do not have any basis upon which to conclude that they should be released, but nor do we have one upon which to conclude that

[2] 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).

they should not be. Secondly, in this context we can argue that although we are confronted with many unknown factors when assessing the risk of genetically modified 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 possible 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.[3]

3.2 Explanatory models for GM plants

The way in which we determine what is required to make a judgement about the release of GM plants depends on the way in which we attempt to describe genetically modified plants. Two explanatory models are distinguished.

3.2.1 GM plants are the sum of the original plant[4] and the genetically engineered additional characteristics (first model)

The first model refers to 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. 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. Nor should the genetically engineered additional characteristics be toxic or allergenic, in as far as this can be determined.[5]

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.[6] 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. 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 to create a GM plant which does not fit into this 'cloud', parameters must be tested other than those compared when an assessment of

[3] One member believes the term 'incomplete knowledge' could lead to misunderstanding, as it might suggest that the unknown factors can be identified.
[4] The original plant is that which provides the basis for the genetically modified plant.
[5] See also the explanation of substantial equivalence in ECNH, Gene Technology for Food, 2003, p.8 ff.
[6] 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.

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. If, as a result of a newly added characteristic, the GM plant expresses a substance which is already known, in this case also there are empirical knowledge which can be referred to.

Taking this model, assessing GM plants involves no more than testing a list of parameters – substantial equivalence, degradability, allergenicity and toxicity of the new genetic products for selected target and non-target organisms.[7]

3.2.2 GM plants can have unexpected effects and are therefore more than the sum of the original plant and the additional characteristics (second model)

The first model – according to which a GM plant is the sum of the characteristics of the original plant plus the additional genetically engineered characteristics – runs the risk of failing to take account of the complex regulatory and physiological interactions within cells and organisms, according to the second model. The expression of a foreign gene, e.g. which leads to the creation of a new protein, may alter the physiological condition of a cell or of a whole organism. Besides the primarily desired and expected effect, the genetically engineered mutation may have further effects on the organism as a whole, both unintended and unexpected.[8] In addition to these pleiotropic effects[9], epigenetic effects[10] may also lead to changes in the characteristics of a plant. These epigenetic changes can be triggered by the environment, which often explains why plants react differently in field trials to laboratory trials.
If we accept this understanding of a genetically modified plant[11], then an assessment based solely on the observed effects of the added characteristics proves inadequate. It is not enough to assume that we are familiar with the original plant (or the species variations, or 'cloud') and to compare this with the GM plant, and to test the effects of the newly added characteristics. The pleiotropic and epigenetic effects of the plant must also be considered.[12] Because our level of knowledge is insufficient when faced with these complex interactions, this second model takes a probabilistic rather than a causal approach to assessing the GM plant; a *risk assessment* must be made. There is always the possibility that when a plant is genetically modified, the pleiotropic and epigenetic effects will result in unintended and unexpected consequences.

The ECNH **unanimously** supports this second explanatory model, according to which GM plants can have unexpected effects because they are more than the sum of the original plant and the newly added characteristics. The first model is considered to be inadequate and is therefore rejected.

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[7] Advocates of this model believe that the possibility of unexpected and unintended effects is so small that it is insignificant and as a result no action need be taken.
[8] See ECNH, Gene Technology for Food, 2003, p.11.
[9] Pleiotropic effects are effects on different characteristics in an organism produced by a single gene. A modification to a single gene can lead to changes in several phenotypical characteristics in a plant.
[10] Epigenetic effects are changes in phenotypical characteristics which do not result from changes in the genotype but can nonetheless be inherited.
[11] Or also of plants which are created by other means.
[12] This second model is also advocated when dealing with genetically modified animals, when it is understood that these are new animals which may have unexpected characteristics. Natural mutants are also judged in the same way as organisms which demonstrate new characteristics as a result of a genetic modification. For example, pleiotropic effects have been observed in growth hormone-transgenic animals, which grew more quickly as intended, but at the same time suffered pathological changes to their inner organs.

What are the practical consequences of the second explanatory 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 once the interests in an individual case have been considered. 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, even though the opportunities may be considerable. 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.

4. What is the purpose of release experiments?

4.1 Purpose of release experiments in the first explanatory 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.

4.2 Purpose of release experiments in the second explanatory 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 added characteristics. 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.

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.

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

5.1 Requirements for release under the first model

Under the first model, an assessment of biological safety is complete once a release experiment has confirmed laboratory results that a GM plant has no negative effects. If a release experiment shows that the negative effects examined under laboratory conditions are also absent in the field, the GM plant can be considered as safe, and released.[13] Since this approach is based on a causal and not a probabilistic model, its advocates consider that monitoring 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'. According to this model, we can only respond to this imponderability *ex post*. It cannot be considered *ex ante* in a security assessment, as this would require a risk model to be adopted.

5.2 Requirements for release under the second model

Under the second model, trials provide data which allow us to draw 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 genetically modified 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 GM plants into the

[13] This position can be understood in terms of an opinion held by some that risks can only be assessed on a purely scientific basis. However, this stance fails to recognise two things: firstly, it talks about 'risk' but ignores the aspect of probability inherent in risk, considering only the damage dimension. It therefore assumes that damage can be assessed in definitive terms. Secondly, it fails to take account of the fact that the question as to whether risk is acceptable and therefore permissible is not a scientific (empirical) one, but a normative one, which cannot be answered with methods used in natural sciences.

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

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 involved in releasing a GM plant, 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 far the next step may be, according to whether or not the risks associated with it can be considered acceptable for third parties.

This gradual approach is also expressed in the Gene Technology Act.[15] Legislators have also based their decisions on the prevailing theory[16] that there is insufficient knowledge about the effects of releasing genetically modified organisms into the environment to provide the basis for an adequate assessment. In order to reduce the existing uncertainties and generate a sufficient level of knowledge for an assessment, it is therefore necessary to introduce GMOs 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.

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 unexpected and unusual occurrences, or those which only become evident after some time, may 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 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.

[15] If the step-by-step approach were weakened it would not be possible to react adequately to the risks involved in releasing GM plants. This would not be compatible with the fact we are dealing here with decisions made in *risk* situations.

[16] 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.

d. Guarantee of independent research

Currently, seed companies wishing to produce and market GM plants essentially enjoy a monopoly position. They are not required to make genetic material available for independent research. Yet independent research is essential in providing data for an adequate risk assessment. As the state carries out this risk assessment as part of the approval process for the release of GM plants, it must ensure that access to genetic material for independent research purposes is guaranteed. If necessary, legal provisions must be enacted to ensure that the material can be accessed. If intellectual property rights should in any way restrict independent research, it would be necessary to codify a corresponding research privilege in law.

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. A further aspect to be considered is to what extent international data on unexpected effects can be applied to the situation in Switzerland.

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. 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.[17] The overwhelming majority of the ECNH argued that when dealing with foodstuffs, precedence should be given to an interpretation of freedom of choice as a right to refuse, because what we eat is to a large degree linked to who we are. 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

[17] ECNH, Gene Technology for Food, Bern 2003. See also ECNH, statement on the popular initiative ‘For foodstuffs from GM-free agriculture’.

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 is, in addition to protecting personal property, a prerequisite for guaranteeing freedom of choice for consumers and economic freedom for producers. Genetically modified 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 is currently the subject of a series of research projects.[18]

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 genetically modified 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.

6. 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 explanatory models. According to the first model, GM plants are the sum of the original plant plus the additional genetic characteristics. This model is based on the concept of substantial equivalence. The ECNH considers this 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 explanatory model, according to which it is always possible that GM plants may behave unexpectedly as the result of pleiotropic and epigenetic effects. As our knowledge is incomplete, we are 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.

[18] e.g. in NRP 59.

The consequences of the second explanatory 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 gradually, 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 in the 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, however, 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 genetically modified 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**.

7. 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 genetically modified plants:[19]

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

[19] These recommendations are also supported by the minority which is essentially opposed to the release of GM plants for the time being.

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

5. **Guarantee of independent research**. When an application is made for authorisation to release GM plants, access to genetic material of these plants must be granted for the purposes of independent risk research. If intellectual property rights or other regulations place a restriction on independent risk research, it would be necessary to codify a corresponding research privilege in law.

Further questions would need to be answered in connection with guaranteeing independent research: whose responsibility is it to ensure that independent data are available for an assessment? Who should bear the costs of this independent research? Should the research receive government support?

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 exact criteria and processes by 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 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.** Publicly funded research must not mean supporting particular technologies to the detriment of research into other technologies or practices intended to achieve general research objectives.