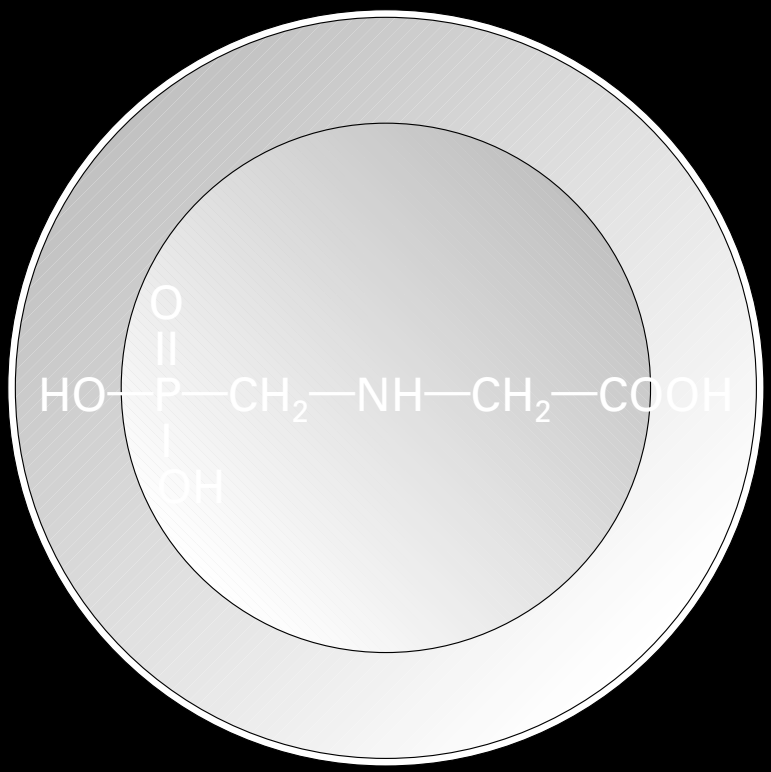
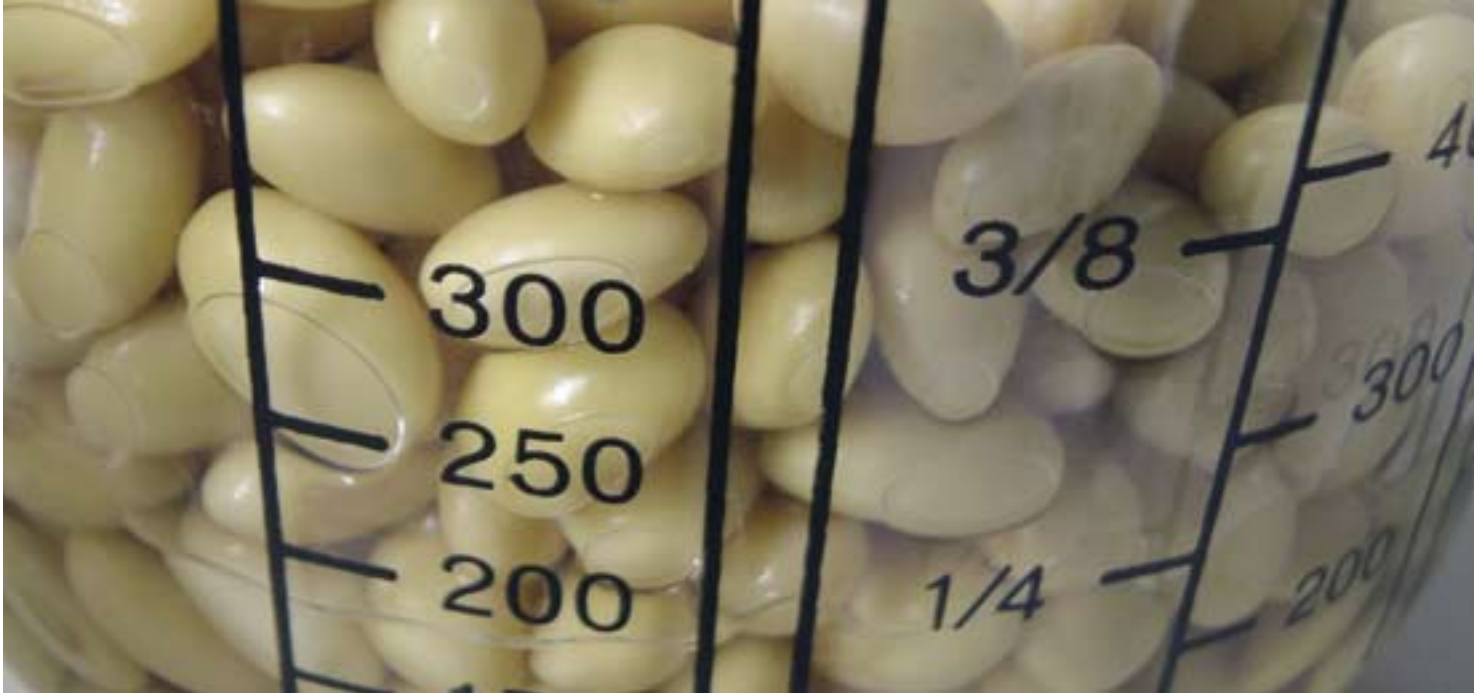
Gene Technology for Food

Swiss Ethics Committee on Non-human Gene Technology (ECNH)

Ethical considerations for the marketing of genetically modified foodstuffs and animal feed





1 Introduction

The evaluation of foodstuffs and animal feed is affected by divergent interests. Scandals such as the outbreak of foot and mouth disease or BSE (mad cow disease) and the new variant of Creutzfeldt-Jakob disease to which it is linked, have led to general insecurity and increased public discussion. This provides the backdrop for the political debate about genetically modified foodstuffs and animal feed.

All surveys show that in both Switzerland and EU countries, the great majority of the population is against the production and marketing of genetically modified foodstuffs and animal feed. While some fear adverse *effects* on human health, the environment, domestic agriculture or farmers in developing countries, others have *fundamental* objections to genetically modified foodstuffs and animal feed.

In this brochure, the ECNH intends to take up these anxieties and considerations, and contribute an ethical point of view to the debate. The Committee is well aware that the topic of marketing genetically modified foodstuffs and animal feed is very complex and cannot be handled comprehensively within the framework of this brochure. It will therefore limit itself to those ethical aspects that mark contemporary discussion in Switzerland.[1] It takes a particular look at the current evaluation criteria of Swiss legislation on foodstuffs and animal feed. It will also discuss the additional aspects, going beyond the valid criteria, that should be considered from an ethical point of view.

Genetically modified food or animal feed[2] is either a genetically modified organism itself (e.g. soybeans), is obtained from genetically modified organisms (e.g. flour from genetically modified wheat), contains constituents which are genetically modified or have been obtained from genetically modified organisms (e.g. spreads containing genetically modified soya flour), or is produced using genetically modified microorganisms (e.g. yoghurt produced using genetically modified bacteria). There are also foods that, although they have been produced

GM products currently permitted in Switzerland

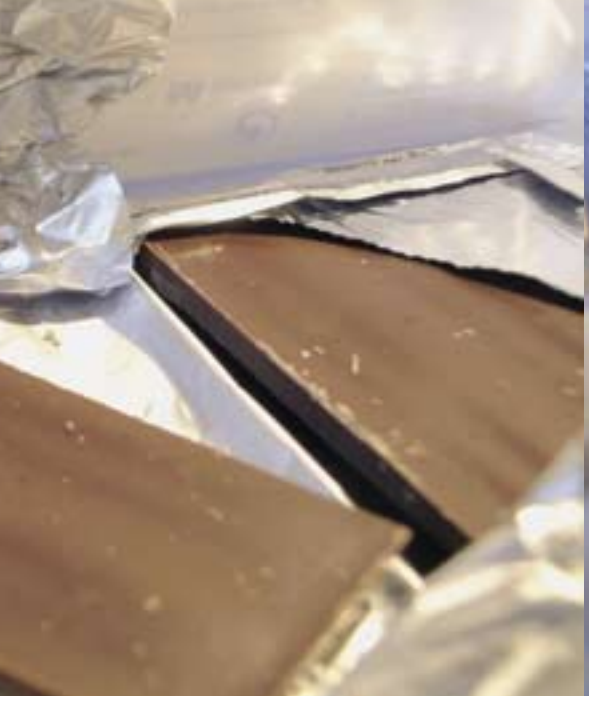
Currently permitted in Switzerland as foodstuffs and animal feed, for marketing and for import but not for cultivation: "Roundup Ready" soya and "Mon 810, MaisGard" maize from Monsanto, as well as "Bt11" and "Bt176, Maximizer" maize from Novartis.

In the transgenic Roundup Ready soya, the soya has been modified to be tolerant of the herbicide Roundup, which is used as a weedkiller. Soya is used as a foodstuff and animal feed, and also processed as an ingredient for foods and feeds. Whole soya (as soybeans or beansprouts), processed soya (e.g. as soya flakes in müesli or as soya flour in countless processed foods), and products that have been produced from soya, but in which processing has rendered the DNA undetectable (e.g. soya oil or lecithin), are found in a wide range of foods.

All the types of maize approved so far (Mon 810, Bt11 and Bt176) contain a technologically inserted gene from the soil bacterium Bacillus thuringiensis (Bt). The gene produces a protein that is poisonous to insects and protects the maize from larvae of the European Corn Borer. This pest causes loss of harvest in conventional maize and may lead to increased infestation of the plants with moulds.

Permitted additives and processing aids: Vitamin B2 from Roche and Vitamin B12 from Rhône-Poulenc Rorer. These vitamins are not themselves genetically modified, but are manufactured using genetically modified organisms.

B group vitamins are essential, but the human body cannot make them itself. They must therefore be obtained from food. In the industrial production of foods, vitamins may be lost. This applies particularly to the water-soluble B vitamins.
Vitamin B2 is formed in all plants and various microorganisms, and plays an important role in cell metabolism. It is added to a variety of foods, and sometimes used as a yellow food colouring (E101). For use in foods, vitamin B2 produced using gene technology is purer than the chemically synthesised form currently most used.
Vitamin B12 is produced by fermentation in (normal) bacteria. The production of the vitamin using genetically modified bacteria permits larger-scale and therefore more efficient production.



from genetically modified organisms, have subsequently been so purified that the genetic modification is no longer detectable (e.g. soya oil from genetically modified soya, or vitamins produced using gene technology). Because of the risk of contamination by mixing during production, processing and transport, the current trend is to evaluate food and feed according to the same criteria. Therefore, we do not differentiate here between food for animals and humans, but refer to GM production in general.

This brochure focuses on the ethical analysis of a particular aspect of GM products: *approval for marketing*. Although marketing should be separated from production in any evaluation, issues of production do play an indirect role and thus cannot be completely ignored.

Definition of the term "marketing"

In the Gene Technology Law, marketing is defined in Article 5 as any kind of passing on of organisms to third parties within Switzerland, in particular selling, exchanging, giving as a gift, renting, lending, or sending on approval, as well as import. Marketing does not include the passing on of organisms for activities in contained systems or for field trials.[3]
The term marketing applies only to genetically modified organisms handled outside contained systems such as greenhouses and laboratories. Put simply, it means that a product is put on the market; the size of the market does not play a role and a commercial component is not required.
Approval for the marketing of a foodstuff or animal feed does not include permission to use the organisms as seeds for cultivation. Approval for this must be given explicitly.

2 Discussion of the current evaluation criteria in food and feed legislation

Article 27 of the Swiss Federal Constitution (FC) guarantees the fundamental right of economic freedom. This fundamental right – as all fundamental rights – may be limited if exercising it endangers other important values protected by fundamental rights, and insofar as the other conditions of limitation of fundamental rights are fulfilled (Art. 36 FC).

In the food sector, good faith and human health are considered to be such values. Article 97 para. 1 and Article 118 FC therefore give the Confederation the power to legislate to protect these values. Applications for authorisation to market GM products are, according to current regulations, also judged by the criteria of fraud prevention and health protection. These criteria are supplemented by an environmental risk analysis, which will not be discussed in detail here.

The criteria of prevention of fraud and protection of public health are indisputable from an ethical point of view. However, the adequacy of the current use of these criteria in the practice of authorisation for the ethical evaluation of marketing GM products is sometimes hotly disputed.

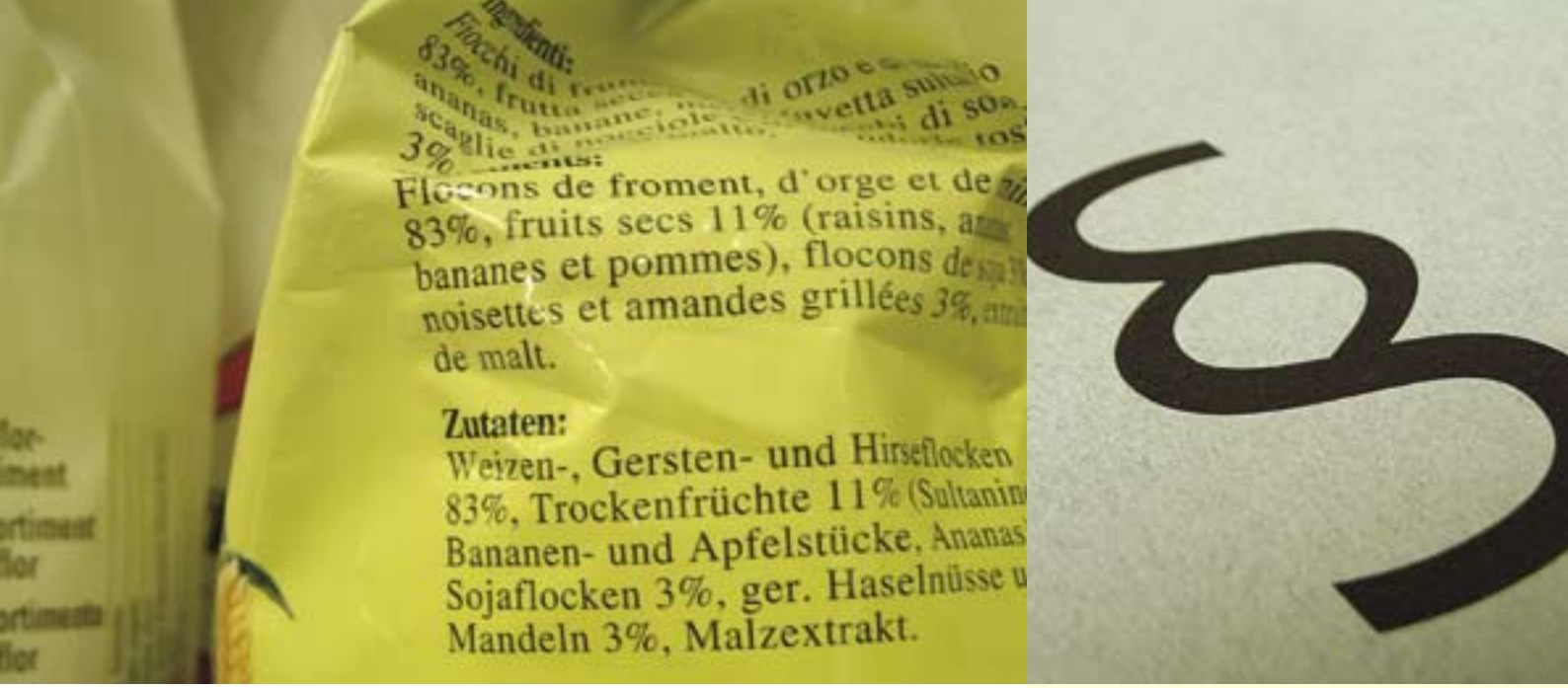
2.1 Prevention of fraud

The objective of fraud prevention is to guarantee the protection of good faith in the trade of goods, so that consumers can trust that they are properly informed about their purchases. Because of today's complex production, processing and distribution processes, protection of good faith is particularly important in the trade of foodstuffs and animal feed. Consumers should not only be protected from possible health hazards, but public trust in production and distribution should also be strengthened.[4]

One instrument of fraud prevention is a *declaration*. The applicable laws and ordinances therefore require GM products to be labelled as such. In Switzerland there is a basic duty of declaration.[5] It is not simply that the public discussion of the approval of GM products has proven that consumers want to know whether products contain genetically modified organisms (GMOs). From an ethical point of view, a duty of declaration is justified so that consumers can inform themselves about the ingredients, which are important to them for health or ethical reasons.

The mixing of GM products and non-GM products can only be avoided through the strict separation of production, processing and distribution paths. This requires considerable financial resources, and the question arises of who should pay for it.[6] Traces of GMOs cannot be avoided, or only with great effort. With the currently available analytical procedures detecting GMOs, it is not sensible to demand that foodstuffs and animal feed contain 0% GMOs. For purely pragmatic reasons it has therefore been decided to introduce *declaration limits* for foodstuffs and animal feed.

Establishing such limits is currently one of the key issues in the international discussion of GMOs. Under current regulations, if a product does not have to be declared it does not necessarily mean it is GMO-free. It may still contain a percentage of GMOs that is under the permitted limit. In Switzerland the limit for foodstuffs is currently 1%. This means that the proportion of GMOs in a foodstuff does not have to be stated on a label as long as it is below 1%.[7] For feed, the limit is 2 or 3%, depending on whether it is mixed feed or a single ingredient.[8]



How should these limits be judged from an ethical perspective?
One argument is that this practice is not justifiable in terms of the prevention of fraud, because it means that even well-informed consumers are being misled. The practice implies that it is possible to choose freely between GM- and non-GM products, but in reality the choice is only between food containing either more or less than 1% GMOs. Although a limit of 1% would be ethically justifiable according to the principle of proportionality, this would only be the case if a lower limit were linked to disproportionate conditions for the producers. Because of the social significance and contentious nature of GM products such disproportionality should not, however, be assumed lightly.

According to the Ordinance on Foodstuffs, foodstuffs may be labelled as "produced without gene technology" ("negative declaration") if full documentation is available to verify that no genetically modified organisms were used in the production process, if equivalent genetically modified foodstuffs have been approved and if they contain less than 1% GMO. However, even if no GMO can be traced we cannot assume a zero percent GMO content for these foodstuffs, since the limit of detection is currently about 0.1%. The situation is improving for consumers, as they can choose products with GMO contents that are probably considerably below the limit of 1%. But it could also be argued that fraud prevention is still not complete, as the label "produced without gene technology" gives the false impression that the GMO content is 0%. Furthermore, this label does not alter the misleading situation in which products with GMO contents below 1% do not have to be labelled.

The ECNH is unanimous in rejecting the current tripartite division – declaration at more than 1% GMO content, no declaration at less than 1% GMO, and the voluntary "negative declaration" mentioned above with the label "produced without gene technology". In the Committee's opinion, the current limits for GM products are not compatible with the criterion of prevention of fraud. Although the ECNH takes seriously the pragmatic reasons and considerations of proportionality that are raised here, it still maintains that these reasons are not strong enough to justify violating the ban on fraud which is so central to food law. The existence of other foodstuff sectors in which limits are permitted does not provide a justification. Rather, an investigation of these sectors would also be necessary.

Limitations of Fundamental Rights, Article 36 FC

Article 36 FC:

1 Any limitation of a fundamental right requires a legal basis. Grave limitations must be expressly foreseen by statute. Cases of clear and present danger are reserved.
2 Any limitation of a fundamental right must be justified by public interest, or serve for the protection of fundamental rights of other persons.
3 Limitations of fundamental rights must be proportionate to the goals pursued.
4 The essence of fundamental rights is inviolable.

The ECNH is unanimous that fraud could be avoided if consumers were informed that, using current analytical methods, a level of 0% GMOs in foods cannot be guaranteed. Additionally, the declaration limit should be the lowest value technically possible.

2.2 Protection of public health

According to Article 1 of the Food Law, consumers' health shall be protected from actual and possible hazards.[9] In order to evaluate the safety of GM products and thus prove that they pose no risk to human health, in 1993 the OECD formulated the concept of *substantial equivalence*. This concept has since become established in many countries as a standard. In recent years its significance in risk assessment has somewhat decreased, but it still plays a considerable role and will therefore be explained in more detail below.

2.2.1 The concept of substantial equivalence

The concept of substantial equivalence is applied in the safety assessment of foodstuffs and animal feed made of GMOs (usually plants), and components thereof. In the authorisation procedure for GM products it serves in the evaluation of health hazards, but not in the evaluation of environmental safety. The evaluation asks whether a GM product is just as safe, or just as unsafe, as the corresponding normal product.

The original understanding of the concept of substantial equivalence is based on the assumption that a genetically modified foodstuff can be compared with a normal, non-genetically modified foodstuff, and is equivalent to it except for the additional properties inserted using gene technology. Selected properties of the GM products are compared with the corresponding properties of the food not made using GMOs. The question is whether or not the additional property, inserted using gene technology, substantially changes the character of the GM food compared with the normal product.

The focus is on the biochemical and toxicological character of the new property. If the additional protein for the new property in a GM product is similar to the plant's own proteins, and is not toxic or allergenic – as far as can be determined – substantial equivalence of the whole product is assumed. The product then counts as "substantially equivalent". However, if the genetic

Differences between conventional breeding and genetic modification

Crop breeding usually takes place through the new combination of genetic information or of individual genes. The aim is to increase the expression of properties that are desirable for agronomic or nutritional reasons, and to select them in a targeted way for further breeding. Conventional breeding crosses different varieties of the same or a very closely related biological species to produce "better" crops. The spectrum of new properties is determined by the original plant and the limits of the genetic starting point. No properties can be created that are not already present, although unexpressed, in the DNA of the plants used. This means, for example, that in the breeding of conventional crops containing known health hazards, care should be taken that concentrations of the hazard are not raised in the new variety.[10]

In contrast to conventional breeding, which is based on crossing the same or very closely related species, gene technological methods can insert genes from completely different biological species such as viruses, bacteria or animals, into the DNA of a plant. With the technology used today, the site of integration of foreign genes into the DNA (the genome) is completely random. This may lead to disruption of the genes, regulatory sequences or so-called non-functional DNA sequences at that site. The foreign genes are usually equipped with their own regulatory sequences, which are not under the control of the plant's control mechanisms.

The possibility of (re-)combining genes beyond the species limits, and of inserting them, with their own autonomous control mechanisms, into the DNA of organisms, is the main characteristic of gene technology and explains its potential, both benefits and hazards. In nature, exchange of genes across the biological species barriers occurs only in a few biological systems. For example, viruses are able to integrate their genetic information into the genome of other organisms.

modification causes a toxicologically or immunologically significant difference, the products compared are no longer considered substantially equivalent.

From an ethical point of view, two points should be particularly borne in mind:

First, the concept of substantial equivalence relates to the food safety of GM products *only* with regard to *human health*. Other values relevant to the ethical evaluation of marketing GM products, some of which are mentioned in para. 3, are not considered.

Second, the concept of substantial equivalence permits no absolute statements, "only" a risk assessment comparative to normal foodstuffs. Long-term experience of safe use is assumed for normal foods, but not that these foods are absolutely safe. Even normal foods may contain ingredients that have adverse effects. At best, then, a GM product may be just as safe for consumption (just as harmless), or just as unsafe (just as dangerous) as the normal product.

2.2.2 Criticism

The concept of substantial equivalence rapidly found broad acceptance, and soon after its introduction by the OECD in 1993 the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the United States of America and Canada, the EU and Switzerland all recognised it as an important component of the risk assessment of GM foods. Nevertheless, critical voices were soon to be heard. In particular, the concept was accused of being a theoretical idea for which only very vague conditions existed to put it into practice.[11]

The controversy sparked off by this criticism[12] led the OECD, WHO and FAO, as well as the permit authorities of Canada and the EU, to reflect further on the basic idea of substantial equivalence, its applicability and its value in authorisation. During the course of this the understanding of the concept underwent certain changes. The value of substantial equivalence in the approval procedure was put into more precise terms and its significance for risk assessment of GM products relativised. According to this revised understanding the evaluation of substantial equivalence occurs at the beginning of a risk assessment and is *not itself a safety assessment*. The OECD is working on developing principles for a methodological implementation of the concept.

The idea on which the concept of substantial equivalence was originally based, according to which a genetically modified plant is the sum of the original plant's properties and the new genetically inserted property, fails to recognise the complex regulatory and physiological relationships within a cell or an organism. The expression[13] of a foreign gene, i.e. the presence of a new protein, may alter the overall physiological condition of a cell or an organism. In addition to the primary, desired and expected effect, this may have further, unintentional and unexpected effects on the organism as a whole.

This approach enables a more differentiated consideration of genetically modified plants. The currently accepted view assumes that a foreign gene in the genome of a plant could produce unwanted and sometimes unexpected effects in addition to the desired ones, and that these may not be immediately recognisable. This understanding of the effects of a gene modification in a cell or an organism has led to risk assessments being extended. As well as the intentional effects, *unintentional and unexpected* effects of a gene modification must also be determined.

Difficulties of methodology and principle arise, however, in the attempt to determine and interpret the differences between a GM plant and its conventionally bred template. For example, it is almost impossible to search for effects that are not anticipated. Even if the number of parameters investigated in a GM plant is substantially increased,

there can be no guarantee that all the consequences of a genetic modification will be recognised. Analysis could become so expensive as to be no longer practicable. Furthermore, whether an effect caused by a genetic modification is intended, unintended or unexpected, implies nothing about its significance for the safety of GM products in terms of human health. The concept of substantial equivalence is no further help here.

Although the concept is an important component of a risk assessment, it is not in itself a safety assessment. One key difficulty is that no such test exists that can make a reliable statement about the long-term risks of GM products for human health. In such situations of uncertainty or ignorance, the precautionary principle should therefore be included in an ethical evaluation.

2.2.3 The precautionary principle

In situations of uncertainty or ignorance, precautionary measures can be taken in order to avoid possible adverse effects, such as major damage to health.

As far as environmental policy is concerned the precautionary principle plays an important but not uncontroversial role, particularly in discussions about risk in the area of gene technology and biotechnology. Its central significance is clear and uncontested. It legitimises government intervention in the liberty of individuals and companies in order to avoid the threat of long-term severe and/or irreversible damage. The ethical foundation of the precautionary principle also contributes to the understanding of the damage principle, according to which limitations on freedom are morally justified or morally required in order to prevent possible large-scale damage.

As a rule – and this is where it becomes controversial – other aspects are linked to the precautionary principle, such as the demand for a reversal of the burden of proof or the "priority of bad predictions".

A central point in the discussion of the precautionary principle is, what conditions justify reversing the burden of proof? According to one particular reading of the *strong* precautionary principle, it is enough if *severe damage is conceivable, irrespective of scientific evidence or indications*. Understood like this, the precautionary principle means that if it is conceivable that GM products could severely harm human health or the environment they should be prohibited until they have been proved safe. However, some kind of catastrophic effect is always conceivable, and there is no scientific evidence that could ever remove this conceivability. This would mean that practically every new product and every new technology would have to be prohibited.

Thus it is more proportionate to link a reversal of the burden of proof to the following conditions. The possible extent of the damage of a product or technology must not just be very great; there must also be *empirical, scientifically comparable grounds* for this. Where these grounds are lacking, reversing the burden of proof must be justified at least by *well-founded hypotheses and models*. If such hypotheses or models exist, producers and traders of GM products can justifiably be required to produce adequate documentation of their safety, and marketing can be prohibited until these documents are available.

If there are no empirical grounds, models or hypotheses that provide reasons to prohibit marketing of GM products until they are proven safe for human health, an ethical evaluation using the strong precautionary principle is inappropriate. In this situation, the weak precautionary principle is used. It is clear that according to this principle, the *possibility* of severe harm is insufficient ground to prohibit marketing GM products, as the principle requires the



Strong and weak precautionary principle

There are two variants of the precautionary principle, with risk-avoiding measures of differing strength: the strong and the weak precautionary principle.

The *strong precautionary principle* is characterised by three properties:

1. requirement for reversal of the burden of proof;
2. emphasis on ignorance; and
3. the priority of bad predictions.

"Requirement for a reversal of the burden of proof" means the State does not have to provide proof that a product or a technology is hazardous. Rather, the proponent of a potentially hazardous product or technology must prove that this product or technology is not hazardous.
"Emphasis on ignorance" means abandoning the principle of scientific provability, that is turning away from a technocratic environmental and health policy that believes the extent of any damage and probability of its occurrence can be calculated using "objective" methods.
Finally, the "priority of bad predictions" means that in a situation of ignorance, decision making should assume the greatest possible damage. No activity should be undertaken if the possibility of severe harm to human health or the environment cannot be ruled out.

It is this last requirement that differentiates the strong from the *weak precautionary principle*. According to the maxim "be cautious, but act", the principle permits products or technologies which could be hazardous to be approved, without first having scientific proof that they are safe. The State is allowed to impose proportionate precautionary measures on private individuals or companies, for example, by ordering long-term monitoring of the potentially hazardous product. With the weak precautionary principle, the burden of proof is set according to the general rule, "if in doubt, decide in favour of freedom". This means the State is allowed to intervene only if it has good reason to believe that there is a threat of possible severe and/or irreversible damage. The proof of there being a risk of damage is and remains the State's concern, although the precautionary measures include taking into account the state of research and technology, and carrying out careful risk-benefit analyses.

State to provide proof that this foodstuff *is in fact* – and not just may be – a considerable health hazard. As long as this proof is not provided, the State may require the proponents to take certain precautions, but may not prevent GM products from being put on the market.

Thus to the question of whether GM products should be marketed in terms of their effect on human health, the precautionary principle offers two possible answers:

According to the *strong* precautionary principle, the marketing of GM products should be prohibited until the proponents have provided sufficient proof of safety. This, however, requires an adequate foundation for the assumption of a potentially very great extent of damage through – even if incomplete – empirical scientific grounds or well-justified models or hypotheses.

According to the *weak* precautionary principle, the marketing of GM products should be permitted if the State cannot prove they are hazardous to human health. This requires there to be enough scientific grounds to justify the assumption that if marketing is permitted, there is a risk of severe or irreversible damage.

Although something is known about the potential health risks of GM products, there is no agreement among scientists over the probability of this happening or the extent of any possible damage. The same data may be interpreted by one expert to mean that GM products are relatively harmless in the long term, while others are convinced of the opposite.

There is a consensus in the ECNH that precautionary measures are necessary when placing genetically modified products on the market. All members of the Committee are also of the opinion that current safety research is inadequate and should be intensified. There is no unanimity on the issue of which variant of the precautionary principle should be applied in safety assessment. The great majority of the ECNH believes that the *weak* precautionary principle is appropriate, although the concrete conditions should be established on a case-by-case basis.[14] A minority believes that the safety of GM products should be evaluated according to the *strong* precautionary principle.[15]

Examples

In terms of the health risks of GM products, there are three main points under discussion: could the products trigger allergies? Are they poisonous? Could antibiotic resistance genes inserted into plants lead to a further spread of antibiotic resistance in humans?

Allergies: Most of the new properties of GM plants are based on the production of proteins that do not normally occur in plants and that until recently were not a general component of human food. Thus, there is only a little experience to judge whether these proteins could trigger new allergies. Some allergenic properties of proteins can be identified in advance using biochemical markers, but more in-depth can only be made by medical examination of consumers and monitoring following market approval.
In 1998 the United States approved the maize variety StarLink for cultivation and use as fodder, but not as food. Biochemical analyses suggested increased allergenicity due to the inserted Bt toxin, the protein that makes the GM maize resistant to pests. The GM maize was therefore not considered substantially equivalent as a foodstuff. Because StarLink maize was nevertheless still found in 2000 in various foods, and because there the health authorities had received reports of allergic reactions in connection with the consumption of this food, all StarLink products were recalled from the market and its approval as feed was also withdrawn.

Toxicity: The *acute* toxicity of a protein that is newly produced in GM plants can easily be tested. These tests are part of the standard evaluation of the substantial equivalence of GM products.
However, it has not yet been possible to make experimentally based statements about *chronic* toxicity, i.e. the health effects of long-term consumption. If a GM product is considered substantially equivalent, this means it is no different from the traditional product in terms of its chronic toxicity. Conclusive statements are however only possible after long-term monitoring and comparison between groups of consumers and non-consumers of GM products.

Antibiotic resistance markers: Antibiotic resistance markers are used in the construction of most GM plants. The antibiotic resistance genes are generally not active in GM plants, but are only expressed as the corresponding proteins in bacteria. The resistance genes may, however – even if only rarely – be transmitted via gut bacteria to pathogens. Whether this contributes to the current spread of antibiotic-resistant pathogens is highly controversial. The EU and Switzerland nevertheless plan to prohibit completely the use of antibiotic resistance genes in genetically modified organisms cultivated in the field from 2008.

3 Further ethical criteria

In addition to the criteria of fraud prevention and health protection, which are important according to current legislation, an ethical evaluation of GM products should consider some additional aspects. These include free choice for consumers, whether the coexistence of different forms of production is possible or not, respect for the dignity of living organisms, the socioeconomic impacts of the production and marketing of GM products, and the possible effects on the environment and on biodiversity.

The ethical literature generally differentiates between arguments that relate to the *consequences* of an action, and those that are *independent of possible consequences*. The arguments that judge production and marketing of GM products independently of possible consequences include the considerations of natural order and the dignity of living organisms.

3.1 Natural order and the dignity of living organisms

The essence of the argument of natural order is that the production of GM products is morally unacceptable because the transgression of species boundaries is incompatible with natural order. In contrast, arguments that use the concept of the dignity of living organisms are not always so absolute. According to which fundamental values are weighed against intervention in the dignity of living organisms, the production of GM products may be considered compatible with the dignity of the respective plant or animal and therefore morally acceptable.

However, these are *indirect arguments*: they are not directed at the marketing but at the *production* of GM products, without which marketing would not be possible. In the debate about marketing they play a subordinate role, which is why the Committee has refrained from discussing them at this point. Furthermore, the natural order argument has not been used within the ECNH. We mention our brochure "Die Würde des Tieres" on this subject, which the ECNH has produced together with the Swiss Committee on Animal Experimentation.

3.2 Socio-economic and ecological impacts

The possible impact of the production and marketing of GM products at the socio-economic level include issues that arise through the possibility of patenting. These questions, which are important for a complete ethical analysis, have previously been considered by the ECNH elsewhere.[16] The complex impacts of genetically modified foodstuffs and animal feed on living conditions in developing countries, as well as the issue of how GM products should be evaluated in terms of sustainability, will be considered by the ECNH in a further Statement.

There is one important point that engaging with these issues presents, and which should be considered as part of the key problem of possible ecological impacts. There is frequently too little validated empirical knowledge about the impact of the production and marketing of GM products on different areas. Although it is known, for example, that genetically modified crops are able to cross with related wild plants, it is still very unclear what effects this has on biological diversity. And much experimental research remains to be done to obtain reasonably reliable results. More money should be invested in the corresponding research. One possibility would be to link the authorisation to market GM products with the condition that supporting research and long-term monitoring must be undertaken.

3.3 Freedom of choice

We normally understand freedom of choice, i.e. being able to choose between several options, to be a *claim right*. Although freedom of choice is not a general right – for example, we do not have the right to drive both ways on a one-way street – many hold that food is important enough that in the case of being able to choose between GM and non-GM products, such a right is indeed appropriate. In this case, two claims are connected with freedom of choice. First, the State should ensure that the products are appropriately labelled. This duty of declaration is usually justified by saying that consumers should be able to inform themselves in order to be able to make an autonomous choice. Second, the State should ensure that it is possible in practice to choose between GM and non-GM products. If the food market were to develop such that only GM products were available, we could refer to freedom of choice to require the State to intervene and ensure that non-GM products are also available.

If we understand freedom of choice like this it would, conversely, mean that the production and marketing of GM products is also required. We could conclude that the State is obliged to guarantee that, in addition to non-GM products, GM products are always available on the market.

We can also understand freedom of choice not just as a right to claim something, but as a *liberty right*. In this case, liberty right means that nobody should be *compelled* to consume GM products. The State accordingly has a duty to protect consumers from this compulsion. It can only do this by ensuring that, even if GM products are on the market, consumers also have access to *non*-GM products.

This liberty right is based on the consumers' belief that the GM products are hazardous, or rejecting them for other reasons. It would then not be ethically justifiable to place consumers in a situation where they are forced to buy GM products. Conversely, it does appear justifiable to require the proponents of GM products to renounce them. We conclude that the State should ensure that non-GM products are always available; but the State is not obliged to guarantee access to GM products.[17]

The ECNH unanimously rejects the interpretation of freedom of choice as a claim right to choose a particular product. Conversely, the great majority of Committee members approves the interpretation of freedom of choice as a liberty right. In the Committee's opinion the claim that GM products be

just as available as non-GM products, cannot be justified by calling upon freedom of choice. But what *can* be justified is the claim that the option of buying GMO-free products should always be available.

This claim may theoretically be fulfilled in two ways: either through the import of GMO-free products, or through the domestic cultivation of such products. For domestic cultivation, there is the question of whether it is feasible for traditional forms of production and those based on gene technology to co-exist. This issue also has considerable political significance. A major goal of Swiss agricultural policy is more ecological farming. As long as we hold to this goal, farmers may choose a gene technology-based form of production only if it does not threaten the survival of traditional forms of cultivation.

One problem is that Switzerland is small, and this must be taken into account. Organic farming and traditional methods of production, especially integrated production (IP), appear to be endangered – at least in the long term – by the production (and marketing) of genetically modified crops and the vertical gene transfer associated with it. Farmers who use the traditional methods will not be able to guarantee that their products have no transgenic components. All this argues in favour of taking appropriate measures to protect gene technology-free agriculture in our own country, to ensure access to GMO-free products. This may mean refraining from production based on gene technology in Switzerland.

4 Public participation

The requirements of fraud prevention guarantee consumers a limited degree of transparency in terms of product composition. At the end of the process, on the supermarket shelf, it exerts a certain influence on the sales success of a product – as long as alternative products are available. If this remains the only possible influence, citizens are reduced to a role as consumers. Ethical questions, however, arise much earlier, with the *creation* of the product and the *objective* of marketing it.

Reservations about GM products make it important to emphasise public participation even at this early stage. The question of marketing GM products is a basic one that affects all citizens, and should therefore also be discussed by all. Since it is known that public consultations as part of legislative procedures address only an extremely small part of the population, it would be wrong to rely exclusively on this opportunity for public participation. Additional routes to the active participation of citizens have already been tried: we should highlight here the "PubliForums" organised by the Swiss Centre for Technology Assessment (TA-SWISS). By these means the risk that the moral opinions of the public are ignored, while the voices of the experts remain privileged, can be avoided.

1 *In particular, we do not consider the issue of the possible impacts of genetically modified food on the living conditions in developing countries, or the question of how food and feed should be evaluated in terms of sustainability. These aspects, which are important for a complete ethical analysis, will be dealt with in a future Statement by the ECNH.*

2 *Federal Office of Public Health leaflet "Deklaration gentechnisch veränderter Lebensmittel in der Schweiz", July 1999 (available in German, French and Italian)*

3 *See also Ordinance on the Release of Organisms into the Environment (Release Ordinance, RO), Art. 3 para. e.*

4 *Message concerning the Food Act, Federal Gazette 1989, 893 ff.*

5 *Conversely, the US Food and Drug Administration (FDA) rejects the obligation to declare. According to the FDA, genetically modified food should essentially be evaluated as traditional food, which renders a special declaration unnecessary. The FDA justifies this with the concept of "substantial equivalence" (see Para. 2.2.1).*

6 *In the ECNH's view, it should not automatically be assumed that the state should bear these costs.*

7 *Ordinance on Foodstuffs of 1 March 1995, Art. 22b.*

8 *Declaration limits apply only to approved GM products. All other GMOs have a tolerance of 0%. Since contamination of non-genetically modified products with traces of GMOs cannot be ruled out, applications are made for approval of marketing despite the rejection of GM products by a large majority of consumers.*

9 *See also Message concerning the Food Act, Federal Gazette 1989. 893 ff.*

10 *To combat pests or conserve parts of the plant (root vegetables, e.g. celery), some plants are able to produce substances which are nutritionally undesirable and which can be harmful to health at high concentrations.*

11 *No methodology with prescribed parameters for investigation and permissible deviations of the relevant ingredients yet (2002) exists for practical application. The border between "fundamentally equivalent" and "fundamentally not equivalent" cannot be precisely defined scientifically, as "substantially equivalent" or "fundamentally equivalent" are different from "biochemically identical".*

12 *This controversy was provoked in 1999 by a commentary published in the scientific journal Nature, in which the concept of substantial equivalence for the evaluation of food safety of GM products was called into question.*

13 *"Reading" a gene forms or expresses a protein.*

14 *The majority opinion is based on the fact that both experience in the United State with the consumption of GM products and also the results of safety research up to now do not justify reversing the burden of proof as part of a reinforced precautionary principle.*

15 *The minority opinion is justified by the delay between development and marketing on the one hand, and possible ecological or other damage on the other, being far apart. So that safety research does not lag hopelessly behind development, the strong precautionary principle, and as a result a moratorium, is necessary. The converse argument, that in the USA millions of people have been consuming GM products for years, does not convince the minority. The period of time is far too short to be able to make statements about long-term health risks, which are characterised by a long latency period until damage becomes apparent. In addition, no scientific studies of the effects of consuming GM products in the United States are yet available.*

16 *See the ECNH brochure "Patents on animals and plants. A contribution to discussion", 2001, and the commissioned report by Anwander N. et al., "Gene patentieren. Eine ethische Analyse", Mentis-Verlag, Paderborn, 2002.*

17 *Proponents of GM products may not base their argument on their belief that GM products are just as safe as ordinary foodstuffs. Respect for persons requires that individual risk assessments and ethical positions be taken seriously.*

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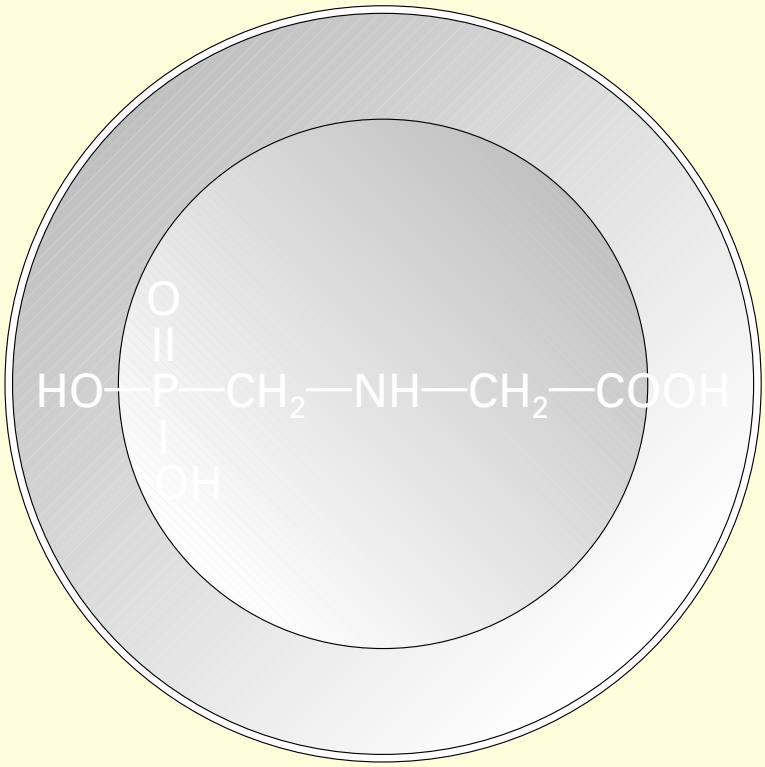
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