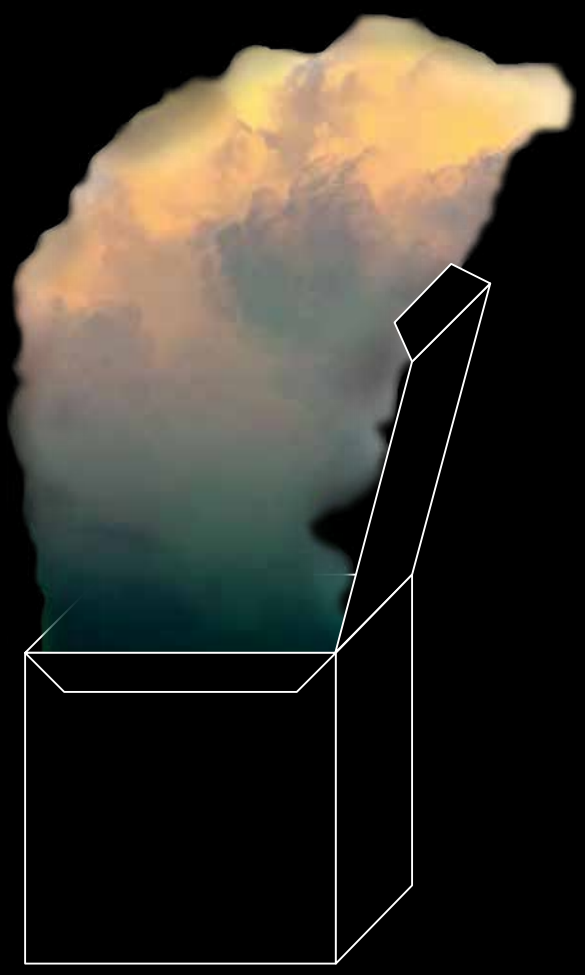
Precaution in the environmental field

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

Ethical requirements for the regulation of new biotechnologies



1 Introduction

The rapid development of new techniques which allow us to selectively alter genetic material and are thus termed *genome editing*[1] has sparked public discussion about how such biotechnologies are to be regulated. The considerable potential that the new techniques present, or at least promise, for research and many areas of application also harbours risks. Besides the legal issues involved, there are also fundamental ethical questions to be answered. In the following report, the Federal Ethics Committee on Non-Human Biotechnology (ECNH) looks at the general ethical requirements for regulation of the new procedures and their possible application in the environment.

Currently, the authorities in Switzerland assume that all so-called new procedures are genetic engineering procedures, and so fall under genetic engineering regulations. This approach is, however, criticised and rejected by some. In the 1970s, initial debates about genetic engineering techniques sparked discussions about their safety and thus led to changes in the law. In Switzerland, various parliamentary proposals and popular initiatives – the first of which took place back in the 1970s – led to the passing of the Gene Technology Act in 2003[2] after many years of debate. The Act imposes strict authorisation procedures for the use of gene technologies in non-human biotechnology. Some believe that certain new procedures should be exempt from these authorisation requirements for genetic engineering methods because the intended alterations to the genome are no longer detectable in the product or may be the result of natural mutations. Therefore, in all these instances the regulatory requirements for the application of such procedures should be the same as those for conventional breeding procedures. Others – such as, currently, the relevant Swiss authorities – invoke the precautionary principle, a tenet of environmental law. According to this group, treating the new technologies and genetic engineering procedures in the same way under the law is (currently) justifiable, since the use of these new technologies in the environment also involves considerable uncertainty and lack of knowledge, linked with the fear that, in complex systems such as

1 The so-called CRISPR/Cas systems are among the genome editing methods currently under discussion. They allow the targeted modification, insertion or removal of individual DNA building blocks. The method was scientifically documented for the first time in 2012 and can be applied to almost all organisms.

2 For example, in 1974 National Councillor Oehen posed a question in Parliament about the control of molecular biological research; in 1976 National Councillor Salzmann submitted an interpellation in which he demanded the review of suitable protective measures against genetic manipulation.

those found in the environment, possible slight modifications could lead to widespread damage.

The precautionary principle (or precautionary approach) is a concept originally found in environmental law. However, in the discussion about regulation of new (bio)technologies in the environment, the principle is particularly controversial. The criticism is raised that this principle is unreasonably restrictive, both in research and in the development of fields of application. Furthermore, the objection is voiced that the precautionary principle cannot be rationally justified. Since this principle plays a central role in this discussion on regulation, the ECNH addresses it in detail in this report, examining the *ethical* significance of precaution and the *ethical* justification of precautionary obligations.

The precautionary principle arose from the legal and political discussion. Therefore, when first addressing the topic, the ECNH initially considered the possible legal and political justifications. In order to gain a general overview of the discussion on the precautionary principle, in 2016 the ECNH began by inviting three experts: Christoph Errass (University of St Gallen) gave an introduction to existing regulatory approaches from a legal perspective; Andreas Bachmann (Federal Office for the Environment FOEN and permanent guest of the ECNH) supplemented this with an introduction to the precautionary principle from an ethical perspective; Helmut Gaugitsch (Environment Agency Austria) presented the precautionary concepts that shape understanding within the EU and OECD working groups. At the same time, the ECNH commissioned Christian Munthe (University of Gothenburg) to draw up a philosophical report on how to address situations of uncertainty.[3] Meanwhile, the ECNH worked on its own report. When Munthe's draft report was presented in May 2017, the committee used the occasion to also invite Nicolas de Sadeleer (Saint-Louis University, Brussels) and Helmut Gaugitsch to a workshop. De Sadeleer also contributed to the discussion, providing an additional legal perspective. The workshop findings have been included in the discussion leading to this ECNH report.

3 Christian Munthe, Precaution and Ethics. Handling risks, uncertainties and knowledge gaps in the regulation of new biotechnologies, 2017, Volume 12 in the ECNH book series "Contributions to Ethics and Biotechnology".

2 Precaution as a concept in environmental law and the term "precaution" in specialist and general parlance

2.1 Precaution as a concept in environmental law

The classic legal model to protect the public from damage comes from hazard prevention. Towards the end of the 20th century, the conviction became established in environmental policy that in certain situations it is not enough to react only when a threat is imminent or when a threat of damage is certain. Protective measures should also be taken – as a precautionary measure – even if there is a fear of damage occurring but it is not yet known whether and with what probability such damage will occur. This idea of precaution was increasingly included in the discussion on environmental law and has subsequently become firmly established in various legal documents at national and international level.[4]

An important milestone in the establishment of the principle in law at international level was the 1992 Declaration of the United Nations Conference on Environment and Development of Rio de Janeiro (Rio Declaration). Principle 15 formulates the idea of precaution:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The European Commission addressed the concept of precaution in its Communication in the year 2000. In the meantime, it has become an established regulatory principle of environmental legislation.[5] Precaution is applied when preliminary risk assessment indicates that there are reasonable grounds for concern that something has a potentially dangerous impact on the environment, human, animal or plant health, even when scientific evidence is insufficient, inconclusive or uncertain.[6] Swiss environmental legislation also addresses the issue of precaution. The Federal Constitution requires that damage or nuisance be avoided.[7] The Environmental Protection Act[8] and the Gene Technology Act[9] state that such damaging and disturbing impacts are to be limited at an early stage.

4 See also the appendix.
5 See appendix.
6 See appendix.
7 Art. 74 Federal Constitution, "Protection of the Environment".
8 Art. 1 EPA ("Aim") and Art. 11 EPA, which regulates protection against emissions.
9 Art. 2 GTA, "Precautionary and polluter-pays principles".

These documents differ in the way in which they formulate the concept of precaution. Whereas the European Commission talks of the *precautionary principle* in its communication, the Rio Declaration uses the term *precautionary approach* in the English version, *Vorsorgegrundsatz (engl. precautionary policy/principle*) in German, and *mesure de précaution (engl. precautionary measure)* in French. The Swiss formulations talk of avoiding damage and nuisance. The Environmental Protection Act and the Gene Technology Act state that such impact is to be limited at an *early* stage.

It is conceivable that different things are intended with these different formulations, and that the idea of precaution may not involve one principle or approach, but a whole array of different principles or approaches. Or it may be that the idea of precaution is formulated differently in varying contexts, but that the same set of legal instruments is ultimately established. In any case, it can be said that all formulations have a common core. Precautions should be taken to avoid damage when two criteria are met: (1) it is feared that damage (of a certain extent) may occur and (2) knowledge about the probability of such damage is restricted. According to the Rio Declaration, the possible damage must be serious or irreversible and the restricted knowledge must constitute scientific uncertainty. In the European Commission's communication, the severity of the damage is not qualified, and a preliminary scientific risk assessment must give cause for concern.

The formulations in Swiss law differ from the internationally established understanding of precaution in a variety of ways. They state that not only harmful effects but also nuisances must be prevented. And restricted knowledge is not an explicit criterion. There is no mention of scientific uncertainty or of preliminary scientific risk assessment.[10] It may be said that the idea of precaution, as it has been discussed since the Rio Declaration in 1992, only finds expression in Swiss environmental law in individual pieces of legislation such as the Gene Technology Act.

This report aims to respond to the core requirement of all these formulations, namely the need to react to the fear of potential harmful effects, and to the question of how such a requirement and the resulting obligations can be ethically justified.

2.2 Precaution and prevention

The terms *Vorsorge* (precaution) and *Prävention* (prevention) are widely used synonymously in German, in both technical jargon and in everyday language. German-language legal texts sometimes use the term *Prävention* in the context of precaution. In French and Italian, the two terms are also generally used synonymously in everyday usage. On the other hand, specialist literature in these two languages distinguishes clearly between *précaution/precauzione* and *prévention/prevenzione*. If the probability of occurrence of damage is known, the term used is *prévention/prevenzione*. If there is uncertainty, however, about

10 The criterion of restricted knowledge could perhaps be construed from the formulation that measures shall be taken early. This would have to mean that action should be taken not at the time when imminent danger is to be averted, but earlier, when there is no certainty as to the probability of the damage or nuisance occurring.

the probability of damage occurring, the term *précaution/precauzione* is employed. This report examines the question of how uncertainty is to be addressed and thereby the ongoing discussion in French and Italian specialist language of *précaution/precauzione* respectively.

2.3 The broad understanding of precaution in everyday language and the narrow understanding of the precaution requirement in environmental law

In contrast to the (international) concept of environmental law, in our day-to-day lives we do not only speak of precautionary measures when there is a threat of serious, major or irreversible damage. Precautions and measures are taken even against minor harmful scenarios: for example, if unsettled weather is forecast, we might take along a raincoat as a *precautionary* measure. Moreover, according to this general understanding, we also speak of precaution when a situation that is to be assessed negatively might occur not only possibly, but with a very high probability, or even with a probability bordering on certainty. In everyday language, therefore, we use the term "precaution" for situations in which one could (also) speak of prevention. Saving for an old-age pension provides an example of this: even if a person does not know with certainty whether they will reach retirement age, it is rational to take precautionary measures for the loss of income associated with retirement. Or if a single parent knows there is a probability bordering on certainty that they will soon die, and if they can prevent or alleviate some of the negative consequences for the family members left behind after their death, they have a moral duty to take appropriate precautions. Similarly, a person is obliged to take (preventive) measures if they must assume with near certainty that their behaviour will result in others becoming infected with a dangerous disease.

This broad and general understanding of precaution thus means preparing *on the basis of one's own or another's assessment of the risk* to avoid or alleviate harmful effects that could occur as a result of *subjective or objective assumptions of probability*. Precautionary measures are decided on this basis. Leaving aside the question of moral duty towards oneself, precaution can also be generally understood as an *ethical duty* when it is a question either of protecting others from harm or of avoiding risks that we ourselves inflict upon others.

However, it may well be that even this general understanding also incorporates the idea that possible harmful effects must be of a certain quality before we say that someone is obliged to take precautionary measures. On the other hand, according to this broad understanding, there is no precautionary situation and therefore no obligation to take precautionary measures if there is no indication that harmful effects may ensue. This does not mean that no harmful effects can occur, only that it is at present unknown that something

is unknown. Moreover, one is not required to be aware of not knowing. This means that even in the everyday understanding of precaution, no one has a moral duty to take precautionary measures against previously unobserved harmful effects or harmful effects that have not yet been observed or deemed possible.

In environmental law, the understanding of precaution is somewhat narrower. Here, the demand for precaution is made as a reaction to the fact that the scope of our knowledge is restricted. The understanding of precaution in environmental law thus refers either to a special case of the general concept of precaution in our everyday understanding, or it designates an ethical principle that is distinct from the broad and general understanding of precaution described above.

A look at both environmental law and everyday language serves as a first approach to the possible meaning(s) of the precautionary idea and provides indications as to which situations can call for precautionary measures. However, neither environmental law nor everyday language can provide an answer to the questions of how a precautionary obligation can be *ethically justified*, who bears an obligation and what this obligation consists of. Below we will now examine whether and to what extent the criteria for introducing precautionary measures found in the law are also relevant from an ethical point of view. It is also necessary to clarify whether there may be grounds for further obligations beyond these legal criteria. In this analysis the criteria in environmental law are taken as a starting point, but the analysis is then continued separately from the legal considerations. A link to the law is only re-established after the conclusion of the ethical analysis, in order to reflect these considerations in existing law and to clarify any need for action.

3 The ethical idea of precaution

3.1 The criterion potential damage

The core idea of precaution is that certain harmful effects should not occur and that one should take measures to prevent or limit them whenever possible. In formulations in internationally relevant environmental legal texts, the duty to take precautionary measures does not relate to all harmful effects, but to those of a certain quality. According to the Rio Declaration, the duty to protect in the sense of precaution only extends to potentially serious or irreversible damage to human health and the environment. The communication of the European Commission accord this particular quality to damage to the environment and human, animal and plant health if it exceeds a certain level. This damage can be understood to constitute the impairment of legally defined objects of protection or protection goals. Besides damage to health and the environment, there may be other (also serious) effects of an economic nature. However, under international environmental law there seems to be no precautionary obligation to protect against such effects.

On the one hand, it may be asked how extending the protection obligations to damage that is not certain to occur but may do so (although there may be plausible grounds to fear that it may) can be justified. On the other hand, we must establish the relevance of restricting these obligations to a particular type or quality of possible damage. In order to answer these questions, we must first look more closely at what constitutes damage.

3.2 What constitutes damage and who or what can suffer damage?

A plausible definition of damage is a change that must be judged to be negative. It is irrelevant who causes the damage. The damage is the same whether it is caused by humans or it is the result of natural forces.

Damage is morally relevant when it affects entities that themselves have moral value. Who these entities are depends on the position held in environmental ethics. From a selection of options, here we list four that are most frequently referred to within the ECNH:

– Anthropocentric positions place humans at the centre. Only humans count morally for their own sake. Only humans, therefore, can suffer damage for their own sake. According to this reading, serious damage to animals, plants or the environment is only relevant if it affects humans, because these entities are of instrumental or relational value to them.

– Pathocentric positions place a living being's sentience and ability to feel pain as the main criterion to determine whether it can suffer damage. A living being can suffer damage provided it has some form of inner experience or if it can experience something as good or bad.

– Biocentric positions morally consider all living beings for their own sake. For these positions, sentience is not a prerequisite for a being's inherent value. There are two main biocentric approaches. Either living beings have inherent value and can therefore be damaged, because being alive has value for its own sake. Or living beings can be damaged because as bearers of a good life they have a good of their own. This second approach assumes that living beings have, so to speak, an inscribed aim specific to their species.

– Ecocentric positions focus not just on living beings but the whole of nature as a comprehensive, complex interaction between entities. If we interpret this position holistically, collective entities such as ecosystems, biotopes, species and populations, nature, the earth or even the whole universe have inherent value. For advocates of an individualistic reading of this position, all individual beings that are a part of nature count morally for their own sake, both living beings and non-living beings such as lakes, mountains or landscapes. All of these collective or individual entities can be harmed.

Depending on the position held in environmental ethics, different entities will be among those beings that can be harmed for their own sake. This, however, does not tell us how much the damage caused to such an entity counts. There are essentially two answers to this. The egalitarian position assumes that equal damage caused to any entity that can be harmed must be assessed equally, and unequal damage differently. According to the hierarchical position, all entities that can be harmed should be considered, but not all entities have equal value. Either the nature of the species counts, so that interests, such as those of humans, are weighted more highly than equal interests of other entities, or the complexity of characteristics counts, and the more similar the characteristics to those of humans in terms of their complexity, the higher the harmful effects are weighted.[11]

11 Cf. ECNH, Dignity of Living Beings with regard to Plants. Moral consideration of plants for their own sake, 2008, p. 19, and ECNH, Ethical Treatment of Fish, 2014, p. 21 f, including criticism of the different positions.

3.3 The ethical significance of qualifying damage in the context of precaution

In contrast to the broad everyday understanding of precaution, according to which precautionary measures should be taken against even the slightest of harmful effects, in a narrower understanding of the concept, as it is formulated in environmental law, the quality of the damage plays an important role.[12]

One reason for restricting precautionary obligation in environmental law to a particular type of damage may lie in the fact that the State is under an obligation to intervene in basic rights, in particular rights of freedom. Any intervention in basic rights requires justification. Another or further reason could be that at international level only a qualified type of damage could be agreed on for political reasons.

For the purposes of this discussion, irrespective of any possible politically motivated reason for limiting the concept of precaution to certain types of damage, we will look at the normative question (which is also relevant for a legal justification) as to how far such a limitation can be ethically justified. Two main positions can be distinguished regarding the normative meaning of damage. The first assumes that certain types of damage cannot be compared with others; the second assumes that all types of damage can and may in essence be compared:

1 The first position assumes that certain types of damage represent an evil that cannot be compared with other evils. These types of damage thus form their own normative category. If it is conceivable that damage of this type could occur in a certain situation, there is either a duty to refrain from action or a requirement to act (e. g. to generate knowledge as a prerequisite for a risk assessment). Damage of this kind must always be avoided. Even if the probability of damage occurring is extremely slight, it is the extent of the potential damage that is of relevance. For if risk is a function of damage and probability of occurrence, and if the evil is astronomically severe damage, then even the smallest probability of occurrence would result in an immeasurably great and therefore impermissible risk. The key question to be asked in this position is: what constitutes incomparably severe damage?

There are two variations of this first position. For the *first variation*, the *physical* destruction of the whole of humanity would constitute incomparably severe damage. For the *second variation*, this would be the *cultural* destruction of humanity. Even if, following a catastrophic nuclear event, a large number of people could continue to live biologically, but not in a way that constitutes the cultural nature of humans, then according to this variation this would constitute incomparably severe damage and thus an evil that must

12 In terms of precaution, the Rio Declaration talks not only of possible *serious*, but of *irreversible* damage. Any change is, essentially, irreversible. If a forest is destroyed, it is not possible to restore it to exactly the same form, even if reforestation takes place over a long period. The living creatures that formed part of the forest cannot be brought back. The forest is a new forest with new living creatures. In an ecological context, however, the concept of irreversibility is not usually understood in this way. A forest that can be restored, or a particular moth which disappears but of which examples of the same species become re-established, are not considered to have been lost irreversibly. According to this understanding of irreversibility, the damage can be compensated. The term is used to qualify a particular type of damage: damage that has long-term effects and affects things that are considered to be particularly important and valuable to the human community (possibly also to later generations) and its environment. Understood thus, irreversibility serves as an indicator when assessing how serious any damage caused may be, but not as an independent criterion for precautionary measures.

be prevented at all costs. It is inadmissible to weigh up such damage against other interests.

Advocates of both variations of this first position agree with the second position set out below that a weighing of interests is admissible with regard to all other interests.

2 According to the second position, no damage can be of a quality that does not allow comparison with other types of damage. If different instances of damage can only be distinguished by their extent, it can still be assumed that only once the damage reaches a certain extent is it necessary to act (which may also mean refraining from doing anything). This would then give us a conception of a threshold. Only when the possible damage reaches a certain level does precaution come into play in situations where knowledge is limited, and the obligation arises to take measures to prevent damage of this magnitude. If the possible damage does not reach this threshold, precautionary measures are not required, even in situations of scientific uncertainty. The key question to be asked in this position is: when is this threshold reached?

A *variant* of this second position also includes small-scale possible damage in the consideration of precaution. According to this position, requiring precautionary measures may also be justified with regard to such types of damage, even if the probability of their occurring is uncertain or vague. This at least, provided the costs of the measures taken are reasonable.

A further *variant* of this second position does not require precautionary measures to be taken if the possible benefits of an action are scientifically and plausibly weighted higher than any potential severe damage.

3.4 The epistemic bases of precaution decisions

A precaution situation is one in which damage could occur but in which there is only limited knowledge about the probability of this possible damage occurring. The ethical idea of precaution, according to the thesis to be examined, justifies an obligation to take measures to prevent possible damage or to limit it to an extent not exceeding a permissible degree. This obligation exists even if no more is (yet) known about the probability of occurrence other than that it is greater than zero. Precaution situations can therefore be seen as a particular type of risk situation. Decisions about precaution situations are thus a type of risk decision.

Firstly, a distinction must be made between four types of epistemic basis on which risk decisions are made.

1 We know that damage will occur with 100% or 0% **certainty**: the damage is either sure to occur or sure not to occur. No statement of probability need be made.

2 The damage scenario and its probability of occurrence are fully determinable. There is a situation of **complete or certain knowledge of the risk**. We know the statistical probability with which damage will occur. This risk is therefore calculable. In French and Italian specialist literature on the subject, this type of epistemic basis would be the object of *prevention*, not of precaution.[13]

3 The damage scenarios are known. The bases on which their probability of occurring can be calculated are, however, imprecise to varying degrees. The probability of occurrence cannot therefore be calculated quantitively but can only be estimated qualitatively. There is a situation of **incomplete or uncertain knowledge of the risk**. An example of this might be the exact prediction of avalanches. We know what the damage scenario is, but despite the various calculation models available, can only make a qualitative assessment of the probability of an avalanche occurring – as "high" or "low".

4 There are scientifically plausible indications for possible damage. Unlike type 3, however, it is not possible to estimate the probability of their occurrence. This epistemic situation is referred to below as **vagueness**. An example of such an epistemic situation of vagueness is the risk posed by a nuclear final storage facility. Our geological and biological knowledge and experience are insufficient for us to make even a qualitative estimate of the probability of damage occurring, owing to the time dimension.

The situations of **ignorance** are to be distinguished from the four epistemic bases. Even in these situations it cannot be ruled out that damage may occur. If, however, we have no idea of the damage potential, nor do we have any (scientifically plausible) indications that give rise to fears, then there is no vagueness, but rather ignorance. We cannot react to ignorance. A meaningful and thus ethically relevant decision is not possible in a situation of ignorance. There can thus also be no obligation to take precautions.

It is important to bear in mind that uncertainty or vagueness always refers only to the probability of occurrence, not to the damage scenarios. The damage is always known or at least there must be scientifically plausible indications of the damage scenarios. If the damage is not known or if there are no such indications, a situation of ignorance exists. Even complex situations do not mean that the damage scenarios are uncertain or doubtful, but rather that assessing their probability of occurrence becomes correspondingly more complex and therefore more difficult.

In the same way, psychological uncertainty is to be distinguished from epistemic uncertainty. If, based on a subjective assessment, someone fears that damage may occur and therefore feels insecure, this does not

13 See also 2.2.

necessarily mean that there is epistemic uncertainty. There may be sufficient risk data to calculate the risk. Despite the psychological uncertainty, there would then be no epistemic uncertainty, but rather sufficient knowledge of the risk.

In practice, assigning a concrete decision situation to one of the theoretical types of epistemic basis regularly gives rise to controversy. Thus, it is debatable when a certainty of 100 % or 0 % can be assumed outside of controllable contexts, such as those that can be generated in a laboratory. When technologies are applied in the environment, there will always be a degree of uncertainty or vagueness. In the context of environmental risks in particular, some people point to the complexity of the system and argue that such risk assessments are not only currently impossible, but that they are not feasible in principle. Others, on the other hand, assume that, even in complex systems, for certain types of event sufficient data may be available to determine the probability of occurrence or at least to provide a rough qualitative estimate. According to this position, even in the case of complex systems one should not, therefore, generally assume that a risk assessment is impossible.

These assignment issues and their role in precaution decisions are discussed in Section 3.6. For the time being, it is noted here merely that the precautionary idea relates to the epistemic bases of uncertainty and vagueness. Accordingly, measures are to be taken under the heading of precaution, although it is (still) uncertain or vague whether the feared damage will occur.

3.5 How do ethics theories respond to the epistemic situation of uncertainty?

What should be done when there is epistemic uncertainty and vagueness with regard to ethically relevant damage in the context of precaution? The answer to this depends on the ethical risk theory embraced.

Even if there are many risk theories, these can be assigned to only a limited number of types. The ECNH concentrates here on those two theory types which, in its view, play the most important role in answering the question of how to deal with precaution situations: the consequentialist theories (the most well-known of which is the utilitarian theory) and the deontological theories. These two theory types can be linked to all the environmental ethics positions mentioned in Section 3.2.

3.5.1 Deontological ethics theories

Common to all variants of deontological ethics theories is the notion that an action is morally right if it corresponds to the obligations that we have towards morally relevant entities. According to deontological ethics theories, entities are morally relevant because they have inherent value, i. e. value in themselves, regardless of their use or significance for others. Depending on the position taken, different entities have such

inherent value: only humans or only living beings with certain characteristics, or all living beings or all collective entities. The obligations always exist towards the individual morally relevant entity with inherent value.

If there is a possibility that such an entity could suffer damage in an ethically relevant way, this would trigger a precautionary obligation. A precautionary obligation towards this entity does not rule out the possibility that measures must also be taken to protect other protection objectives which do not have an inherent value. For example, if a precautionary obligation only exists towards people, this does not mean that no measures are to be taken to protect animals or environmental goods. The reason for these measures, however, lies not in the obligation towards these other beings or goods, but in the precautionary obligation towards the person for whom these beings or goods are of instrumental value according to this position.

Advocates of absolute deontological theories are obligated to refrain entirely, i. e. under all circumstances, from deeds that (could) damage entities with inherent value. Such absolute forms of deontological theory do not allow for any weighing up, even when there is a conflict of obligations. As inherent value cannot be weighted, making it impossible to calculate which obligation is of greater importance, in such cases such advocates find themselves facing a dilemma. One variant of this approach excludes the weighing up of certain qualified goods only, such as human dignity. For all other goods, a *prima facie* approach applies, which is described below.

Advocates of prima facie approaches of deontological risk theories permit a threshold value for damage, provided that it does not violate morally justified claims. They justify this by saying that an obligation to act always implies that it can also be fulfilled. An instruction to act that basically cannot be fulfilled is not plausible. If all action that could damage morally relevant entities were prohibited, life would not be possible, because with every action there is a probability that an entity with inherent value will be damaged. According to these prima facie approaches, exposing these entities to risks is reasonable provided that these risks are below the threshold value. If, on the other hand, they lie above the threshold value, measures should be taken to reduce the risks to below this value. If this is not possible, the action must be refrained from completely or at least until the risks can be reduced to below the threshold value. A special case of this *variant* of a threshold position assumes that, even below the threshold value, there is still an obligation to take further measures, insofar as they are proportionate.

In deontological risk theories, opportunities (i. e. more or less probable benefits) associated with an act may not be weighed against the associated risks.[14]

14 There is controversial debate among advocates of deontological ethics over whether opportunities that enable the fulfilment of positive obligations should be taken into account.

If complete risk knowledge is available, that is to say, it is known with which probability an entity with inherent value will be damaged by a certain action, advocates of deontological risk theories always decide according to the obligations which they have towards this entity. If the risk of being damaged is reasonable for the entity, the action is permissible. If the risk lies above the threshold value and is therefore unreasonable, the action must be refrained from.

If the risk knowledge is incomplete, the reasonableness and thus the admissibility of a risk cannot be determined. It is not known whether a certain action (or the application of a technology as a whole) exceeds the permitted threshold value. In such a situation, deontological approaches will require more data and information on the probability of occurrence of damage to morally relevant entities. The same is true to an even greater extent for situations in which there are only scientifically based theses that make serious damage appear plausible. In these cases, too, an obligation to carry out research may stem from this theory.

It should be borne in mind that risks must also be taken in order to obtain further risk information. These risks must also be reasonable. It follows from this that, according to deon-tological theories, this additional information can only be obtained gradually. This is the only way to obtain this information without exceeding the permitted risk threshold.[15]

3.5.2 Consequentialist ethics theories

There are also many types and variations of consequentialist ethics theories. The most well-known and politically influential is the utilitarian. It is therefore the focus of the following considerations. What all variants of this theoretical family have in common is that an action is assessed *solely* on the basis of its consequences. For example, according to the act utilitarian theory, each action must maximise the expected net utility.

Because only the consequences of an action count, this precludes entities having inherent value in the deontological sense.[16] A change which is judged to be negative for a morally relevant entity according to deontological theory does not necessarily represent morally relevant damage according to utilitarian theory. Rather, it may be necessary to bring about such a change if it increases the net utility for all morally relevant entities. According to utilitarian theory, there would be morally relevant damage if an act did not increase this net utility.

If there is complete knowledge about opportunities and risks, these can be weighed up against each other and the best possible outcome for all ethically relevant entities can be calculated.

If the risk knowledge, i. e. the knowledge of opportunities and risks, is incomplete, according to consequentialist theories further information is required just as it is in the case of

15 It remains to be seen how these threshold values are to be set and how one knows when enough information is available in order to establish when the risk is no longer reasonable.

16 For advocates of a utilitarian theory, the individual being or individual entity never has value for its own sake.

deontological theories, until it is possible to calculate the consequences (according to the utilitarian theory: the net utility). This is all the more the case when there are situations of vagueness in which there are only (scientifically founded) indications that serious damage may result.

In order to calculate the risk, information about both opportunities and about the risks for entities with moral value is required. New data is continuously considered in this calculation. Obtaining information also has its price.[17] In situations in which the opportunities are fully known, it may be that the price for additional risk information becomes so high that the calculation requires one to act, despite the lack of risk information. But a step-by-step approach must also be taken according to the logic of the consequentialist theories presented here. According to utilitarian theory, a step is taken when the calculation of the available information suggests that the net utility will be greater than if this step is not taken. As long as the data necessary for a calculation is unavailable, and the estimated cost of acquiring the data is not higher than the estimated opportunities, then there is a need for research.

3.6 How can an ethical decision be made when expert opinions differ?

How do the different ethics theories react to a situation of disagreement or indecision about risk knowledge? If there is knowledge about possible damage, but the data on the probability of its occurrence is interpreted differently in expert circles,[18] advocates of both deontological and consequential risk theories will ask about the plausibility of the deviating interpretations. If the degree of plausibility of different interpretations varies, the more plausible expert opinion must be considered.

The degree of plausibility depends on the data available, the state of the art or the care taken in applying scientific methodology. Plausibility is decided on the basis of the criteria for scientific excellence recognised by the scientific community: theory or hypothesis must, among other things, explain a particular phenomenon and be testable, meet coherence requirements and satisfy the principle of organised scepticism (e. g. undergo a peer review). A scientific hypothesis is plausible if, under these circumstances, there is much to be said for its correctness. This is, so to speak, the threshold that separates plausibility from non-plausibility.

It is the task of the scientific institutions to assess plausibility. In order to fulfil this task according to scientific criteria, the institutions need access to the information that led to the formulation of the scientific theses. The data must be presented in a comprehensible manner, including data that does *not* support the scientific thesis. Furthermore, the scientific institutions must be independent so as to ensure that plausibility is assessed impartially and according to scientific criteria.

17 See: Christian Munthe, Precaution and Ethics. Handling risks, uncertainties and knowledge gaps in the regulation of new biotechnologies, Report commissioned by the ECNH, published as Volume 12 of the ECNH publication series "Contributions to Ethics and Biotechnology", 2017.

18 There are many reasons why scientific results are interpreted in a variety of ways. Scientific disagreement often results from ambiguous and inaccurately positive results of research. There is a further problem with interpreting data when studies do not meet statistical relevance requirements. This makes it all the more important to create transparency about the basic assumptions on which scientific interpretations are based.

What should be done when disagreement or indecision still exists within the scientific community and the question of plausibility cannot be decided in a scientific manner? If there are two or more different positions that all meet the plausibility criteria and have large groups of advocates in the scientific community, it is usually also accepted within the community that there is a state of disagreement. From an ethical standpoint, therefore, research is required. More information is required to find out which of the interpretations is more plausible.

If, on the other hand, a large majority of the scientific community considers the data situation to be clear, the role of a deviating minority opinion must be examined. Must the majority opinion be followed or is there a situation of scientific uncertainty? First of all, it should be noted that neither the fact that a scientific position is held by a majority nor by a minority is a criterion for its correctness. Even when everyone agrees, this does not mean the position is true *for this reason*. Conversely, the plausibility of a position cannot be determined independently of the sciences. If this were possible, it would be possible to make an objective and unequivocal decision on which theories are plausible based on criteria independent of science. It is conceivable that there are several plausible theses concerning the same facts or phenomena. Theoretically, it should be possible to use plausibility criteria to decide which of gradually differing plausible positions is the most plausible. In practice, however, the scientific community is generally unable to judge so easily either the question of plausibility or the question of the degree of plausibility.

Nevertheless, in such undecided and indecisive situations, decisions have to be made. For this reason, it is imperative that decision-makers such as public authorities check whether the criteria for scientific research have been adhered to and to what extent positions are plausible, in order to be able to understand the assessments of the scientific institutions and classify them appropriately. They therefore also require access to the necessary information in a comprehensible form, including diverging data that does not

support the scientific theses. These authorities should therefore also have employees with this kind of scientific training. It is not their responsibility to carry out a plausibility assessment themselves, but they must be able to critically understand those made by the scientific institutions. It should be noted that these employees act as representatives of the political decision-making authorities and thus play a role different to that of the academic institutions.

3.7 Different theories, converging practices

There are different approaches to justifying the precautionary concept depending on the ethical risk theory. If there are indicators of a precautionary situation and if the criteria that trigger measures are met, advocates of both the deontological and the consequentialist theories are largely in agreement over the consequences of the precautionary measures and the form that they should take. According to both risk theories there is an obligation to act in a precautionary manner. Both demand an obligation to obtain comprehensive information in order to reduce uncertainties, with the aim of enabling suitable risk assessment.

4 Precautionary obligations

Precaution situations differ from other risk situations in that, firstly, *serious damage* is possible and secondly, their *probability of occurrence* is *epistemologically uncertain*. The members of the ECNH are **unanimous** in believing that if both these criteria are met, there is an ethical obligation to take precautionary measures. Precautionary measures can and must be taken, therefore, if the existence of the two criteria is established. There are two conceivable options:

– According to the *first option*, those who fear that serious damage may occur must show that their fear lies within a plausible range.

– According to the *second option*, there is a reversal of the burden of truth. It is not up to those who fear the occurrence of serious damage to demonstrate plausible grounds for this fear; it is the responsibility of those whose actions give rise to the fear of damage occurring to demonstrate plausibly why such damage is extremely improbable or scientifically absurd.

The ECNH members are **unanimous** in supporting the second option. In their view, if there are plausible indications of serious damage, the reversal of the burden of truth is justified.[19]

In precaution situations, i.e. in situations in which it is feared that possibly serious damage may occur, the obligation lies primarily with the state authorities responsible for safeguarding the protection objectives in question.

The issue of how to apply new (bio) technologies in the environment and identify the role of precaution in this context is more than a purely legal one. Owing to the far-reaching consequences of these technologies, not only are the state authorities called upon, but the answers must be negotiated by society in the political process. The state is also solely responsible for these political decision-making processes. This is not inconsistent with the fact that the public authorities rely on the involvement of others in order to fulfil their responsibilities.

19 A further option is theoretically conceivable, namely that a precaution situation can always be assumed, i.e. that it is always clear that the criteria are met. Such a position, which means a general reversal of the burden of proof for all actions, would however encroach on freedom rights to a disproportionate degree and cannot therefore be ethically justified.

The obligation to ensure that an ethically unjustifiable occurrence of damage is (highly) unlikely may conflict with rights to personal and economic freedom, the expression of which must be protected in research and in industry. Interventions resulting from precaution obligations can therefore only be justified if they are proportionate. They may only go as far as necessary and may not limit our actions unnecessarily.

Various precaution instruments are conceivable considering both the political decision-making processes and actual proposals for regulations. No attempt is made to provide a definitive list of these instruments here.

Precautionary measures in favour of protection objectives always involve restricting freedom rights in some way. Taking precautionary measures may mean prohibiting or refraining from an activity or a certain application. This may be justified if the measures taken are proportionate with regard to the rights mentioned above. If, for example, plausible fears exist, but owing to a lack of knowledge or unanimity about the knowledge available it is still unclear whether these fears will continue to be justified in the future, the appropriate measure is not a general prohibition, but a temporary one (moratorium). Furthermore, rather than general prohibition, spatial or application-specific prohibition should be considered.

However, there is a need to counter the frequently expressed reservation that precautionary measures necessarily only involve proscription. Precautionary measures can also exist as *orders* to act. The obligation to proceed step by step, for example, means that missing knowledge can be acquired and potential serious damage restricted at an early stage. When the first astronauts landed on the Moon, it was feared that they might bring back microbes which could lead to catastrophic effects on Earth. This fear, which was plausible considering the state of knowledge at that time, did not mean that the moon landing was prohibited. Instead, the astronauts had to spend three months in quarantine upon their return, a precautionary measure which effectively assuaged the fears.

Besides the state agencies responsible for determining precaution situations and for the binding definition of measures, other players also have a moral duty. These might be companies and manufacturers that produce potentially harmful substances or that introduce them into the environment. These also include agricultural holdings. Businesses and manufacturers have the duty to work with such substances in accordance with the regulations and the rules of good professional practice. The idea of precaution also obliges them to report any unexpected adverse effects noticed, so that appropriate precautions can be taken. As a result, the state also has a duty to create agencies to which such observations can be reported, and to react in good time.

Research scientists and research institutes also have a responsibility, as they are often the first or the only entities able to recognise the damage potential of their research activities. They have a duty to work according to rules set within their scientific field and to take precautionary measures to avoid serious damage in the context of their research activities. This may mean that precautionary measures are already called for when research projects are appraised or funded, if scientifically plausible damage scenarios are apparent. For example, state research funding may not be one-sided and a range of research prospects and research paradigms should be considered. Furthermore, researchers and research institutions are required to draw the attention of the authorities and the public at an early stage to developments which may have precautionary relevance. Here also, it is the state's duty to receive such information and to react expeditiously.

If all the players involved are to be able to observe their precautionary obligations, the responsible actors in the education system are also called upon. Pupils and students should be made aware of the issues in a way appropriate to their level and taught how to deal with knowledge and uncertainty and with risk situations. This should happen above all at tertiary level, i. e. in universities, and in vocational courses for occupations which are confronted with such precautionary situations. In the context of biotechnology, this includes agricultural colleges.

Dealing with the new technologies in the environment does not, however, only affect those in the research field or who apply these technologies in their work. Because of their potential impact, how to deal with new technologies in the environment and the extent to which it is permissible to expose third parties to risks are issues of importance to the whole of society. In Switzerland, therefore, they are regularly the subject of political popular votes.

5 Conclusion

The rapid development of new biotechnologies such as CRISPR-Cas systems and other genome editing processes opens up new opportunities and promises a wide range of applications, although it is yet to be seen whether all this potential can be realised. At the same time, the new technologies and their application potential confront us with considerable uncertainties. On the one hand, we do not know everything about how the new technologies function or about their impact on organisms on which they are applied. If the technologies and organisms which have been altered by the processes come into contact with the environment, this not only increases the complexity of possible interactions, but also our uncertainties.

Environmental law responds to this epistemic situation of uncertainty with the legal concept of the precautionary principle or precautionary approach. If serious damage is not merely conceivable, but there is also a scientifically plausible foundation for the fear that such damage could occur, then a precautionary obligation exists. In its report, the ECNH concludes that the concept of precaution in environmental law and the precautionary measures to which it gives rise can also be justified ethically, irrespectively even of the underlying risk ethics theory.

6 Recommendations

1 **Consistent strengthening and application of the idea of precaution.** With regard to new biotechnologies, the applicability of the legal concept of precaution is frequently questioned. The ECNH concludes in its report that the idea of precaution can also be legitimised ethically, irrespective of the underlying theories of risk ethics. This leads to the ECNH's first recommendation, namely to adhere to the concept of precaution in the regulation of new biotechnologies, to establish it firmly in the further development of environmental law and to support its application at international level.

The question of how to deal with epistemic uncertainties and thus with precaution situations is closely related to the question of how we generate knowledge. It also affects the political culture in which we make decisions dealing with technologies and uncertainty. The following recommendations therefore affect the conditions under which knowledge is acquired, as well as those under which political decisions are made.

2 **Improving the reliability of risk assessments.** The data on which a risk analysis is based must satisfy scientific criteria. It is the responsibility of the scientific institutions to comply with these criteria, and they have their own mechanisms for doing so. The ECNH recommends strengthening the framework conditions of the scientific institutions in such a way that they are able to meet the criteria in a scientifically independent manner and can consistently demand that all actors comply with the scientific standards and justification requirements. Scientific data and assessments must also be verifiable and comprehensible in order to meet internal scientific controls and thus satisfy scientific criteria. This involves granting access to all information necessary for scientific evaluation, including to divergent data that does *not* support a scientific thesis.[20] Furthermore, attention must be paid to promoting and cultivating diversity of perspectives and cross-sectional competences.

20 In view of recent developments in science and education policy, care must be taken to ensure that conflicts of interest do not restrict impartial research at universities. Such restrictions not only compromise the independence of scientists but also alter the self-conception of scientific institutions. They may affect the quality of scientific data, influence the choice of research approaches and, at worst, lead to interest-based solutions and results. In all cases, such restrictions undermine confidence in the independence of science and the scientific quality of data and data assessment.

Access to data and transparency of scientific assessments are also essential for the experts responsible in the decision-making authorities; they must be able to understand the plausibility of the scientific data and how they have been assessed, in order to be able to make reasoned decisions. Moreover, they must be able to present these decisions concerning risk to the public, which is affected by them, in a transparent and understandable manner.

This is the only way to ensure that voters can form free and informed opinions, and thus that risk decisions also made reliably in the political process.

3 **Respecting the different roles of expert committees on the one hand and of decision-making authorities and the courts on the other.** Decisions about dealing with new (bio)technologies in the environment have far-reaching consequences which are of relevance to the whole of society. The decisions may therefore not be left to individuals. It follows, therefore, that the democratically legitimate instances charged with making these decisions may not delegate them to others.

This also means that decision-making within specialised bodies advising the competent authorities must be subject to democratic control. Their decision-making process must be transparent and comprehensible, and majority opinions and minority positions must be presented openly and comprehensibly with justifications. Furthermore, given both the plurality of scientific opinions and the fact that the state may not delegate decisions in such matters, it follows that neither the decision-making authorities nor jurisdiction automatically accept the expert opinions of specialised advisory bodies. The decision-making authorities must therefore also have appropriately trained staff. They must be able to critically follow the plausibility checks and assessments made by the scientific institutions.

4 **Strengthening political awareness in dealing with technologies and uncertainties**. Decisions on how to deal with technologies involve uncertainties and possibly have far-reaching consequences. The decisions are based on risk assessments that involve making decisions about values. In democratic societies, the responsibility for these value decisions lies with the citizens, not with scientists. Awareness of this fact must also be raised among the employees of authorities who implement such value decisions when assessing individual cases. If they are involved in this decision-making process as specialists, they do so on behalf of the political authority. Their role as scientists in this context is thus different from that of their colleagues in scientific institutions.

Appendix

Below is a list of definitions which are usually referred to in the discussion regarding the idea of precaution, and which shape the discussion to a large extent.

Rio Declaration on Environment and Development of 1992

Principle 15:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

(http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm)

Wingspread Statement of 1998

(Expert conference in Wingspread, Wisconsin, USA)

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

(http://www.sehn.org/wing.html)

European Commission Communication (2000)

According to "Communication from the Commission of 2.2.2000 on the precautionary principle", the principle "covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN)

EU guideline 2001/18/EC

(on genetically modified micro-organisms)

Art. 1 Objective

In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment.

Art. 4 General obligations

(1) Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

Cartagena Protocol on Biosafety

(of genetically modified organisms)

Art. 1 Objective

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Art. 26 Socio-economic considerations

(1) The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Art. 27 Liability and redress

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Swiss Federal Constitution

Art. 74 Protection of the Environment

1 The Confederation shall legislate on the protection of the population and its natural environment against damage or nuisance.

2 It shall ensure that such damage or nuisance is avoided. The costs of avoiding or eliminating such damage or nuisance are borne by those responsible for causing it.

Swiss Federal Act on the Protection of the Environment (EPA)

Art. 1 Aim

1 This Act is intended to protect people, animals and plants, their biological communities and habitats against harmful effects or nuisances and to preserve the natural foundations of life sustainably, in particular biological diversity and the fertility of the soil.

2 Early preventive measures must be taken in order to limit effects which could become harmful or a nuisance.

Art. 11 Principle ("emissions")

1 Air pollution, noise, vibrations and radiation are limited by measures taken at their source (limitation of emissions).

2 Irrespective of the existing environmental pollution, as a precautionary measure emissions are limited as much as technology and operating conditions allow, provided that this is economically acceptable.

Swiss Gene Technology Act (GTA)

Art. 2 Precautionary and polluter-pays principles

1 Early precautions shall be taken to prevent hazards or harm that may be caused by genetically modified organisms.

2 Any person who causes measures to be taken under the provisions of this Act shall bear the costs.

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