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**Genetically Modified Organisms (GMOs)**

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**Report**
Committee on the Environment, Agriculture and Local and Regional Affairs
Rapporteur: Mr Wolfgang Wodarg, Germany, Socialist Group

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*Summary*

The production of genetically modified organisms (GMOs) in the farming and food sectors and the controversy surrounding them have grown in the last ten years. Opinions differ between the producer countries that are favourable (chiefly the United States) and countries that are hostile (above all in Europe), between developed and developing countries and among farmers, scientists and consumers for example. Some advocate unrestricted distribution while others favour the precautionary principle. Claims that they carry no health risk are countered by others that the ecological risks are unknown.

It is true that there are question marks remaining over the development of GM crops, scientific research in this area, coexistence with traditional crops, consumers' freedom of choice, free competition, international trade, patents, the needs of developing countries, proper public information (including through compulsory labelling), the animal feed chain, the precautionary principle and the notion of sustainability.

This report takes stock of the issues and calls inter alia for consumers' and producers' freedom of choice, the preservation of sustainable development in agriculture, the precautionary principle, objective scientific debate and public participation. It advocates stricter regulation of labelling, liability, good farming practice and GM-free zones and recommends that parliaments ensure that these proposals are acted upon.


## I. Draft resolution *[Link to the adopted text]*

1. As the production and use of genetically modified organisms (GMOs) increases world-wide, the Parliamentary Assembly recognises that clear political rules which pay due regard to the precautionary principle are needed in order to ensure that new and traditional agricultural production methods are able to co-exist in the member states. The purpose of these rules must be to safeguard in the long term the ecological and economic fundamentals of human life and the biodiversity of our living environment.

2. The Assembly notes that biotechnological research and applications in the sphere of agriculture have contributed considerably to new knowledge about plants and animals. Major improvements have been achieved in breeding methods. However, a distinction has to be made between biotechnological methods in general and the specific method of gene transfer enabling scientists to produce GMOs.

3. It also notes that the production and use of GMOs is the subject of extreme

controversy in Europe and that there is as yet no reliable information concerning their medium- and long-term environmental effects.

4. Huge investments have been poured into genetic applications. In addition to the large number of plant varieties approved world-wide, transgenic fish and genetically modified micro-organisms are about to enter the market.

5. According to the GMOs producers, the expected benefits range from the improvement of agronomic characteristics and lowering of production costs, with an associated increase in profits, to improved quality foods. Research is also taking place into the biological elimination of contaminants. Those new technologies should allow to meet better the needs of the developing countries.

6. The Assembly believes that although green biotechnology offers a broad spectrum of potential benefits, many risks - for example horizontal gene transfer - have not been sufficiently evaluated. While the risks to health associated with current GMOs can be regarded as slight, provided that safety controls prove effective, future developments with modified output characteristics will entail new and different risks that will have to be assessed on an individual basis.

7. Long term effects on biodiversity are difficult to estimate, particularly as there is no generally recognised definition of "ecological damage". The Assembly emphasizes that there are currently no uniform standards for the assessment of mandatory monitoring of crops in cultivation. Long-term monitoring is obligatory to allow the ecological effects of GMOs to be assessed.

8. Too little attention has been paid to date to the breeding of transgenic animals and genetically modified micro-organisms. Experiments with transgenic domestic animals have been underway for many decades. The objectives are almost the same as those of conventional breeding methods: increasing productivity, particularly in the sphere of agriculture.

9. In addition to the health risks to humans (allergies, nutritional effects, zoonoses) which so far have hardly been examined, biotechnological modifications to domestic animals involve serious health effects for the animals themselves. The question arises as to whether it is ethically justifiable to develop transgenic animals for economic reasons.

10. The Assembly considers that besides the economic, social and ethic consequences, in particular the ecological consequences and a possible further reduction in locally endangered species of domestic animals must be taken into account.

11. The Assembly is aware that a great variety of political strategies for dealing with GMOs have been seen internationally. Whereas in the USA neither separation of the flow of goods nor mandatory labelling has been set up and in Brazil and Mexico repeated incidents of contamination of native species have been detected, the European Union has decided to align its policy on the side of caution and to allow producers and consumers permanent freedom of choice (strict approval process, labelling, co-existence). The GMO-free criterion has become a decisive quality criterion for export and import.

12. Several Council of Europe member states want stricter GMO regulations than those in force in the European Union as there are concerns that a creeping and uncontrollable

spread of GMOs is taking place via countries in Central and Eastern Europe. Any action intended to undermine an explicit decision against the release of GMOs by the mere accomplishment of facts must be clearly rejected. Any illegal action designed to destroy the plants of release trials must also be rejected.

13. Since there has been a de-facto moratorium for the authorisation of GMOs since 1998, the European Union wishes to set up a uniform regulation for handling GMOs in the member states, in line with the negative attitude of consumers but also to further extend the innovative potential of biotechnology and to create reliable conditions for trade in GMOs approved in the EU. Within the EU, from April 2004, human foodstuffs and animal feeds, the production of which involves the use of biotechnological processes, must be labelled even if the products themselves no longer contain GMOs (transition from product labelling to process labelling).The labelling of GM animal feedstuffs is mandatory, though not the labelling of meat, milk and eggs from animals fed with GM feed.

14. The Assembly considers that the major reservations expressed by consumers are not only attributable to the fact that new products do not show any benefit. The loss of consumer confidence, particularly in the area of food manufacture, is due to a variety of causes and should be taken very seriously by producers, retailers and politicians irrespective of possible irrational factors. On the one hand, one must accept that individuals have different and differentiated perceptions of risk. On the other, it must be appreciated that the use and promotion of certain technologies do not take place in isolation but are bound up with more complex political decisions on matters such as the direction of agriculture policy or the use of public resources.

15. It states that to date it has been apparent that the use of gene technology in the agricultural sphere is a continuation of intensive farming, based on increasing yields with the help of chemicals. Relieving pressures on the environment by reducing the use of agrochemicals has proved not to have lasting benefits as resistance has developed. Land management in accordance with ecological principles offers an alternative to traditional practice which ought not to be jeopardised by an over-hasty plunge into widespread commercial cultivation of GMOs.

16. The Assembly believes that against a non-quantifiable risk involved in the release of genetically modified organisms there stands a so far unproven advantage for the consumer. Ethical aspects such as animal protection, the quite considerable supervisory and control requirements of long-term monitoring of the environmental effects, conformity with threshold values and, in future, the identification of potential health implications and the resulting costs, as well as the ensuing restrictions on existing freedoms to grow whatever crops one wishes, suggest that the social debate should continue and the research agenda be extended to include the concepts of sustainability.

17. It states that the present world trade situation should be regarded in terms of the demands of sustainable economic policy. The system of patents which protects intellectual property, for example, does not ensure a fair balance between the rich countries and the poorer ones. Patent law is increasingly proving a trick device for the acquisition of quasi-proprietary rights to agricultural resources. Patents on biological material intensify and consolidate dependencies and bring with them the danger of monopolies and merciless cut-throat competition to the disadvantage of farming structures and farmers. The social consequences of such economic promotion may create or aggravate serious problems of poverty.

18. The Assembly considers that the transgenic varieties developed to date are not suitable for growing in the developing countries but that it is vital to them that there should be technology transfer and not just the opening up of new market outlets. World hunger is the result of unfair distribution and the effective fight against poverty must start with trade structures and participation rights.

19. Consequently the Assembly recommends that Governments of member states when defining their policies on GMOs:

i. take into account four general principles:

a. *respecting freedom of choice for consumers and producers:* maintaining simple access to GMO-free foods is the central objective of GMO regulation. This implies that the viability of an agriculture without GMOs can be safeguarded in the long term. In contrast to other forms of traditional agriculture, regional organic farming cannot be safeguarded by threshold values above the limit of technical detection. In any case, consumers of organic products will not accept a tolerance of 0,9% GMOs;

b. *preserving sustainability in agriculture:* GMO-free agriculture should be guaranteed in law without ruling out the cultivation of GMO crops and the confined release of GMO for scientific purposes. Organic farming in particular deserves protection because it is the best form of agriculture in terms of ecological sustainability as mentioned in the Assembly's Recommendation 1636 (2003) on the development of organic farming;

*c. precaution:* given large gaps in scientific knowledge, both in the field of molecular genetics and with regard to ecological consequences, irreversible manipulation of nature and creeping contamination with transgenes should be avoided and the environmental precautionary principle recognised at all times;

d. *objectivity of the scientific debate and public participation :* it is in the interests of all concerned that a sound scientific base will be constructed at various levels of safety research, to make it possible for standards and regulations to be redirected, eased or tightened under agreed procedures. Only on the basis of broad social discussion can clear political decisions be taken. Research should also be more open to this debate. A debate involving the whole of society should focus not only on the risk aspects of green genetic engineering but also on the question whether or not social models, objectives and practical expectations justify the move into green biotechnology on a larger scale;

ii. bring safety standards relating to the use of GMOs into line with EU legislation as a minimum standard;

iii. additionally take precautions in view of:

a. *labelling of GMOs:* the labelling of animal products following the use of genetically modified feedstuffs should be a mandatory requirement. A consistent conception of process labelling ought to be strived for;

b. *labelling of seeds:* following the precautionary principle, compulsory labelling of the seed at the limit of technical detection (0,1%) is the most effective means of checking environmental consequences and securing conformity with threshold values for labelling purposes;

c. *liability regime:* clear regulations on the questions of liability, together with clear decisions on who is to bear the additional costs incurred in making co-existence possible. These rules should obey the causal agent principle;

d. *good agricultural practice:* regulation of good agricultural practice in terms of production and use of GMOs (minimum distances, public register, etc.);

e. *GMO-free zones:* GMO-free reference areas should be established to fix natural baselines. Regional agreements for GMO-free zones should be possible to safeguard co-existence and ecologically sensitive areas;

iv. take the following steps in view of the fact that the commercial introduction of transgenic domestic animals is imminent:

a. *risk investigations:* thorough risk investigation in a number of areas (human health, animal health, ecological effects) is urgent. The use of genetically modified micro-organisms in livestock farming should consider the animal and his life cycle as a whole;

b. *secure fencing systems:* under no circumstances should genetically modified livestock be kept in open herds. In order to restrict the risks to the surrounding ecosystem arising from transgenic fish, these should not be kept in cage systems in the open sea;

c. *pharmaceutical products:* transgenic plants and animals supplying pharmaceutical products should be kept only in closed systems. A distinction must be drawn between health-promoting and therapeutic effects.

20. The Assembly recommends that Parliaments of member states and the European Parliament look after the proposed principles and measures being taken into account in their

respective legislations.

21. The Parliamentary Assembly recalls its Recommendation 1425 (1999) on Biotechnology and intellectual property and the request that farmers may use their own harvest for reseeding in order to reduce the dependency on seed producers increasingly dominating the market.

## II. Explanatory memorandum by Mr Wodarg

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### 1. General considerations

1. The use of genetic engineering in agriculture and food processing has shown a constant increase world-wide since the first hectare of genetically modified plants were

cultivated for commercial use in the USA in 1996. However, this use is concentrated in the four main grower countries, USA, Canada, Argentina and China, and is opposed by a large number of countries particularly in the European Union (EU), who consider strict regulation of GMO to be essential. The moratorium on cultivation and marketing imposed in the EU in 1998 was based on the absence of comprehensive genetic engineering legislation and was widely copied, primarily due to a fear of shrinking marketing opportunities but also for reasons based on precautionary principles.[1]

2. Since the existing legislation on genetic engineering in the EU was revised and supplemented in 2003 (for details see paragraph 40), the moratorium is to lapse and cultivation of commercially used GMO, on a scale that is currently impossible to assess, is to become possible. A further, possibly more basic consequence would be the opening of the European market to genetically modified products from all over the world, or even the closure of market access, because the developing countries are unable to follow the complex and costly tightening of regulations by the EU with regard to GMO.

3. Indirectly, agricultural subsidies in the northern countries are also subsidising gene technology, since the artificially high price of produce leads to a high degree of intensification of production, with which the poorer countries cannot compete. The consequences of protectionism, price guarantees, support buying, tolls and subsidies that distort trade, all on the part of the industrialised countries and the openness of food systems in the South affect primarily the small growers.[2] Their national governments often also direct their agricultural policies toward export, at the cost of supplying their own population. Insufficiently close attention is often paid to the concerns of the developing countries in the debate on green gene technology. Technical solutions for socio-economic problems are usually ‘end-of-the-pipeline’ solutions: they do not address the causes of poverty and malnutrition, but bring with them new problems and risks.

4. The establishment of bio- and gene technology goes hand in hand with an unprecedented assault on the world’s biological resources. These are largely found in the developing countries, but are generally patented and commercialised by large concerns from the North. Although gene technology in the North-South relationship is embedded in a constantly evolving international system of regulations (Convention on biological diversity, Biosafety protocol, Codex Alimentarius), in fact the World Trade Organisation (WTO) agreements are effectively more powerful, as the USA respects them and uses them as a means of furthering its own interests.

5. Since 2003 the EU, which has reached no united stand on GMO policy, is also under pressure from a complaint by the US to the WTO. In the view of the USA, the EU requirement for the compulsory labelling and traceability of GMO is a barrier to trade. The European Commission hopes to be able to scale down the threatened all-out trade war by rapidly lifting the moratorium.[3] The potential for conflict within the EU with regard to GMO is to be pacified by a compromise on the coexistence of various forms of cultivation, though the European Commission has so far formulated only voluntary guidelines on this subject. Whether coexistence is possible in the long term will depend on which priorities the individual EU member states establish in their national legislation (promotion of the new technology versus the protection of GMO-free forms of agriculture) and whether these can be harmonised.

6. There is a perceived risk that in the absence of effective controls a gradual introduction of GMOs will take place via the Central and Eastern European countries. A

greater risk of contamination possibly exists, however, in the area of feedstuffs if in the absence of compulsory labelling for animal products no separate market segment remains for GMO-free feedstuffs.[4]

7. There are good reasons for regarding the green biotechnology controversy that has gone on for many years now as a kind of “proxy dispute” over a fundamental approach to the future.[5] In the area of risk assessment, this is quite obvious: short term health risks have been researched relatively thoroughly, albeit with methods and test procedures that are doubtless no longer adequate in scientific terms, particularly with regard to organisms that have undergone multiple changes in their genetic makeup (substantial equivalence); long term ecological risks, on the other hand, have hardly been researched at all and are totally unpredictable under the conditions of large-scale cultivation of GMOs, particularly in view of the predominantly small areas of agricultural production in the European Union. The highly complex scientific questions raised by the new technology are thus also on a time continuum.

8. This is the core element of the conflict: policy decisions in the past have been made predominantly with a view to achieving short term goals and on the basis of existing structures. The objective was to increase and safeguard prosperity for everyone, and this took place in the expectation that the potential for economic growth would be unlimited. The Utopian dream, that there would always be “more and more for everyone”, could be achieved only by consuming environmental capital that was seen as replaceable by human efforts and for this reason was written off in the cost-benefit analysis as a negligible factor. Several decades ago scientists began to point out the limits of this kind of growth and since then the field of environmental protection has assumed increasing importance.

9. At present, with the concept of sustainability we are dealing intensively with a new and much more complex ideal: the idea of “more for everyone” being replaced by principles that postulate not only “enough for everyone now” but also “enough for people in the future” as well.[6] The discussion on sustainable development is also an attempt at social self-determination by means of appropriate environmentally tolerable, socially just and economically sound development. The idea and the objectives arising from it are relatively uncontroversial. This is not the case, however, with regard to the steps that need to be taken and the decisions that have to be made in order to move us closer to sustainable environmental, economic and social policies. [7]

10. In many ways, the ideal of sustainable development is in competition with current trends in international economic development. The sustainability objectives and strategies that are derived from them (efficiency, sufficiency, consistency and resilience)[8] are, to put it mildly, not entirely compatible with the liberalisation of world trade and the economically driven process of globalisation. We lack clear criteria supported by a majority of the population, something that would give us clear indicators that would make developmental trends controllable and, in specific instances, would also make it possible for us to take decisions for or against, say, the introduction of a new technology. Green biotechnology is the ultimate controversy, confronting us with difficult decisions between the questionable but familiar values of yesterday and the as yet still unclear and unfamiliar values of tomorrow.

11. The numerous controversies that accompany the use of green technology[9] can be resolved only in part through further research and the acquisition of empirical factual knowledge. Differences of opinion at the level of political beliefs, personal values, policy

decisions taken, and legislation passed are more important, given that these values are usually an implicit element in the debates conducted on specific issues. For this reason, in this report, specific issues will be embedded in the more general question as to a coherent and generally acceptable sustainability strategy. The explanatory memorandum is divided into four parts, headed by the following simple questions: 1. What do we know? 2. What do we not know? 3. What should we be arguing about? 4. What will move us forward?

12. This is an attempt to clarify what constitutes a matter of knowledge that can be determined empirically and what is a question of arguable value judgements. These are different kinds of knowledge and separating the levels is an important step in the rational solution of controversy. This is not a matter of presenting a complete plan or of offering a further compendium of matters of fact – a wealth of factual information on green biotechnology is readily available.[10] The intention here is to define the levels of the discussion clearly and therefore to make a contribution to further discussion on the subject. The additional comments in the last section on the subject of research, estimation of technical consequences and social visions make a link with the debate on sustainability.

## 2. What do we know?

13. The concept of genetic engineering or biotechnology covers all processes in which extracellular hereditary information prepared under artificial conditions (nucleic acids, unmodified or recombined) is introduced into organisms either directly (by microinjection or microprojectile bombardment) or via vectors (viruses, bacterial plasmids). Analytical methods based on the isolation and characterisation of parts of the genotype also form part of genetic engineering. These include, for example, the characterisation of particular genotypes using a genetic "fingerprint", a process that has become very important, for example, in conventional breeding as marker-based selection, or diagnostic procedures based on enzymic replication of certain sequences (PCR). However, these processes do not involve either recombination of isolated nucleic acids; nor are genetically modified organisms created.[11] While detection techniques at DNA level are now established and accepted in many areas, the production and use of genetically modified organisms in Europe is a matter of controversy. The concepts of biotechnology and gene technology should not be used synonymously. Critics of the gene transfer method do not necessarily reject biotechnology, which involves numerous methods below the threshold of gene transfer, the use of which is unproblematic.

14. The science of genetic inheritance underwent massive development during the 20th century and, after the identification of DNA as the genetic substance (1944), clarification of its structure (1953), determination of the genetic code (at the beginning of the 60s) and the first genetic experiments in bacteria (1973), became what we now know as molecular genetics. Since around 1980 the genetic modification of plants has also become possible. The two basic methods (introduction of genetic material via the soil bacterium Agrobacterium tumefaciens and use of the "gene cannon") also require the use of selection marker genes in order to identify the successfully manipulated cells. Antibiotic resistance genes were often used as selection markers but for some time now this practice has been criticised in view of the implications for human health and is to be phased out in Europe.[12]

15. The new technology is regarded by its advocates as an extension to the repertoire of methods used in conventional breeding. The possibility of transferring any chosen DNA sequence to plants, however, represents a fundamental departure from traditional plant

breeding techniques. The introduction of genetic engineering has not only brought an extension of the gene pool (just as a combination and hybridisation did before in conventional breeding), but has also removed all the biological limitations on the exchange of genetic information. This becomes clear in the case of the more recent research projects (2nd and 3rd generation GMO: manufacture of vaccines, drugs, polymers) compared with the products of the 1st generation GMO, which affected mainly agronomic characteristics.

### *2.1 Transgenic domestic animals and genetically modified micro-organisms*

16. Experiments with transgenic domestic animals have been under way for many decades, particularly for the production of animal models in the pharmaceutical industry, details of which cannot be dealt with here.[13] The first experimental animals for agricultural purposes were sheep, pigs and rabbits. In the meantime cattle, goats and chicken and a total of 35 different species of fish have been investigated.[14]

17. The objectives in the creation of transgenic domestic animals are the same in principle as those of conventional breeding and come under 6 headings:

a. the primary objective is *to increase productivity,*which has so far been successful particularly in fish.[15] For pigs, there have been reports of quick-growing animals that produce low fat meat and in sheep there are attempts to increase wool production.[16]

b. in the *modification of certain characteristics of agricultural products*(meat, milk, eggs, wool) transgenic modifications aimed at the production of pharmaceutical substances are dominant (e.g. the iron-binding protein lactoferrin that is present in human breast milk and protects infants from gastrointestinal infections).[17] The objective of producing cow's milk that is better tolerated by humans, with a lower lactose content, has so far succeeded only in experiments with mice.[18] With sheep's wool the attempted modification of fibre characteristics has proved very difficult. Research is being carried out into the modification of fish meat characteristics such as colour, fat and protein content and also flavour.[19]

c. to *reduce susceptibility to disease* (a high-priority goal since disease in domestic animals, particularly in intensive rearing, represents a high cost factor). Various different approaches are possible: strengthening of the immune system, insertion of resistance genes, immunisation and destruction of genes that cause disease.[20] There are actually few experiments underway at present.[21]

d. for *improvement of nutrient uptake,* research is under way in pigs to enable them to form an enzyme for absorption of the vital mineral phosphorous.[22] This would allow supplementary feeding of phosphorous in pig rearing to be reduced and, as a positive side effect, smaller quantities of phosphorous would be spread on agricultural land in the form of fertiliser from pig excrement. This would help to alleviate the particular problem of water pollution due to excess fertilisation with phosphorous.

e. since each animal species and strain of domestic animal is adapted by evolution or breeding to certain environmental conditions, limitations exist with regard to the areas in which they can be reared successfully. *Adaptation to particularly environmental conditions*takes place with regard to the cold tolerance of salmon in Canada, for example, where salmon farms have so far only been a possibility in the southern coastal areas.[23] With the introduction of genes from the American winter flounder that code for frost protection it is hoped that these limitation will be abolished. To date, formation of a precursor of innate frost protection has been achieved in the transgenic salmon.

f. in the Netherlands, the USA and Japan, a number of groups are working on the development of transgenic fish (particularly zebrafish), for use in *detecting environmental contaminants*in water. The idea is to enable the animals, by gene transfer, to form detectable substances in the presence of the contaminants (heavy metals, aromatic hydrocarbons, dioxins or other mutagenic substances). Alternatively, there are studies that are inserting genes that mutate in the presence of contaminants.[24] The development of means to *combat invasive species*(species generally introduced deliberately or accidentally by humans into certain areas) is a further goal of genetic modification, since this is a major source of damage to ecosystems and can drive out previously native species. Model studies are currently under way with zebrafish.[25]

18. Each species has its own specific system of reproduction, so that species-specific techniques are required in each case and the already advanced experiments carried out in mice are generally not transferable directly. The fewest complications are currently being seen in the development of transgenic fish, compared with other vertebrates. However, the risk that transgenic fish may escape into the environment is particularly high, because aquaculture is generally set up in the sea alongside the coast rather than on land, for reasons of cost.[26]

19. The most commonly used method of gene transfer to date is the microinjection method, in which segments of DNA prepared in the laboratory are injected into the fertilised egg cell using a fine microneedle. The precise location at which the injected fragment of DNA enters the genome of the fertilised egg cell cannot be predicted.[27] The transformed fertilised egg cells are then kept in culture and later implanted in surrogate mother animals as embryos. In order to improve the very low success rate for this technique, the use of cloning has been considered as an additional technique for the production of transgenic animals, although here again the success rate is very low.[28] Another fully developed and frequently used cloning technique, by which only a limited number of identical clones can be produced, is “embryo splitting” in which embryos several days old are divided.

20. Only 0.5 to 4 percent of embryos transferred into the surrogate mother are born live and are actually transgenic.[29] The success rate varies depending on the experimental method used and the species selected. A major proportion of live born transgenic animals do not reach the average age. Pathological modifications to the internal organs are often the reason for their short life. In addition, in some cases transgenic animals do not transfer their foreign genes to the subsequent generation. Further breeding is problematic even if the genes are passed on successfully, since the random division of the maternal and paternal genes in sexual reproduction can result in the loss of certain characteristics and the development of new ones. Animal consumption and the input in time and money are therefore extremely high overall in the production of transgenic animals.

21. In agriculture, genetically modified micro-organisms (GMMs) can be used both in the plant sector (biopesticides, promotion of plant growth) and also in the animal sector (higher yields). Here there are mainly ecological risks associated with release that may rule out comparable medical applications if enzymes are produced in the fermenter and used as feed additives (contained use).In medicine, in the processing of foods and the manufacture of washing products, enzymes obtained from GMMs have long played a major role;

intensive research is currently being carried out in virus-resistant bacteria cultures for sour milk and yoghurt products, since over 80% of production losses in the milk processing industry are caused by viruses that attack and kill lactic acid bacteria.

22. In the animal sphere, research in micro-organisms is concentrating on the microflora of the digestive tract of ruminants.[30] The ruminal microflora that, after genetic modification, lead to better utilisation of the feed (particularly fibre) or modified protein metabolism or modified amino acid composition are of particular interest and secondly animals are to be enabled to digest otherwise toxic plants.[31] To achieve improved feedstuff utilisation, there are studies to modify the ruminal flora itself. This has not yet been well researched; there are also experiments to equip better known organisms such as yeast, which is already used as a feedstuff additive, with the desired characteristics. To prevent the release of GMMs, the enzymes required could be produced in a fermenter and used directly as a feedstuff additive.

23. Scientists at the British Rowett Institute have recently discovered soil bacteria that break methane down into hydrogen and carbon dioxide, and are to administer this to cows with their feed, to reduce methane output (greenhouse effect). Scientists expect a 20% reduction in methane output.[32]

24. In the plant sector, GMMs are to be used firstly as “environmentally friendly” biopesticides (against insects and fungal infection, plant diseases) and secondly as growth promoters (e.g. binding of nitrogen by nodule bacteria). To protect against fungal attack or pathogens, various micro-organisms have been used which mostly achieve their effect by excreting certain antibiotics. The protective mechanisms are often not understood, since they rely on a complicated interaction between the micro-organisms e.g. in the root area of the plant. Micro-organisms as biopesticides do not have to be genetically modified.

25. Just recently an attempt was made to genetically “improve” existing biopesticides such as *Bacillus thuringiensis*.[33] The development of highly potent Bt strains must also be regarded with scepticism, because precisely the characteristics that have enabled the Bt preparations to be authorised as insecticides in organic farming and have prevented the development of resistance (high specificity, rapid breakdown), are now being modified.

26. Soil micro-organisms, such as the nitrogen-forming nodule bacteria on the roots of legumes (e.g. soya, beans, clover) also frequently promote plant growth. These improve the nutrient supply and protect the plant from environmental influences such as frost. The bacteria *Rhizobium*, *Bradyrhizobium* and *Frankia* in particular have been subject to genetic processing to increase their nitrogen binding capability or to enable them also to colonise plants that form no nodules in their roots.

### *2.2 Transgene plants and co-existence*

27. For about 1000 years human beings have used a process of selection and cross-breeding to produce new forms of particular plant species that have been improved for agricultural purposes and that vary considerably from their original characteristics. This expansion in the variety of forms was possible because of the high variability and flexibility of the plant genome (recombination, chromosome shifts, mutations, "jumping" genes) and the not infrequent occurrence in plants of the mixing and combination of different genomes by natural hybridisation across the species and genera. In the last century the basis for the selection of new forms and characteristics was increased further by chemicals or radiation

that produced mutations and by means of deliberate cross-breeding of species by breeders.

28. Whereas in the industrialised countries modern plant breeding following the green revolution has displaced more than 75% of the robust traditional varieties and replaced them with the new high-yield varieties, the old varieties still play an important part in the developing countries. Seed companies try to sell the highly bred seed to small farmers with the promise of greater yields. The package includes agrochemicals, which in traditional agriculture were not required. The seed is genetically modified to an increasing degree, and the suppliers are no longer small local seed companies but multinational pharmaceutical concerns which are buying up more and more seed producers.[34]

29. Applied breeding research up to the mid-90s directed its attention mainly to the introduction of mostly bacterial genes to mediate characteristics such as resistance to insects or non-selective herbicides, and to the transfer of envelope proteins to create virus resistances. After the first experimental releases in 1987, the first transgenic varieties were marketed in the mid-90s. The first genetically modified plants were sown in the USA in 1996. Now there are a total of about 60-70 genetically modified varieties that have been approved for cultivation in various OECD countries. Areas of cultivation increase steadily each year (from 1.7 million hectares in 1996 to about 68 million hectares in 2003) – though it should be borne in mind that almost 99% of these areas are to be found in the USA, Argentina, Canada and China.

30. The commercial exploitation of green biotechnology is concentrated mainly on four plant species: soya, maize, rape and cotton. The proportion of GM plants is highest for soya, at 51% of world production. In the EU, GM plants have not been grown commercially, except in Spain (Bt maize 20,000 – 25,000 hectares) but only in small quantities for test purposes.

31. With respect to future generations of GMO, there are far-reaching reports that consumers will benefit directly. Basically, a distinction is drawn in the case of plants between input characteristics (characteristics affecting cultivation and yield; agronomic characteristics important to breeders and growers) and output characteristics (quality of the end product: elimination of undesirable constituents, addition of nutritionally desirable substances, improvement in processing characteristics; molecular farming as a special case), that are of importance to the consumer or the food production industry. On the basis of release studies reported throughout the world, recent studies show that GMO with input characteristics will remain dominant in the next 5-7 years, while release studies with GMO that have modified output characteristics have decreased by contrast for several years, both in the USA and in the EU.[35]

32. The plants already grown commercially possess almost exclusively input characteristics (in particular herbicide and insect resistance) and have been developed by the large companies that control the process, of which there are now few.[36] Since the beginning of the 90s, transgenic plants with output characteristics have been tested in the open air, representing around one fifth of all releases carried out in the USA and the EU. Three transgenic plants with output characteristics have so far received cultivation authorisation world-wide: tomatoes with a longer shelf life; rape that forms lauric acid; and soya that forms more oleic acid than usual. None of these three plants has yet been cultivated commercially. The development of output characteristics has largely been unsuccessful to date.[37]

33. The widely publicised genetically modified rice by Syngenta, which produces beta-carotene (precursor of vitamin A), should help to prevent blindness and infection in millions of children suffering from vitamin A deficiency, according to promises from the industry. A Greenpeace report reveals that a two year old child would have to eat seven kilos of golden rice a day to reach the recommended daily dose and an adult would require nine kilos. One reason for the delay in market readiness could be that no published study yet confirms that the human body is capable of converting the beta-carotene from golden rice to vitamin A. Also, other nutrients such as fat and proteins are needed to allow the body to absorb vitamin A and undernourished children also often lack these other substances.[38]

34. In the next five years, transgenic plants with input characteristics will continue to dominate the marketing process. The range of plant species already on the market will be extended by the following new varieties: banana, pea, peanuts, mangels, barley, cucumber, cabbage, lettuce; alfalfa, pepper, sunflower and wheat. The input characteristics they will show are resistance to insects, herbicides, viruses and fungi as well as increased yield. As far as output characteristics are concerned, the following may reach the market in the next five years: increased shelf life, improved digestibility, modified fatty acids, modified starch and protein metabolism, reduced mycotoxin content, more efficient ethanol production and modified secondary metabolism. The effort of developing such products is small compared with the funds invested in input characteristics. For the few products with qualitatively modified characteristics that will enter the market it is mainly the industrial processors of foods and feedstuffs who will profit.

*Excursus: molecular gene farming*

35. The plan to use gene technology to produce pharmaceutically active substances cheaply and in sufficient quantities has been approached in a variety of ways for some considerable time. Research has shown that it is possible to produce complex non-vegetable proteins that are biologically active in GM plants (molecular farming). These proteins can form the basis for vaccines, antibodies and therapeutically useful proteins. The production of enzymes, new polymers and industrial materials is also possible.[39]

36. Many proteins produced in our bodies can be used therapeutically in medicine (e.g. insulin in diabetes; growth hormones in growth disorders). In the past these proteins were obtained from cadavers or animal cells. This process was expensive, provided limited quantities and involved risks, since the proteins were often contaminated with viruses or other pathogens. For this reason, recombinant human proteins are now produced in genetically modified cells. The human genes are transferred into these cells and produce the corresponding protein. Many pharmaceutically useful proteins and industrially exploitable enzymes are produced using genetically modified micro-organisms and cultured mammalian cells, but these systems in themselves have two main disadvantages: firstly, the proteins produced in the micro-organisms are often not identical with their human counterparts, because the cells do not have the ability to synthesise all components correctly. Secondly, it is very expensive to culture mammalian cells and they may still contain pathogens. Therefore there is a great shortage of production capacity throughout the world and expensive production and purification methods are needed to ensure that the end product is pathogen-free.

37. Since plants are capable of producing many authentic recombinant substances and agriculture represents a cheap way of providing for some of these substances in unlimited quantities, science is pinning great hopes on this production method.[40] European

scientists now want cheaper methods of producing drugs to combat AIDS, rabies, diabetes and tuberculosis in genetically modified plants. In the next five years genetically modified maize and tobacco plants are expected to be tested in South Africa in the open air or in greenhouses. The Frauenhofer-Institut in Aachen is coordinating the project, involving a total of 39 partners in eleven European countries and South Africa, which the EU is sponsoring to the tune of 12 million euros from the sixth basic research programme. The project involves provision of the necessary genes, the breeding of plants and their cultivation, up to extraction of the substances and their testing in clinical trials. This may well take more than five years, but the scientists hope that the combination of red and green gene technology will improve the acceptance of green gene technology in Europe as a whole because people will realise the direct benefits. According to press reports, all project partners have committed to making available all useful findings including possible patents from the project to the developing countries free of charge. In industrialised countries a strict licensing policy will maximise the commercial benefits of the project.[41] Many questions remain to be answered, however, regarding both economic aspects and applications on the one hand and the ecological and health effects on the other.

38. Certainly since the conclusion of the Human Genome Project, genes have been seen as functional units: DNA sequences are information carriers but do not allow conclusions to be drawn with regard to the cause of individual functions. In plants, additional effects occur that suggest a highly complex interaction between genes and other regulatory processes within the cell, depending on growth and environmental influences. It can no longer be assumed that genes alone determine which proteins will be produced. We talk about epigenesis, i.e. genes never work in isolation; their effect is also determined by the genetic background and the environment.

39. The concept of substantial equivalence (see paragraph 53, 72, 73), which was subject to much criticism in the case of first generation transgenic plants, cannot be used to assess transgenic plants with output characteristics. Since the objective of genetic modification in these plants is their specific novelty, far reaching innovations with regard to method are required for testing and authorisation.[42] Unlike other technologies or substances introduced into the agricultural and food economy, GMOs have the characteristic that they can replicate and exchange genetic information with other cultivated and wild plants. As with any technology it must be assumed that risk assessments are subject to error and may be overtaken by subsequent scientific findings. The essential point in the context of risk assessment is therefore the question of reversibility of the marketing and release of GMOs. Essential factors on the user side are: seed management, agricultural practice, liability regulations.

40. Whereas marketing authorisation, release and requirements with regard to labelling and traceability of GMOs are subject to uniform and mandatory regulation throughout the EU, the cultivation of transgenic plants and co-existence with other types of crop are to be regulated initially within the individual member states and harmonised according to guidelines.[43]

41. Co-existence relates to the development of seed and its replication, cultivation and agricultural practice in all its aspects, including environmental protection, transport, cooperative processing storage, processing and distribution of foods and feedstuffs at their various stages down to the end user and the export and import of agricultural products and foods. At all stages of food and raw material production, the separation of GMO and non-GMO will be important and lead to changes in operating and marketing conditions. Only if this overall context is taken into account will regulations have validity and permanence in

practice.

42. Seed is at the beginning of the production chain and, depending on variety, multiplies by a factor of 40 to 1000 and can sometimes remain in the soil for a long period. GMOs in seed fertilise neighbouring crops via foreign pollinators and related species in the wild, where these grow nearby. Seed and pollen can therefore be transported over long distances.[44] The contamination of traditional varieties and related wild plants with GMO (vertical gene transfer) has been seen in many regions of the world. A particularly striking case is that of Mexico: in spite of a prohibition since 1998 on the cultivation of genetically modified maize, GMO contamination has been seen even in remote areas. The cause is suspected to be the undeclared importation of GM maize from the USA.[45]

43. The environmental risks that demonstrably can occur as a result of the release of GMO are: vertical gene transfer, migration into the wild of transgenic plants, damage to useful animals, resistance development in insects, creation of new plant viral pathogens from the effects of combination with virus-resistant crops, damage to micro-organisms in the soil from e.g. Bt toxin.[46] The expected positive environmental effects such as reduction of pesticides, however, are questionable.[47] In the bee gut it was found that antibiotic resistance genes from rape (incorporated in these plants as marker genes) had entered the DNA of gut micro-organisms by horizontal gene transfer, which promotes the development of antibiotic resistance in the environment. Horizontal gene transfer is the transfer of transgenes across species.[48]

### *2.3 Central and Eastern Europe*

44. Within the EU, consumer-friendly and cautious attitudes have tended to become established in the sphere of agrogene technology. All the new Eastern European EU member states acceding in 2004 (Hungary, Poland, Czech Republic, Slovakia, Slovenia, Lithuania, Latvia, Estonia) have introduced legislation on gene technology in recent years, to comply with the EU standard. The main problem here is monitoring of adherence to the law, since the necessary capacity is still by no means in place. Spot checks on products sold on the market in these new member states, carried out by consumer groups and environmental protection organisations show that the labelling requirement is not being met.[49]

45. The extent to which genetically modified foods, feedstuffs or seeds are circulating in the markets of the new member states is largely unknown. Only Hungary and the Czech Republic so far have certified laboratories that allow genetically modified organisms or their constituents to be detected. Even here, regular checks are not being performed. Provision of information to the public and its involvement in the decision-making processes concerning the release of GMO is also deficient at present in the new accession countries. Public debate on the benefits and risks of transgenic organisms is taking place only to a very limited extent.[50]

46. Bulgaria and Romania, which are expected to join the EU in 2007, show major policy divergences from the EU policy on gene technology. Bulgaria still has no comprehensive law on gene technology, although it was the first state to sign the Biosafety Protocol. Transgenic plants have been grown commercially for a number of years, some of which are not approved for cultivation or marketing in the EU.

47. In June 2004 new labelling regulations came into force in Russia. The percentage

GMO content above which the food product concerned must be labelled as genetically modified was reduced from the previous 5% to 0.9%. Though this does provide similarly strict labelling requirements to those pertaining in the EU, few manufacturers actually observed even the old regulations, due to lack of knowledge and controls. The first national laboratory came into operation this year. According to unofficial information, 30% of foods sold in Moscow contained GMO, though the figure could be considerably higher. The commercial cultivation of GMO is not yet permitted in Russia. Six genetically modified varieties of maize have been authorised for use, two transgenic varieties of potato, one of sugar beet and one of rice.[51]

48. In the autumn of 2000 the US Senate approved the allocation of 30 million US $ to the promotion of US agro-biotechnology in the countries of central and Eastern Europe. Various environmental organisations in Eastern Europe and the former Soviet Union (NIS) have accused the USA and the internationally active seed companies of exploiting the often inadequate and ineffective legislation which in these countries usually goes hand in hand with weak democratic structures and limited public awareness, in order to establish their products.[52]

49. Slovakia and also Slovenia are countries with high biological diversity and formulate their policies on this basis with a focus on eco-tourism and ecological agriculture. Both countries incorporated the EU release regulations into their national legislation at a very early stage. Slovenia wished to establish itself as a GMO-free zone, but state-designated GMO-free zones are forbidden by EU law. Rapidly regions have joined together on a voluntary basis and committed themselves to GMO-free production.[53]

## 3. What do we not know?

50. Scientists who are critical of gene transfer methods consider that there are major differences between natural DNA (and mutations in conventional breeding selection) and transgenic constructs introduced by artificial methods into the genome of organisms.[54] They consider these differences to be significant with regard to safety and see more recent research findings as worrying. In the view of the critical scientists, numerous findings indicate that the commonest methods of gene transfer in plants, in which soil bacteria are used as vectors, “may also serve as a ready route for horizontal gene transfer”. While this is a still unproven hypothesis, neither has it been convincingly disproved which, in view of the huge potential risk of horizontal gene transfer, is what is needed.[55] On the other hand, the currently accepted hypothesis of ‘substantial equivalence’ also remains unproven. Since early assumptions of this kind impact directly on the nature of safety research, the critical position and the research requirements arising from it will be quoted in abbreviated form in the following paragraphs. The very detailed discussion of the literature that was incorporated in the original paper cannot be included here.

*51. GM crops are neither needed nor wanted; they failed to deliver their promises, and instead, are posing escalating problems on the farm. There is no realistic possibility for GM and non-GM agriculture to coexist, as evident from the level and extent of transgenic contamination that has already occurred, even in a country like Mexico where an official moratorium has been in place since 1998. GM crops are unacceptable because they are by no means safe. They have been introduced without the necessary safeguards and safety assessments through a deeply flawed regulatory system based on a principle of ‘substantial equivalence’ that is aimed at expediting product approval rather than serious safety assessment. Despite the lack of data on safety tests of GM foods, the available findings* *already give cause for concerns over the safety of the transgenic process itself that are not being addressed.*

*At the same time, gene products introduced into food and other crops as biopesticides, accounting for 25 % of all GM crops world wide, are now found to be strong immunogens and allergens, and dangerous pharmaceuticals and vaccines are being introduced into food crops in open field trials. Under the guise of transgene containment, crops have been engineered with "suicide genes" that make plants male sterile. In reality, these crops spread both herbicide tolerance genes and male sterile suicide genes via pollen, with potentially devastating consequences on agricultural and natural biodiversity. About 75% of all GM crops planted worldwide are tolerant to one or two broad-spectrum herbicides, glufosinate ammonium and glyphosate. Both are systemic metabolic poisons expected to have a wide range of harmful effects on humans and other living organisms and these effects have now been confirmed.*[56]

*By far the most insidious dangers of genetic engineering are inherent to the process itself, which greatly enhances the scope and probability of horizontal gene transfer and recombination, the main route to creating viruses and bacteria that cause disease epidemics. New techniques such as DNA shuffling are allowing geneticists to create in a matter of minutes in the laboratory millions of recombinant viruses that have never existed. Disease-causing viruses and bacteria and their genetic material are the predominant materials and tools of genetic engineering, as much as for the intentional creation of bio-weapons. There is already experimental evidence that transgenic DNA from plants has been taken up by bacteria in the soil and in the gut of human volunteers. Antibiotic resistance marker genes can spread from transgenic food to pathogenic bacteria, making infections very difficult to treat. Transgenic DNA is known to survive digestion in the gut and to jump into the genomes of mammalian cells, raising the problem of triggering cancer. Evidence suggests that transgenic constructs with the CaMV 35S promoter, present in most GM crops, might be especially unstable and prone to horizontal gene transfer and recombination, with all the attendant hazards: gene mutations due to random insertion, cancer, reactivation of dormant viruses and generation of new viruses.*

*There has been a history of misinterpretation and suppression of scientific evidence especially on horizontal gene transfer. Key experiments failed to be performed, or were performed badly and then misrepresented. Many experiments failed to be followed up, including investigations on whether the CaMV promoter is responsible for the 'growth-factor-like' effects observed in young rats fed GM potatoes.*

52. The thorough feeding trials in rats conducted in 1998 by the food geneticist Prof. Arpad Pusztai showed that the rats developed modified organ weights, growth disorders and irritation of the immune system. The animals were fed with three different type of potato: transgenic potatoes into which a snowdrop gene had been inserted (to produce the protein lectin which is non-toxic to humans as an insecticide), conventional potatoes to which the same quantity of lectin had been added as that produced by the transgenic potatoes, and conventional potatoes with no additive. Only the GM potatoes led to the effects described. Pusztai with his unpleasant findings became the victim of an incredible campaign, was dismissed and was not permitted to continue his experiments.[57] He now works as an expert assessor for the EU authorities and is at present assessing a current feeding study by Monsanto (BT maize MON 863) for, amongst others, the Bundesinstitut für Naturschutz (German Institute for the Protection of Nature).[58]

53. The assessment of safety to health is based on the concept of substantial equivalence. According to this, a "novel food"[59] is regarded as being as safe as a comparable product produced in the traditional way if it does not differ substantially from this with regard to composition of the contents and other characteristics. Safety investigations are to be conducted by the manufacturer. This concept in itself does not provide a safety assessment, but only represents a comparison with conventional foods and leads to an elevated impression of the safety of genetically produced foods. These are investigated for their phenotypic characteristics, main nutrients (proteins, carbohydrates, fats, vitamins, minerals) and their physiological nutritional characteristics. Independent investigations and studies often cannot be conducted on an adequate scale in view of the industry-dependent science alone for cost reasons, and with the decreasing proportion of state-financed research are limited with regard to scope and precision.

54. There are so far no clear tests for new allergens and there is still no information on the allergenic effects of GM foods. Allergies take years to develop. Only by means of clinical studies in which humans ingest GM foods in short and long term tests could a reliable evaluation of allergenicity be undertaken. There are as yet no adequate, effective animal models or sufficiently sensitive and specific methods by which the unwanted effects of GMO could be determined. Long term studies are not available. Consequences for health cannot therefore be assessed finally because the instruments for their discovery are not available.[60] For the ecological consequences, it is the same story. Here again there are no baseline data which could form the basis for thorough concomitant research and no binding methods or standards.

### *3.1 Transgenic domestic animals and genetically modified micro-organisms*

55. While research projects into the production of transgenic animals have received strong financial support in the last few decades both from industry and government, investigations into the possible risks of these genetic modifications to humans, the environment and domestic animals themselves have remained largely unexamined. Although the objective of research is now often commercial application, there is a large research deficit with regard to the possible risks.

56. The probable ecological effects vary greatly between the various groups of transgenic domestic animals. In principle, there is the risk with transgenic domestic animals that their foreign genes may pass into wild populations of their species or closely related species by mating. Cross-breeding with other herds of domestic animals is also a possibility. Risks must be estimated specifically for each species, region in which they are kept and rearing conditions.[61]

57. For genetically modified rabbits, the risk of cross breeding with wild populations, by contrast with other species of mammals, is very high in view of the difficulty of securing outdoor enclosures and the high reproduction potential.[62] In the case of chicken, mating with wild fowl species is possible depending on the region. In fish, serious ecological problems are already coming to light with non-transgenic stocks, because fish in aquaculture are generally kept in the direct vicinity of their wild relatives and outbreaks frequently occur from caged stocks kept in coastal areas of the open sea, due to weather damage and human failure.[63]

58. Released transgenic fish can be a serious danger, both for wild members of their own

species and also for other populations. Their wild relatives are particularly at risk from the migration of "Trojan genes" into their gene pool. These are genes or groups of genes that have positive effects on the success of mating but negative effects on survivability and can therefore lead to the extinction of entire populations. Populations of other fish species are at risk from possible selection advantages of the genetically modified competitors. A new characteristic, for example, seen in many "turbo-growth lines" is greatly increased food intake which can lead to displacement of native species of fish from their environment and in extreme cases extinction.[64] Various attempts to develop sterile fish lines have not yet been successful in the long term and cannot reliably exclude the ecological risks.[65]

59. Potential health risks to humans from transgenic domestic animals must be assessed individually depending on the transferred genes and species and may result either from consumption or from pathogens transferred to humans during the rearing process. Almost no studies have been carried out in humans on risks from consumption.**[66]** In principle, the risk of allergy should be investigated and also the danger that unexpected toxins may be produced or that modified composition of the fish could result in disadvantageous physiological effects in terms of nutrition.[67] The effect of transgenic modification may differ, not only in relation to the animal species but also in various lines of one species, because the location at which the gene construct is built into the animal's genome is variable.

60. Even without explicit risk research, numerous cases of most severe health damage have been observed in the domestic animals affected: in pigs there are reports of pathological changes to the stomach, heart and lungs, skin disease and reduced fertility.[68] The increased expression of growth hormones produces symptoms in rabbits of pathological growth similar to those seen in humans, and in sheep diabetes and impaired liver, kidney and heart function. In fish extreme deformations of the head and other parts of the body have occurred, as well as tumours, modified colouring, changes in the shape of fins and vertebrae, abnormal jaw growth, absence of body segments and stunted growth of the neck and tail.[69]

61. Most of the unforeseen side effects (pleiotropic effects) are mentioned in association with increased growth due to genetic engineering, which is the best investigated to date. Genetic modification can result in a change in the entire growth hormone balance and even an apparently slight morphological deviation can have far-reaching consequences, for example on oxygen uptake. Impaired swimming capability and feeding behaviour are reported as consequences affecting behavioural biology.

62. Genetic modifications in transgenic animals that affect the ruminal microflora have proved difficult, because gene expression is often insufficient and a number of genetically modified micro-organisms have to be used to reinforce the effect. The complex association of ruminal microflora has not yet been thoroughly researched and in the past it was primarily the antibiotic resistance genes being problematic with regard to human health that were successfully transferred. With the establishment of non-ruminal GMMs, the concentration decreased so strongly within a short period that permanent feed additives were necessary.[70] Whether these additional costs were compensated by increased yields is questionable.

63. For the release of GMMs, their long term survival chances, reproduction capability, competitivity and genetic stability as well as their ability to adapt must be taken into account. The characteristic pattern in studies to date is that after an initial decrease in cell

numbers these usually stabilise at a low level; depending on seasonal and other environmental influences, however, a clear increase is then observed.[71]

64. Moreover, it cannot be guaranteed that GMMs will remain at their release location (transport by wind, running water and rain, tractor tyres, harvesting equipment and animals and also by organisms living in the soil). Escape into ground water cannot be ruled out.[72] Even if GMMs do not survive in the environment, their characteristics can be transferred to other micro-organisms by DNA transfer via conjugation, transformation or transduction.[73]

65. GMMs as highly potent Bt strains or even in other primary applications such as, for example, crop sprays will inevitably come into contact with the soil. Therefore, before they are used, it is essential that the effects on soil microflora and the various interactions are accurately observed.[74] Since only a small proportion of the micro-organisms living in soil are known, reliable risk research would be extremely difficult to carry out. Since many biopesticides rely for their protective effect on the production of particular antibiotics by the micro-organisms, questions of resistance development must be taken into account.[75]

### *3.2 Transgene plants and co-existence*

66. In plants, as in domestic animals, genetic modifications cannot yet be controlled, i.e. the position of an inserted transgene within the recipient genome cannot be controlled. Each integration is bound to modify the sequence pattern at the genetic location concerned in the recipient genome, and genes in that location are under some circumstances destroyed. The possibility therefore cannot be ruled out that new, unintentional and possibly also harmful metabolic products or morphological deviations from the original line may be produced. Such unintended effects are not necessarily associated with the function of the inserted gene but may also be caused by genetic changes in other parts of the genome, occurring during the sometimes very long tissue culture phase.

67. Research has so far been carried out only on a fraction of the regulatory processes at genome, protein and metabolic levels and their interaction with biotic (insects, weeds, fungi) and abiotic (drought, salinification) environmental influences. The secondary metabolism of plants, in which sometimes highly toxic substances such as alkaloids, terpenes and phenolic substances are formed, is particularly complex and little understood.

68. Mandatory monitoring, known as post-marketing surveillance (post-registration monitoring or monitoring during cultivation), under the terms of the new version of EU Release Directive 90/220/EEC (new version: 2001/18/EC) is one of the requirements for release approval. If significant harmful effects are observed in the course of monitoring, which were either previously suspected but regarded as acceptable or which had not been foreseen, new cultivation conditions may be imposed or authorisation withdrawn completely.[76] Clear assessment standards are necessary, and also the designation of natural reference areas and the establishment of basic data.

*Excursus: molecular gene farming*

69. It is unclear whether the system for producing pharmaceutical substances in GM plants will prove to be successful economically – whether the amount of protein produced will be sufficiently high and can be extracted easily enough and/ or if intended for direct consumption, whether the product will be stable and uniformly expressed. There are also

questions about the efficacy of the product. For example, in the case of vaccines, will they produce a protective immune response? If the product is intended to be 'seed as pill', will it show a comparable effect when taken orally? Many proteins are at least partly destroyed in the intestine, which is why most protein-based drugs, such as insulin, have to be given by injection.[77]

70. There has been excessive hype about the potential for edible vaccines and other drugs. Clinical trials will be required in the same way as for any other therapeutic product and processing will almost certainly be necessary. The research is almost targeted at the needs of the developed world, and restrictive intellectual property rights mean that it will only be available at considerable cost. It will therefore be largely inaccessible to the developing world.

71. The impact on the environment and public safety if other food crops or wild species are contaminated raises further major questions. Is it wise to use food crops to produce therapeutic proteins at all? What measures are necessary to prevent gene transfer? The potential for inadvertent consumption of a drug in food could lead to very large liabilities for the companies involved. In the USA, new rules are being introduced to reduce the potential for cross pollination and for inadvertent food contamination.[78] However, there are questions about whether such rules are practicable or would be followed. Flowering times are not completely predictable and pollen flow distances can change according to the local weather and other environmental conditions. It is unlikely that genetic isolation is possible if fertile GM crops are grown on the large scale that will be needed for commercial production. Physical containment, for example in green houses or specialised, dedicated farms would be required to make molecular gene farming safe.[79]

72. With a view to their use as foodstuffs, transgenic plants have so far been characterised on the basis of comparison with non-transgenic plants of the same species. In relation to the development of transgenic plants with modified constituent composition (in particular novel functional food) an intensive scientific discussion on the question of uncovered risks related to the concept of substantial equivalence began four years ago. The OECD, which had been involved in the development of this concept and in its promotion, introduced a broad-based initiative for the revision.[80]

73. Approaches include analytical methods to detect the most comprehensive spectrum possible of the metabolites formed during the metabolism of a plant. Detailed knowledge of the range of variation of substances in conventional crop plants is a prerequisite for reliable testing for substantial equivalence. Only in this way would it be possible to ensure that significant modifications in the transgenic plants were not overlooked. The more gene constructs are inserted at once into a plant and the more complex the new metabolic pathways produced by this process, the greater the possibility that side effects will occur.

74. The scientific experience and knowledge available to date in relation to the possible hybridisation, overwintering and accumulation of GMOs in the soil, migration and other forms of spread do not yet permit any dependable and practically reliable conclusions to be drawn concerning the possible extent of contamination of non-genetically modified cultures with GMO in the event of widespread and long term cultivation of GMO crops. Study findings indicate that immense differences are likely with regard to investment and costs depending on the crop product and the situation of the agricultural operation if threshold values for GMO contamination are to be observed. Additional costs of anything from a few percent to 40% must be expected.[81]

75. Research is required if co-existence is to be made possible with regard to

- the spread of modified genes and their potential range,
- agricultural precautions against unintentional spread,
- investigation of possible measures for good agricultural practice (minimum clearance distances, staggered sowing patterns etc.)
- the social consequences of the necessary cultivation regulations.

## 4. What should we be arguing about?

76. Farmers in the EU will be able to choose in future whether or not they wish to cultivate approved GM plants. Depending on the liability regulations in the individual member states, farmers who grow GMO will have to expect to be held liable for any contamination of GMO-free crops in neighbouring farms by pollen transfer, to the extent that marketing as GMO-free produce is not longer possible - in Germany liability does not depend on fault. It is clear from the situation with the beekeepers that the coexistence of different methods of cultivation has so far been simply a legal fiction that leaves many questions unanswered. It supports the assumption that coexistence of all types of agriculture (GMO- aswell as organic farming) will only be possible in the long term if the commercial growth of GMO is carried out at a very low level and in strictly limited regional areas or restricted to varieties with a low risk of contamination.

### *4.1 Coexistence, as with the beekeepers in Germany*

77. Around 76,000 beekeepers in Germany keep approximately 800,000 bee colonies: one half of these stocks are the responsibility of 3500 professional keepers (main and secondary occupation) and around 250 apiaries are run in accordance with ecological principles, a tendency which is increasing. Producing 25,000 tonnes of honey a year, 20% of the domestic demand is met from home production. Turnover also comes from the many by-products of beekeeping such as wax, mead, pollen, propolis and royal jelly. At an average of 1,3 kilogramms per head, Germany has the highest honey consumption in the world. Honey represents 0.7% of revenue from animal products in Germany, so bees are the fourth most important domestic animal after cattle, pigs and poultry, even without taking account of their role in pollination.[82]

78. Jobs are created by beekeeping, both directly in agriculture itself and also in the supply industry. The economic benefits of beekeeping from pollination of crops and wild plants is estimated to be at least ten times that of honey production. Around 80% of all flowering plants are dependent on pollination by bees. Unquestionably additional profits of 10% in rape are due to intensive bee flight and amount to approx. 100 euros per hectare. Adequate setting of fruit and high quality produce in fruit growing would be impossible without pollination by bees and without bees the diversity of our flora would collapse, with considerable consequences for the fauna. The large number of amateur beekeepers guarantees beekeeping over a large area. The bees themselves need the care of a beekeeper, because cultivated landscapes provide them with insufficient nesting places, but also because without the help of keepers they would be wiped out by the Varroa mite.

79. The beekeepers fear for their commercial survival if coexistence becomes a reality

and more and more farmers decide to cultivate genetically modified crops. A bee colony grazes an area of 30 - 160 square km. Bees do not distinguish between conventional plants and GMO crops. Rape (nectar and pollen) and maize (pollen) are a particular problem because the beekeepers cannot avoid them. Crop-free zones and coated seeds are completely useless in this case. The beekeepers reproach the politicians with simply ignoring the problem, because for them the consequences could be disastrous, whether there were to be a labelling requirement for honey or whether the present situation persists in which there is no such obligation. The European Commission classes honey as an animal product which, as such, does not have to be labelled. For pollen the labelling requirement applies only if it is found to contain 0.9% GMO, even if its presence is accidental and technically unavoidable.[83] For beekeepers, the labelling question implies: whether we do or we don't, we are between the devil and the deep blue sea. If labelling is not compulsory for honey, they will have to answer to their customers and the media as to why gene technology is found in honey and yet it does not have to be labelled. Moreover, under the planned German liability regulations, they will have no possibility of claiming compensation.[84]

80. If a labelling requirement were to exist, the beekeepers would incur high costs for analysis of around 500 euros per batch, which for small apiaries could exceed the value of the honey. The costs of analysis per batch would be roughly as follows, and are additive – the more GMO plants are approved, the higher the costs will become. 235 euros to answer the question "Is there anything in it?"; 80 euros to answer "What is in it?" (species of plant); 150 euros per variety of rape for the quantity; approx. 150 to 300 euros for maize. A batch here is the quantity of honey that can be homogeneously mixed in one apiary and from which a representative sample can be taken (between 40 kg and a few tonnes depending on the size of the operation and the number of varieties of honey). A typical professional beekeeper of moderate size with 150 colonies harvests approx. 7 tonnes of honey per year. For 5-7 varieties this would mean 15- 20 tests.[85] Since honey is not subject to labelling requirements, beekeepers are not at present required by the state to pay for these analyses, though the market and consumers can be expected to demand such tests.

81. Almost all food producers and supermarkets have stated that they will not use any gene technology or market such produce while consumers are voicing negative opinions about these products in response to surveys. A reluctance to buy will throw the beekeepers into a serious economic crisis that is not of their making, as the retailers can and will move over to GMO-free foreign honey, as long is this is available.[86] An example of the realities of retail is provided by Canadian honey with GMO pollen, which has been avoided by processors and retailers since 2001. Canada has lost its rape and honey market in the EU, because with 40% GMO cultivation there is now no GMO-free rape.[87] On average, honey contains only up to 0.05% pollen. According to tests by the Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg (Office of Chemical and Veterinary investigation) in 2002 and 2003 the percentage content of GMO pollen in Canadian honey was over 30%. The purity of honey is directly related to the extent of cultivation of genetically engineered plants. If no regular analyses are performed, neither the beekeepers nor the consumers will know whether or not such material is present, the consumer protection organisation Foodwatch warns.

82. Beekeepers are demanding suitable compensation, irrespective of threshold values, for the losses in turnover that can be expected if coexistence becomes reality and GMO-free honey production becomes no longer possible in Germany. It is, of course, impossible to predict precisely how consumers and retailers will react, though it is probable in the event of large scale GMO cultivation that a similar situation will arise for conventional honey

production to that faced by organic beekeepers and organic agriculture generally, who are also subject to the regulations of their cultivation associations, national organic regulations and the EU organic farming directives. These prohibit the use of GMO or GMO derivatives without the tolerances that exist in the threshold regulations for conventional agriculture. Consumers who value honey as a natural product will have similar expectations of beekeepers operating by conventional methods to those of the consumers of organic foods with regard to regional organic farming: zero GMO tolerance.

83. Beekeepers therefore support the fundamental requirements that the European Parliament proposed in its coexistence report dated 22.04.2004 with respect to member states.[88] They also demand highly specific details of GMO release areas and “bee-safe” distances between GMO areas and apiaries. A further fundamental aspect for them is duty of care with regard to the health of bees, if GMOs produce insect toxins show new characteristics that affect insects. The beekeepers’ associations demand that investigations in bees should be incorporated in the registration procedures for GMO plants. [89]

84. Organic farming will not be able to survive under conditions in which large areas of GMO crops are cultivated, because of consumer expectations as described above, if retailers of eco products can move over to other farming regions that are actually GMO-free. For regional organic farming, unlike conventional farming, coexistence will therefore be a fundamental matter of existence and not one of threshold values that can be observed in practice.

### *4.2 Freedom of choice, seed purity, liability*

85. Farmers have the right to produce GMO-free products, consumers must be allowed a choice on the basis of appropriate labelling. The principle of free choice implies that GMO-free cultivation in general deserves legal protection from contamination with transgenes. Sustainable preservation of GMO-free agriculture should be ensured in law and not by voluntary agreements. One issue is whether organic farming deserves legal protection to a particular degree. This can be politically desirable and justified by the fact that it is the best form of agriculture with regard to ecological sustainability.[90]

86. Apart from preserving the purity of seed stocks, national regulations with regard to coexistence costs, resulting mainly from the necessary separation of the flow of goods and the needs for various controls, are an essential prerequisite for the long term guarantee of coexistence. Farmers who wish to grow GMO-free crops may incur economic losses after the development of hypothetical health and environmental risks, if their harvest is so heavily contaminated with GMO (threshold 0.9%) that they have to label it. Compensation for measurable loss of income can be met by a regime of liability. Irrespective of the outcome of the debate about coexistence and the relevant regulations in the member states, more and more insurance companies are declining to insure against any damage caused by GMOs.[91]

87. The precautionary principle, as far as Europe is concerned, requires a cautious and rather restrictive procedure initially, which can be made less restrictive if appropriate in the light of further experience. What must be avoided at all costs is inadequate and imprecise regulations with regard to co-existence leading to a situation where the provisions for registration, traceability and labelling which have just been agreed become unenforceable under the actual pressure of progressive GMO contamination. The European Commission has not yet committed itself with regard to threshold values for seed. Previous proposals

incorporate different threshold values depending on the crop (rape, maize, soy bean). The European Parliament calls for the threshold value for seeds in general to be fixed at the limit of detection of 0.1%.

88. The most important single measure for the avoidance of contamination is strict regulation with regard to purity and labelling for seeds. Only if clear separation takes place at the start of the production chain can cases of contamination, which become "technically unavoidable" in GMO farming, be kept reliably below the labelling threshold at reasonable cost to the neighbouring farmers and subsequent preparation, processing and retail companies. Economic analysis makes it clear that it is much more sensible to keep seed free from GMO, since seed production in any case takes place in a practically closed system. However, if farm production is subjected initially to contaminated seed, complying with the limit value will create an economic avalanche of costs and risks to agriculture and the food sector which will be out of all proportion to the economic advantages of introducing GMOs.

89. In addition, specific standards of good agricultural practice are needed to prevent cross-contamination and accidental incursions of GMOs. Liability regimes should safeguard co-existence, but on the other hand not make GMO farming and the release of GMO for scientific purposes impossible. The right balance will be difficult to find. The EU recommendations which are still not binding could prove a suitable procedure for achieving a balanced system. European states should, however, endeavour to create common liability legislation.[92]

90. Liability and the costs of coexistence can basically be divided into three categories: 1) The polluter (seed company/GMO-farmer) pays and is responsible. 2) The person suffering the damage comes away empty-handed and is forced out (conventional farmer, organic farmer) 3) The State, i.e. the general public pays (e.g. liability fund). Which alternative is chosen depends on the priorities of national policy. Mixed forms with regard to liability are not to be recommended, because in practise the transgenic seed damages all others, while GMO-free seed does not damage the GMO farmer.

91. The increase in ecologically farmed acreages is not only a useful indicator for sustainable agriculture[93], but a reasonable objective overall, also with respect to the developing countries. Policy must incorporate capacity building, to ensure lasting coexistence. In establishing agricultural policy with regard to GMO there is a close connection with the problems of intensive agriculture. Many of the risks that arise from breeding by genetic modification are also present in conventional breeding, the purpose of which is to achieve higher yields. These are not risks specific to green biotechnology, but risks of a particular agricultural policy. For a proper estimation of the potential risk of green biotechnology it is necessary to differentiate between biological-ecological and socioeconomic factors, including the perception of risk by the consumer. The consumer's perception is difficult to assess objectively, but will have direct effects on production and retail.

92. Major social and economic problems for agriculture are unavoidable if the practice of granting broad-based patents on genes and biological material becomes further established in Europe. To date, farmers in countries outside Europe have had to pay licence fees even if they have not purchased the genetically modified seed but have had to tolerate it on their fields where it has arrived as a result of hybridisation – which legislation frequently does not even regard as constituting damage.[94]

### 4.3 Farmers' varieties and biopatents

93. A large number of farmers' varieties exist throughout the world that show a high degree of tolerance to unfavourable environmental conditions. Although countless traditional varieties bred over hundreds of years by farmers have been lost in the course of the Green revolution, there are still a considerable number of valuable varieties that will only survive if they continue to be grown and consumed. The robust farmers' varieties have adapted over long periods to particular regional conditions and ecological habitats. Plant breeders also recognise the value of the old varieties, since they are the basis for their work. Paradoxically, however, new development of high-yield varieties often force out the old farmers' varieties and therefore the basis of their own existence.

94. Scientists at the Indian Agricultural Research Institute regard the introduction of transgenic plants as superfluous when corresponding traditional varieties are available. The development of new varieties is regarded as important, however, where farmers no longer have adequate access to traditional farmers' varieties. The situation becomes problematic when seed companies produce new varieties on the basis of the old ones and cover these with a patent. The farmers are then unable to replicate the new varieties themselves, even though they and their forebears created the genetic basis for these.[95]

95. The European Patent Convention (EPC) forbids the patenting of plant varieties but not the patenting of plants or seed. Under this convention, processes for the treatment of plants and seed stock (for example to achieve particular agricultural characteristics) are patentable provided that the claim does not relate to a variety as an individual entity. It is possible, however, that patent applications may be made for processes suitable for use in modifying a number of plant varieties. According to established legal practice of the Board of Appeal of the European Patent Office (EPO) since 1995 processes for the treatment of plants have not been accepted as patents if this leads indirectly to claims on one or more plant varieties. This legal situation could change since the EU Biopatent Directive (98/44/EEC dated 6 July 1998) has been issued. The directive was adopted in the regulatory provisions of the EPC even before implementation in the individual member states[96]. Depending on interpretation of the directive, the principles contained in it could lead to bypassing of the non-patentability of plant varieties.

96. If the scope of protection for reproducible material is determined in accordance with the standards of patent law, the sowing of part of the crop by the farmer would be subject to licence. The EU Directive on protection of varieties in the community has already restricted the privilege of the farmer and breeder as enshrined in German law.[97] Restriction of these privileges is viewed with criticism. This alone strengthens the dependence of the farmer on the large seed producers. Independent breeding, based on seed varieties from the original patent holder, is a laborious and expensive undertaking for small and medium concerns. Relevant cases in the USA make it clear that the continuing effectiveness of the farmer's privilege will depend fundamentally on the formulation of the patents on the one hand and the decisions of the competent courts on the other.

97. Developing countries are particularly severely affected by this problem. Although the majority of natural resources originate from southern countries, these countries are unable to compete with the large industrialised nations due to lack of technology. *The patents shift wealth creation from the countries* in which these plants have previously been used for economic purposes to the industrial countries[98]. Control of seed markets in the countries of the south is also of interest because in India, Asia, Africa and south America up

to 80% of new crops are sown from the farmer's own harvest. China and Brazil in particular but also Mexico, Morocco, India and Pakistan are regarded as important markets for the expansion of trade in commercial seed.

98. The promise that hunger in the third world could be successfully combated using genetic engineering is viewed with great scepticism by the development aid organisations.[99] Genetically modified high-yield seed could realise its yield advantages to only a limited extent in the agricultural subsistence production of the third world. To realise these advantages, an agro-industrial form of production would be necessary with the use of crop treatment substances, fertilisers, growth regulators, a high degree of mechanisation and frequently the transition from precipitation-dependent to irrigation agriculture. This is impossible for small farmers to afford and favours the major producers since considerable inputs which were previously free of charge for an agricultural system of this kind would have to be imported from the industrial countries using currency, or bought from local breeders who themselves pay licence fees to the seed companies. Estimates suggest that the proportion of costs for seed would increase from 0-19 % to up to 60 percent. The agricultural products obtained in this way must again be sold for currency, which would set up further incentives for growing cash crops for export instead of food crops to meet the needs of the country itself. The loss of rural jobs, a further increase in migration of the rural population to the major cities and considerable social problems would result.[100]

99. Although the current FAO report discusses this problem in detail, it still estimates that green biotechnology has an immense potential for making a significant contribution towards solving the problem of world hunger. At the hearing, it was countered that although green biotechnology offers great potential for improving food supplies, this effort is currently being made only at product level and not at production level (e.g. golden rice). In this way, commercially orientated green biotechnology is very likely to change the structures in agriculture for the worse: "In principle, genetic engineering has some potential to reduce pressure on natural ecosystems on a global scale. In practice however, GMO is rather to increase such pressure because intensified agriculture will replace small subsistence farming and subsistence farming will be replaced onto marginal lands. An increase in global harvests does not imply an enhancement of food security. At the moment, most GMOs are produced for global agricultural markets."[101]

100. In conclusion, from the above discussion, three needs can be identified: The equivalence of natural DNA (or mutagenesis in conventional breeding) and transgenic DNA (transgenesis) must be systematically examined, if necessary with new methods. This equivalence cannot be presumed on the basis that safety research only confirms what has previously been established. Secondly, coexistence is not an end in itself. If it is seen as an appropriate compromise that will satisfy all sides and if the result is the growth of GMO to a wider extent, then regional organic farming cannot survive. Clear decisions must be made here in advance. Haggling over threshold values does not do justice to the magnitude of the problem. Thirdly, agrogene technology must be examined closely for its potential to improve the food situation, so that the technological advance is not the sole reason for spending millions on research projects, money which will then be lacking elsewhere. Sustainability implies problem-oriented approaches that take account of particular regional characteristics.

## 5. What will move us forward?

101. People like to use the word sustainability in political contexts as a kind of semantic gold. But no coins can be minted from it if it becomes an empty soundbite. The crucial need for careful problem analysis in advance is clear from the example of stress-tolerant transgenic plants: the intensification of agriculture aggravates the problem of water shortage and salinification to a level at which the singular advance of a particular technology will be quite unable to correct the resulting loss of yields.

### *5.1 Biotechnology and sustainability in relation to stress-tolerant plants*

102. Against the background of an increasing shortage in the world's water resources and the extensive spread of saline soils, research is being conducted in many countries on the development of transgenic plants that are tolerant to drought and salt.[102] Worldwide, water supply is the most important agricultural production factor. For future increases in food production, water will therefore be the limiting factor. At least 70% of world water consumption is used in agricultural production. 18% of the total area used for agriculture is currently irrigated. This amounts to an area of 240 million hectares. Around 40% of all the world's food is produced on this land.

103. Soil salinification is often caused by incorrect irrigation and represents a constantly increasing problem, because the global water shortage is accompanied by impoverishment of rainwater. Natural soil salinification is a result of capillary rise and subsequent evaporation of salty ground water, leaving the salt in the soil. Where salinification damage has been caused by humans the water table is raised by irrigation, which leads to an increase in evaporation. The fact that it is almost always ground and surface water, with a considerably higher salt content than rain water, that are used for irrigation intensifies the salinification process. In China this results in a reduction in yields in 40% of areas receiving rain, and in the USA saline soils are estimated to be responsible for 25% lower yields overall. In farming areas not sustainably managed and increasingly affected by salinification (wheat prairies in the Western USA), the economic interest in developing transgenic salt-tolerant crop plants is great.

104. An increase in the salt content of the soil does not lead to direct damage to plants but is always associated with increased soil pH. Few plants thrive on alkaline soils and salinification contributes to the destabilisation of soil structure, which can result in silt formation and a reduction in gaseous exchange. A drastic reduction in biodiversity due to high salt levels in the soil contributes indirectly to impoverishment of the soil structure. All these consequences lead to a reduction in agricultural yields and can make soils wholly unsuitable for agricultural use. 10 million ha worldwide are unusable for agricultural for this reason and in a third of the total cultivated area salinification is responsible for lower yields (approx. 491 million ha).

105. Almost all important crop plants are sensitive to a shortage of water and high salt content. While very few crops, such as sugar beet and cotton thrive relatively well under such stress conditions, there are many wild resistant varieties. Research is being conducted into their protective mechanisms, to allow these to be used for the development of transgenic plants. Knowledge of the comparatively complex physiological and biochemical mechanisms that lead to tolerance of abiotic stress factors in plants is still relatively limited. The relevant characteristics probably rely on a number of genes and complex regulatory mechanisms. For this reason the development of transgenic plants was of limited importance for a long time. However, in recent years efforts in research have intensified. The first transgenic stress-tolerant plants cannot be available commercially for at least five

to ten years, as release trials have so far been performed only on a very small scale.[103]

106. Although transgenic drought-resistant and salt-tolerant plants have been developed, varieties that can be cultivated still constitute a hypothetical application of biotechnology. Most experimental findings are based on investigations conducted under unrealistic environmental conditions in the greenhouse. It can be assumed that only 5% of development expectations are realistic. These must be weighed against the risks.[104] 3rd generation transgenic crop plants cannot be used for a relatively long time and our knowledge of their complex mechanisms of inheritance is poor; whether they can make a significant contribution to the fight against world hunger is highly controversial in the light of their single-cause approach and the known risks. The UN development programme gave rise to lively debate when it called, in its annual "Human Development Report 2001" for greater spending on research into high-yield and drought resistant crops. The report accused some western countries of blocking progress in this area by their restrictive attitude to biotechnology.[105]

107. The need for food is likely to double in the developing countries by 2025 due to the population explosion. The annual increase in cereal yields are falling steadily, however, and the opening of new agricultural areas is possible only to a very limited extent. Nevertheless, low productivity is not the cause of regional food shortages, either now or in the future, if forecasts on this subject are accurate.[106] Hunger is the result of a number of factors including unjust distribution of wealth, war or mismanagement. A decisive role in the food security of large portions of the undernourished population is played in particular by access to land, clean water, seed that will germinate and the domestic market: in other words, the underlying socioeconomic conditions. A prime need for the improvement of food supplies is the increase in productivity per household. A scientific study on projects and initiatives in sustainable farming systems (without using GMO) concluded after evaluating 96 different projects that an average annual increase in food production of 73% per household was possible.[107]

108. Protagonists of green biotechnology argue that it is possible to open up additional agricultural areas. However, this applies only to individual regions such as parts of Israel or Egypt. A large proportion of the world's saline soils are increasingly associated with unsustainable irrigation techniques, affecting one quarter of irrigated land (approx. 60 million ha). Here salt-tolerant crops are merely a symptomatic solution, i.e. the cause of the salinification is not addressed and urgently needed investment in improving the soils is avoided where possible. Because of the shortage of water and the associated deterioration of rainfall, it must be assumed that the salt content of the soil may rise to the level at which even salt-tolerant varieties will fail to help.[108]

109. From the example of stress-tolerant transgenic plants it is clear that careful analysis of the major variations in the problems that exist between regions is essential if an improvement in food supplies is to be achieved. This should be approached primarily through projects on the spot and via solutions worked out jointly with those affected, and not, as in the past, indirectly by the regulatory mechanism of the world market. The existing lack of justice in world trade regulation can only be compensated if a new guiding principle is introduced with which world marketing regulations are obliged to comply. A weak concept of sustainability will not solve this problem.

110. In the current discussion on sustainability, different concepts are competing and it is also questionable whether future development will be more planned or whether it is more

likely that a pragmatic approach will be followed.[109] The fact that, in spite of the large number of concepts (nationally and internationally), definitions, research projects, models, lists of indicators and strategies for implementation, there is still evidence of a lack of direction[110] suggests rather that the alternative plans should be clearly set out so that they can be of real assistance in directing political action.

111. With the three pillar model currently favoured in policy, according to which ecology, economy and social policy are to be brought into balance, there is also the danger that no real change in the structure of economic policy will take place.[111] Sustainability in that case is not a promising reform concept but an empty formula with which the deficits of the existing system are concealed rather than corrected. A plan for sustainable development that is vague even at the level of principles will lead to injustices at all subsequent levels.

112. The following levels may be distinguished:

i. Idea (theory of distributive inter- and intra-generational justifiability)

ii. Conception (strong, weak sustainability, intermediate position)

iii. Guidelines (resilience, sufficiency, efficiency etc.)

iv. Dimensions (environment and nature, social, economy, training etc.)

v. Rules for different dimensions (management rules)

vi. Objectives

vii. Set of indicators

viii. Implementation, monitoring etc.

113. Pragmatic considerations should never be used in the area of underlying principles, but at the level of application. In a transitional phase this can be of great importance in order to maintain the innovative potential of a concept even if there are many aspects which cannot yet be implemented.

Within the three sustainability concepts (weak sustainability WS; strong sustainability SS; intermediate sustainability IS) further levels may be defined:[112] The basic difference between weak and strong sustainability lies in the extent to which natural capital and man-made capital are seen as interchangeable values. Depending on whether more or less far-reaching mutual interchangeability of the two is assumed, the need arises to protect natural capital and invest in it. Polluted soils are the man-made capital of the agricultural industry: truly a heavy mortgage on the future which does not appear in the attractively calculated economic balance sheets of the present.

114. The arguments in favour of a concept of stronger sustainability may be summarised as follows:

- Uncertainty with regard to future preferences and habits favours the selection of a future concept that leaves the greatest possible number of options open to later generations. In addition to the option of a completely artificial world, also the option of a natural way of living. This also implies openness to the cultural value of nature for the present.

- Criterion of the multifunctionality of ecosystems.

- Strong sustainability guarantees compatibility with environmental regimes (CBD) and takes account of the fact that “critical” natural capital is difficult to identify and that erroneous assumptions can have very negative consequences. Compared with the concepts based more on the existing economic system of sustainability, it establishes clear criteria for substitution, discounting and compensation of natural capital.

- The concept of strong sustainability satisfies the sensible intuition that it is better to err on the side of caution[113]

- It promotes a broader research agenda, since a number of approaches compete to find the best solution with regard to complex problems.

115. The argument put forward by protagonists of green biotechnology, that a restrictive attitude towards the new technology would mean that the opportunity for progress that would be decisive for future economic wellbeing would be missed (position debate), with the result that scientists would move to other countries (brain drain), contains many preconceptions compared with the above arguments. Whether green technology and large-scale growth of GMO would mean progress is already strongly contested. In principle it is conceivable that sponsorship of basic research in particular will be continued. The problem arises, however, when scientists demand state sponsorship for market introduction of a technology that is of doubtful benefit, which the majority of citizens strongly reject due to unanswered questions on risk and no appreciable benefit. The almost blind faith in progress on the part of many scientists also underestimates the massive changes that have taken place in science itself and its role in society over the last few decades.

### *5.2 General social debate*

116. As a compromise solution there has been discussion in the past of a voluntary agreement on trial cultivation, limited in space and time, of approved transgenic plants to be reached between the plant breeding companies and the policy makers (nationally or internationally). A transition phase of this kind, as a type of extended and well controlled release phase, could help to accumulate new safety information and identify specific regional requirements for the co-existence of various forms of cultivation. Agreement of a limited transitional phase of this kind (5-10 years) could be used to involve the public in decision processes and create a new basis for trust.[114] It must be said that at this trust between science and the public no longer exists. Nor is social dissent over the release of GMO met with any unified view on the part of the scientific community.

117. In the process of social self-determination concerning the permanent management of future tasks, science and technical development will certainly play a prominent role which will only be possible firstly if more interdisciplinary collaboration takes place within the scientific community, and secondly if there is greater focus on actual social problems and needs. It cannot merely be a case of promoting more scientific and more ecologically tolerable techniques; to an increasing extent it will be necessary to find overall solutions for complex areas of need that are suitable for the future (e.g. mobility, living, eating) which

involve technical, social and also structural innovations. For science, this implies not only new substantive requirements but also the need for new communication structures; there is also a need for new concepts of research promotion.

118. The framework conditions for scientific and research policy grouped under the concept of globalisation are not only unfavourable for a research policy directed at the ideal of sustainable development. The increasing competition for raw materials will bring about a burst of innovative activity towards greater resource efficiency. Although the main focus of interest is on efficiency strategy and this option will probably have to be followed up initially, the efforts to achieve sufficiency ("self limitation", "satisfaction") which are currently seen as less acceptable in view of the prevailing economic climate and lifestyle, should not be neglected. Associated with this problem are habits of consumption and lifestyle that are basically responsible for a large number of the diseases of civilisation (cardiovascular disease, obesity, backache) that place an enormous financial burden on the health system. In general it can be said that aligning research and technology policy, but also health and social policy, with sustainability criteria can be grasped as an economic opportunity.

119. Changes in the scientific system itself are also detrimental to a sustainability strategy. Increasing blurring of the traditional distinction between basic research and applied research, the inclusion of new players who used to be largely excluded as outsiders, the increase in transdisciplinary research tasks that allow the natural sciences and the social sciences to move closer together, all indicate that a modified social role is being allocated to science in general.[115] Science is losing its special role as a depoliticising force for the production of objective information and is becoming involved in the process of social discourse, so that it is no longer the arbitrator but part of the dispute and the perception and definition of social problems.[116]

120. The implementation of sustainability concepts requires a high level of social consensus. The combination of social self-determination and political decision finding processes with scientific knowledge and sociotechnical innovation processes is the central challenge.[117] With this great need for consensus and coordinated action by all players, the discipline of assessment of the consequences of technology offers both a suitable concept and means of analysis; it also increasingly involves participatory approaches in the political consultation and therefore promotes the debate between science, economics, politics and society.

121. In relation to green biotechnology, there are only a few approaches available for implementing a particular concept of sustainability and assessing various aspects of the new technologies on the basis of sustainability criteria.[118] Particular attention should be paid here to the ecological consequences of various agricultural systems and to the subject of agro-biodiversity.[119] It should be meanwhile accepted that Europe will probably be a less attractive place for "conventional research" into green biotechnology. Within the concept of strong sustainability there would be attractive starting points for a broader-based research agenda.[120] Social and political decision-making processes should not be conducted under the artificial constraint that market opportunities are allegedly being missed. What is needed for a sustainable plan for the future is not the first best technological solution, but the best solution reached after considering all the alternatives available. Finding this takes time. Investing this time may save wasting millions[121] poured into an investment decision made in a hectic rush to act and an insoluble fundamental disagreement within society.

122. In relation to the situation in the developing countries, biotechnological methods should not be used until they will really help the people there with their work. The public debate and the PR efforts of lobbyists focus too much on the methods of gene transfer and the newly created high-yield varieties. The enormous potential offered by cell and tissue culture methods below the threshold of gene technology is not sufficiently well appreciated and defined. These methods, without which gene technology itself in the industrial production sense could not progress, are in themselves capable of achieving a large number of improvements: shortening of breeding times (from 15 to 5 years), production of virus-free plant material; cheap production of good productive seed in a short time and in large quantities, production of seed with special characteristics and adaptation to regional biotic and abiotic stress conditions.[122]

## 6. Conclusions

123. Peace and wellbeing in a society rely on a consensus with regard to the fundamental values of communal life. Irresolvable conflicts on basic objectives do not lead to a cultural plurality which is desirable in other areas but to a loss of solidarity and impasse. The dispute around the peaceful use of nuclear energy teaches us that even democratic majorities are not sufficient to create social acceptance for the introduction of a new technology if this involves a high potential risk. Since no objective risk assumption can be made where basic knowledge is inadequate, social disputes on these matters are invariably a dispute about beliefs, even though natural scientists would like to distance themselves from this fact. Rational disagreement that sets out the differences clearly is better here than forced consensus which subsequently proves not to be lasting or tolerable.

124. The guiding principles of EU policy on GMOs: caution and freedom of choice have priority over promotion of economic and technological considerations and should be consistent in their formulation. The most important demand of this resolution in the short term is the compulsory labelling of animal products where the animals have been fed with genetically modified feedstuffs. If the market is to decide the controversy over green gene technology, those involved in the market should not be misled. This is the responsibility of politics. The risk of an unwanted spread of GMO by the back door is great if no market segment for GMO-free feedstuffs remains. Almost all food scandals in the past have been attributable to defective controls on the feedstuffs industry. The absence of a GMO labelling requirement for animal products leads to unfair competition and makes it impossible for consumers to autonomously decide when purchasing food.

125. The legal concept of “sound science” assumes that applications are authorised if no solid data based on scientific consensus are available to demonstrate damage. This creates an incentive not to search intensively and widely for possible damage. After all, not knowing means that a product will be approved. This legal concept originated in the USA and became predominant in the WTO. It competes with the principle of care that is enshrined in EU legislation and adopted in the agreements and decisions reached at the Earth Summit in Rio in 1992. If the principle of care is applied, a systematic search must be conducted for possible damage. There is a state commitment to precautionary damage prevention. What is needed is an independent technical assessment of consequences that runs in parallel with the development of technology and is adequately financed.[123] If only a fraction of the shocking reports of manipulation and slander campaigns within the scientific community are true (inspired by representatives of large companies who are spending other people’s money), then freedom of research is not worth much under the commercial pressure of application readiness and marketability.

126. In the medium term the reorganisation of EU agricultural policy should be based on principles of sustainability. The increasing intensification of agriculture, which is associated with a number of ecological problems, stands in the way of reorganisation and suppresses objectives that cannot be achieved in the short term, such as an improvement in soil quality, the decisive factor in production if healthy food is to be produced and reliable yields ensured in the long term.

127. In the long term there must be a change in world trade regulations, so that fairer exchange and partnership on an equal basis is possible with the developing countries. In this connection the EU must meet its responsibilities to a greater extent than in the past and support self-help, instead of emulating the USA with carefully restrained last minute trifles. New, and this time genetically engineered high-yield varieties, the profits from which will benefit first and foremost domestic biotechnology via licence fees, do not represent a seed change in economic and development aid policy but a stubborn insistence on market mechanisms that have now become questionable. We already have the ability to change basic socioeconomic conditions, since no immutable laws of nature are involved. In all our attempts to mould nature to our purposes we shall invariably find that nature will deal with our technological ingredients according to her own rules. The synthesis of biology and technology is not an easy one, even if the new terminology we invent may suggest that it is.

128. A sustainability concept, if it is to be acceptable to all, must be formulated for all citizens of the world. The reform potential from this regulatory idea has by no means been exhausted. In fact consumers may be the best defenders of precaution and freedom of choice if they do not merely demand.

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Members of the committee: Mr Renzo **Gubert**(Chairman), Mr Alan **Meale**, Mr António Nazaré Pereira, Mr Walter Schmied (Vice-Chairmen), Mr Ruhi **Açikgöz**, Mr Olav Akselsen, Mr Stojan Andov, Mr Gerolf Annemans, Mrs *Sirkka-Liisa* Anttila, Mr Ivo Banac, Mr Antanas Baura (Alternate: Mr Jonas **Cekuolis**), Mr Jean-Marie **Bockel**, Mr Malcolm Bruce (Alternate: Mr James **Wray**), Mr Yüksel **Çavusoglu**, **Sir Sydney Chapman**, Mrs Pikria Chikhradze, Mrs Gražyna Ciemniak, Mr Viorel **Coifan**, Mr Valeriu Cosarciuc, Mr Alain Cousin, Mr Taulant Dedja, Mr Hubert **Deittert**, Mr Adri Duivesteijn (Alternate: Mr Arno **Visser**), Mr József Ekes, Mr Bill **Etherington**, Mr Adolfo **Fernandez Aguilar**, Mrs Siv Fridleifsdottir, Mr György Frunda, Mr Fausto **Giovanelli**, Mrs Maja Gojkovic, Mr Peter Götz, Mr Vladimir **Grachev**, Mrs Gultakin Hajiyeva, Mr Mykhailo Hladiy, Mr Anders G. Högmark, Mr Jean Huss, Mr Ilie **Ilascu**, Mrs Renate Jäger, Mrs Corien Jonker (Alternate: Mr Leo **Platvoet**), Mr Ivan Kalezic, Mrs Liana Kanelli, Mr Karen Karapetyan, Mr Orest Klympush, Mr Victor **Kolesnikov**, Mr Miloš **Kužvart**, Mr Ewald Lindinger, Mr Ömer Zülfü Livaneli, Mr Jaroslav **Lobkowicz**, Mr François Loncle (Alternate: Mr Guy **Lengagne**), Mr Theo Maissen (Alternate: Mr John **Dupraz**), Mr Andrzej Manka, Mr Tomasz **Markowski**, Mr Giovanni Mauro (Alternate: Mr Pasquale **Nessa**), Mrs Luisa Mesquita, Mr Gilbert Meyer (Alternate: Mr Daniel **Goulet**), Mr Goran Milojevic, Mr

Valdimir Mokry (Alternate: Mrs Svetlana **Smirnova**), Mrs Carina Ohlsson, Mr Gerardo Oliverio (Alternate: Mr Giovanni **Crema**), Mr Mart Opmann, Mrs Elsa Papadimitriou, Mr Janez Podobnik, Mr Lluis Maria **de Puig**, Mr Jeffrey Pullicino Orlando (Alternate: Mr Joseph **Debono Grech**), Mr Maurizio Rattini, Mr Marinos Sizopoulos, Mr Rander **Steenblock**, Ms Inger Støjberg, Mrs Maria**Stoyanova**, Mr Gábor Szalay, Mr Nikolay **Tulaev**, Mr Iñaki Txueka Isasti (Alternate: Mr Julio **Padilla**), Mr Vagif Vakilov, Mr Borislav Velikov, Mr Klaus Wittauer, Mr G.V. **Wright**, Mr Kostyantyn Zhevago.

*N.B. The names of those members present at the meeting are printed in* ***bold****.*

Secretariat to the committee: Mr Sixto and Mr Torcatoriu

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[1] Overview of GMO moratoria in the various countries and regions of the world at www.genet-info.org (GE-free zones)

[2] FAO 2003-04, *The State of Food and Agriculture, Agricultural Biotechnology meeting the needs of the poor?* Rome 2004.

[3] WTO complaint by USA: On 13 May 2003 the USA lodged a complaint with the WTO court of arbitration (300 million US $ lost in trade due to the EU moratorium). Extension of the complaint to GMO labelling is planned, based on the WTO TBT and SPS Agreement (Technical Barriers to Trade; Sanitary and Phyto-Sanitary measures), that incorporate the principle of "sound science". Cf.: *Inside US-Trade: Likely new WTO challenge on EU GMO Policy*, March 12th, 2004. In the comparable trade dispute on US hormone meat (genetically modified cattle hormone) the WTO did find against the EU, but stated that a WTO member in its sovereign territory can implement the degree of health protection that it considers necessary.

[4] This danger was identified by Greenpeace after feedstuff manufacturers experimentally labelled all feedstuffs as GMO.

[5] Volker Beusmann, *Hearing on Genetically Modified Organisms of the Committee on the Environment, Agriculture and Local and Regional Affairs in Paris on 08.09.04.* (below quoted as *hearing of the COE Committee*). For stages of this discussion: controversy in the 1980s concerning risk led to Release Directive 90/220/EEC; intensification of the risk debate after a drastic switch in opinion in the second half of the nineties even in previously "biotechnology-friendly" countries such as France and Great Britain; among the causes of the massive rejection of gene manipulation in the food production sector were undetected ship-loads of GMOs sent out by US maize and soya exporters in 1996/97; since 1998 there has been a blockade of new registrations and approvals of transgenic varieties (de facto moratorium); revision of the GMO Release Directive (2001/18/EC) in response to on the one hand, scientifically controversial and, on the other, publicly controversial questions with an additional need for expanded parallel research (case by case; step by step); after the creation of a mandatory system for the labelling and traceability of GMOs and the adoption of non-binding guidelines for co-existence of different farming methods, the moratorium is now to be lifted. On this controversy: Grunwald, A., Sauter, A., *Langzeitmonitoring der Freisetzung gentechnisch veränderter Pflanzen (GVP), gesellschaftliche, politische und wissenschaftliche Dimensionen*, Umweltbundesamt (ed.), *Symposium "Monitoring von gentechnisch veränderten Pflanzen: Instrument einer vorsorgenden Umweltpolititk"*, 13. Juni 2002 im Bundespresseamt, Berlin. UBA-Texte 23/03, Berlin 2003, pg. 16-24.

[6] Sustainability is a normative concept, a regulatory idea; in the follow-up to the *Brundtland report* (WCED 1987) and the action program agreed at the Rio summit, *agenda 21* (UN conference for the environment and development 1997) this has been widely recognised. The definition of the Brundtland Commission is as follows: "Humanity is capable of sustainable development – it can guarantee that the needs of the present are satisfied without jeopardising the opportunities for future generations to satisfy their own needs."

[7] Volker Beusman states at the *hearing of the COE Committee*: „In my opinion we have to many public debates on future technologies, and not enough discussions on behaviour and institutions compatible with the future, although the sustainability debate embraces all these dimensions."

[8] The *efficiency strategy* is aimed at increasing resource productivity in the production of goods and services; the *sufficiency strategy* is aimed at bringing about changes in patterns of consumption and behaviour in society as well as changes in values directed towards a more post-materialistic lifestyle; the *consistency strategy* is aimed at the attainment of consistency/compatibility between anthropogenic and natural material flows (for instance natural building materials). Ott, K., *Zu einer Konzeption „starker Nachhaltigkeit",* Düwell, M. et al. (ed.), *Umwelt - Ethik - Recht*, Tübingen / Basel 2003, pg. 25 prefers the term "ecological resilience" over consistency: "preservation of environmental assets with a view to ensuring the comprehensive potentials of the environmental system".

[9] Konrad Ott summarised the arguments against the introduction of green biotechnology at the *hearing of the COE Committee*: 1. Principled ("categorical") ethical arguments; 2. health risks for humans; 3. no benefit for consumers; 4. negative environmental effects; 5. ecological risks; 6. disadvantages to organic farming; 7. threats to food safety in southern countries; 8. control over seeds by TNC's.

[10] Basic information for this report has been drawn from: Heine, N., Heyer, M., Pickardt, Th., *Basisreader zum Diskurs Grüne Gentechnik des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft (BMVEL),* April 2002. The text of the reader and further information can be found in the internet: www.transgen.de; Information concerning developing countries see: Augsten, F., Buntzel-Cano, R., *Die Bedeutung der aktuellen Gentechnikgesetzgebung in der europäischen Union für den Süden*, Forum Umwelt & Entwicklung und Evangelischer Entwicklungsdienst (ed.), Bonn 2004.

[11] The definition of modern biotechnology used by the FAO/WHO is as follows: "application of: in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or application of fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection." FAO/WHO 2001, *Safety assessment of foods derived from genetically modified micro-organisms*, Geneva 2001, pg. 3.

[12] *Directive 2001/18/EC on the deliberate Release into the Environment of genetically modified Organisms,* Art. 4 states that GMOs which contain genes expressing resistence to antibiotics in use for medical or veterinary treatment should be identified and phased out within the next years.

[13] Revermann, Chr., Hennen, L., *Das maßgeschneiderte Tier*, Klonen in der Biomedizin

und Tierzucht, Berlin 2001.

[14] The below listed publications have been taken from: Öko-Institut e.V. (ed.), *Transgene Nutztiere*, Gentechnik-Nachrichten Spezial 13, Juli 2003, Freiburg 2003, pg. 1-16. The newsletters of the Öko-Institut may be found in the internet at: www.oeko-institut.org/bereiche/gentech/newslet/index.html; all of them are available in an English version. Hammer, R. E. et al., *Production of transgenic rabbits, sheep and pigs by microinjection*, Nature 315, 1985, pg. 680-683; Meier et al., *Transgene Tiere: Nutzung, Risiken und Möglichkeiten der Risikovermeidung*, Umweltbundesamt (ed.), Berlin 2003.

[15] In the USA, AQUA Bounty Farms are currently awaiting a permit for their transgenic quick-growing salmon (AquAdvantage™) for commercial aquaculture. Fish production in fish farms now accounts for a quarter of all fish traded on the world market. In Cuba an application has been made for a permit for transgenic African cichlids (Tilapia). Hew, C. L., Fletcher, G., *Transgenic fish for aquaculture*, C & I Magazine 1997, http://ci.mond.org/970812.html. Cf. also: Hew, C. L., Fletcher, G., *The role of aquatic biotechnology in aquaculture,* Aquaculture 197, 2001: pg. 191-204. On 5th January 2004 the transgenic Glofish went on sale in the US without any federal regulatory approval. Nature 426, p. 372.

[16] Niemann, H., *Transgenic farm animals get off the ground*, Transgenic Research 7, 1998, pp. 73-75. Mitchell, A. D., Pursel, V.G., *Effects of dietary conjugated acid on growth and body composition of control and IGF-1 transgenic pigs*, The FASEB Journal 15(5), 2001, A961. Powell, B.C. et al., *Transgenic sheep and wool growth: Possibilities and current status, Reproduction Fertility and Developement 6*, 1994, pg. 621. Su, H.-Y. et al., *Wool production in transgenic sheep: results from first-generation adults and second generation lambs*, Animal Biotechnology 9 (2), 1998, pg. 135-147.

[17] Krimpenfort, P. et al., *Generation of transgenic dairy cattle using in vitro embryo production*, Bio/Technology 9, 1991, pg. 844-847.

[18] Jost, B. et al., *Production of low-lactose milk by ectopic expression of intestinal lactase in the mouse mammary gland*, Nature Biotechnology: 17, 1999, pg. 160-164.

[19] Teufel, J. et al., *Specific research on transgenic fish considering especially the biology of trout and salmon*, Umweltbundesamt (ed.), *Texte 64/02*, Berlin 2002.

[20] Niemann, H., Marquardt, O.-W., *Entwicklungsstand und Anwendungsperspektiven der Gentechnologie in der Tierproduktion*, Sill, B. (ed.), *Bio- und Gentechnologie in der Tierzucht*, Stuttgart 1996, pg. 56.

[21] Examples: concerning hereditary immunisation cf.: Lo, D. et al., *Expression of mouse IgA by transgenic mice, pigs and sheep*, European Journal of Immunology 21, 1991, pg. 1001-1006; On "scrapie" cf.: Denning, C. et al., *Deletion of the (1,3) galoctosyl transferase (GGTA1) gene and the prion protein (PrP) gene in sheep*, Nature Biotechnology, 19, 2001, pg. 559-562. On inflammation of the udder (mastitis) Kerr, D. E. et al., *Lyostaphin expression in mammary glands confers protection against staphylococcal infection in transgenic mice*, Nature Biotechnology 19, 2001, pg. 66-69.

[22] Phosphorous is present in the widely used feedstuffs cereal, rape and soya mainly in the form of phytate, which can only be absorbed after breakdown by the enzyme phytase

and not by the organism directly. Golvan, S.P. et al., *Pigs expressing salivary phytase produce low-phosphorus manure*, Nature Biotechnology 19, 2001, pg. 741-745.

[23] Hew, C. L. et al., *Liver-specific and seasonal expression of transgenic Atlantic salmon harboring the winter flounder antifreeze protein gene*, Transgenic Research 8(6), 1999, pg. 405-414. Hew, C. L., Fletcher, G., *Antifreeze proteins in teleost fishes*, Annu. Rev. Physiol. 63, 2001, pg. 359-390.

[24] Amanuma K. et al., *Transgenic zebrafish for detecting mutations caused by compounds in aquatic environments*, Nature Biotechnology 18, 2000, pg. 62-65. Carvan, M. J. et al., *Oxidative stress in zebrafish cells: potentially utility of transgnic zebrafish as a deployable sentinel for site hazard ranking*, The Science of the Total Environment 274, 2001, pg. 183-196.

[25] McEnnulty, F. R. et al., *A review of rapid response options for the control of ABWMAC listed introduced marine pest species and related taxa in Australian waters*, Centre for research on introduced marine pests, Technical report No. 23 CSIRO marine research, Hobart 2001,101 pp.

[26] The Ministers of the Environment for the states bordering the North Sea supported the Bergen Declaration, agreed at the 5th International North Sea Protection Conference in March 2002 for closed holding tanks on land (known as closed circulation systems) representing an already existing alternative.

[27] Brem, G., Müller, M., *Large transgenic animals*, N. Maclean (ed.), *Animals with novel genes*, Cambridge 1994, pg. 179-233; Amoah, E. A., Gelaye, S., *Biotechnology advances in gat reproduction*, Journal of Animal Science 75, 1997, pg. 578-585; Gibson, Y., Colman, A., *The generation of transgenic sheep by pronuclear mikroinjection*, L. M. Houdebine (ed.), Harwood Academic Publishers, Amsterdam 1997, pg. 23-25.

[28] In the cloning technique known as nuclear transfer, the cell nucleus of a somatic cell is transferred into an unfertilised egg cell, the nucleus of which has already been removed ("Dolly" the sheep) the success rates in sheep. goats and cattle are around two percent.

[29] Amman, D., Vogel, B., *Transgene Nutztiere*, Landwirtschaft – Gene Pharming – Klonen, Züricher Tierschutz (ed.), Zürich 2000. Meier, M. S. et al., *Transgene Tiere: Nutzung, Risiken und Möglichkeiten der Risikovermeidung*, Umweltbundesamt (ed.), Berlin 2003.

[30] Ruminants are capable of converting low-quality food and can therefore be grazed on land unsuitable for crop production. However, the yield for feedstuffs with a high fibre content is low. Only 10-35% of the energy input is converted, as 20-70% of the cellulose cannot be digested by the animals. Green feedstuffs and silage are therefore often mixed with cereals which can lead to rapid fermentation. In order to improve ruminal fermentation, dietary ionophores, antibiotics or microbial feed additives have been used in the past. Whereas the first of these increases feed utilisation, microbacterial additives, which have been used for many years, encourage food uptake and so achieve the increased weight gain and milk production required. Wallace, R.J., *Ruminal Microbiology, Biotechnology and Ruminant Nutrition: Progress and Problems*, Journal of American Science 72, 1994, pg. 2992-3003.

[31] The ruminal bacterium *Butyrivibrio fibrisolvens* was genetically modified to enable it to detoxify fluoroacetate which occurs in the leaves of trees and shrubs in Australia, Africa and central America. Feeding trials for sheep have shown that the GMM can be introduced successfully into the rumen and become established there. The results, however, were still not satisfactory. Gregg, K. et al., *Genetically modified ruminal bacteria protect sheep from Fluoracetate poisoning*, Applied and Environmental Microbiology 64, 1998, pg. 3496-3498.

[32] Vanessa Houlder, *Field trials on gas emission*, Financial Times 26. and 27. 07.2000.

[33] *Bacillus thuringiensis* is the micro-organism most frequently used as a biopesticide to date and the world-wide turnover of Bt preparations has now reached 110 million dollars annually. Emmert, E. A. B., Handelsman, J., *Biocontrol of plant desease: a (Gram-) positive perspective*, FEMS Microbiology Letters 171, 1999, pg.1-9. A drawback of the mass use of these preparations is their comparatively high specificity. Researchers have therefore produced a recombinant Bt strain that shows high potency and also a broad spectrum of action because a further delta endotoxin has been introduced by genetic engineering. Two different toxins are expressed at the same time. In order to circumvent the light sensitivity of previous preparations (the active substance is rapidly inactivated under environmental conditions), the recombinant strain, that produces no spores, stores the toxin in the bacterium. This improves efficiency and also, in the view of the scientists, overcomes the problem of release into the environment. Sanchis, V. et al., *Developement and field performance of a broad-spectrum nonviable asporogenic recombinant strain of* Bacillusthuringiensis *with greater potency and UV resistance*, Applied and Environmental Microbiology 65, 1999, pg. 4032-4039. For further information on genetically modified biopesticides, see: Gorlach, K., *Problems in the Introduction of Genetically Engeneered Microorganisms into the Environment*, Acta Microbiologica Polonica 43, 1994, pg.121-131; Thompson, I. P. et al., *Survival, colonization and dispersal of genetically modified Pseudomonas fluorescens SBW25 in the phytosphere of field grown sugar beet*, Nature Biotechnology 13, 1995, pg.1493-1497.

[34] The green revolution on the one hand has brought about an enormous increase in production particularly of rice and maize, and on the other a gradual pollution of soil and water with herbicides, pesticides etc. In countries where the agricultural technology was introduced a major structural change has taken place in agriculture. Many small farmers have fallen into debt, lost their land and cannot afford to buy food; excess produce is exported. 180 million make up this stratum of the new poor, 22% of all starving people. *The Millenium-Project-Background Paper of the Task Force 2 on hunger*, UNDP, April 18th, 2003.

[35] Vogel, B., Potthof, C., *Verschobene Marktreife,* Gen-ethisches Netzwerk (ed.), Berlin 2003; Lheureux, K. et al., *Review of GMOs under Research and Development and in the Pipeline in Europe*. European Commission, Joint Research Centre, Institute for Prospective Studies, Sevilla 2003.

[36] Between 1997 and 1999 agrochemical trusts have spent 18 billion US-dollars on the acquisition of seed production companies, Orton, L. 2003: GM crops – going against the grain ActionAid. www.actionaid.org/resources/pdfs/gatg.pdf (August 2003). Today the four biggest agrochemical trusts: DuPont, Monsanto, Syngenta und Bayer are also the four biggest enterprises producing seeds. These four players own 90% of the world's commercialized transgenic plants and 50% of all patents. The high investments are well

safeguarded by the system of patents and the quasi monopolistic control of the seed market and they pay well: a profit of 673 billion US-dollars was generated from the sale of transgenic seeds. Vogel, B., Potthof, C., *Verschobene Marktreife,* 8 pp. The reasons for the success story of herbicide and insect resistance are: the characteristics can be achieved by the insertion of a single gene; the genes responsible have been known and isolated since the mid-80s; the characteristics increase yield or reduce production costs without modification of harvesting or processing methods; herbicides and resistant seed in combination bring reliable returns to the companies producing both, so that the high development costs can quickly be amortised.

[37] There are many reasons for reduced interest in output characteristics: Products that succeed only in niche markets make the expensive and painstaking process of development extremely risky; some breeding outcomes have not yet become competitive; the need to separate and maintain identity increases management time and costs; modification of output characteristics is considerably more complicated: while foreign genes for input characteristics can or must act throughout the plant, the genes for qualitative characteristics require differentiated activity and the necessary promoters for this are not always available; many of the desired quality characteristics require the introduction of a number of foreign genes which is difficult with existing technology; interventions in complex and well balanced metabolic pathways will not be possible without undesirable side effects. Vogel, B., Potthof, C., *Verschobene Marktreife,* 74 pp.

[38] Maxime Schwartz (French Agency for Food Safety) stated at the *hearing of the COE Committee*: "Le débat porte essentiellement sur la quantité de riz qu'il faudrait ingérer pour pallier la carence en vitamine. L'étude réalisée par L'AFSSA fait apparaître les incertitudes qui pèsent sur l'evaluation de cette quantité et recherché les causes de cette incertitude. On constate que, selon les hypotheses retenues, la consummation journalière de riz nécessaire pour remédier de facon significative aux carences en Vitamine A va de 90 à 4500g. La consummation journlière moyenne de riz dans les pays considérés étant de 250 à 300g, une telle fourchette permet evidemment à tous les protagonistes de produire des chiffres conformes à leur point de vue. Une conclusion raisonnable serait qu'il trop tôt pour dire si les variétés disponibles actuellement pourront apporter une solution aux problèmes de carence en vitamine A, mais que les travaux sur le "riz doré" montrent que la conception et l'élaboration de plantes transgénique à des fins nutritionelles, notamment au benefice des pays en voie de development, n'est pas une utopie." For NGOs criticism of golden rice see:*GE rice is fool's gold*, Greenpeace, http://archive.greenpeace.org/~geneng/highlights /fbod/ goldenrice.htm; Comment of Benedict Härlin, http://archive.greenpeace.org/~geneng /highlights/food/benny.htm *Grains of delusion*, published jointly by BIOTHAI (Thailand), CEDAC (Cambodia), DRCSC (India); GRAIN, MASIPAG (Philippines), PAN-Indonesia and UBINIG (Bangladesh), February 2001; www.grain.org/publications/delusion-en.cfm.

[39] Mayer, S., *Non-Food GM Crops: New Dawn or false hope?* Drug production (Part 1); Grasses, flowers, trees, fibre crops and industrial uses, report by GeneWatch UK, 2003/ 2004 (below quoted as *Report GeneWatch UK)*.

[40] Compared with the USA, where a pharmaceutically active substance from transgenic plants is expected to reach the market in three years' time (a mouthwash containing antibodies to caries pathogens, from CaroRX), research in the EU is not so far advanced.

[41] AGRA-Europe 29/04, 19 June 2004. Further information: www.pharma-planta.org

[42] Generally FAO/ WHO, *Safety assessment of foods derived from genetically modified micro-organism*, Report of a Joint FAO/WHO Expert Consultation on Foods derived from Biotechnology, Geneva 2001, pg. 8. In Report FAO/WHO 2000, *Safety aspects of genetically modified food of plant origin*, Rome 2000, there was disagreement with criticism of the concept of substantial equivalence which basically continues to be useful, but was said to be "not in itself an end-point but rather the starting-point for safety evaluation."

[43] *Directive 2001/18 on the deliberate release into the environment of genetically modified organisms* is a 'horizontal' directive, which regulates experimental release and the placing on the market of GMOs. *Regulaton 1829/2003 on GM food and feed* regulates the placing on the market of food and feed products containing or consisting of GMOs and also provides for the labelling of such products to the final consumer. *Regulation 1830/2003 on traceability and labelling of GMOs and the traceability of food and feed products from GMOs* introduces a harmonised EU system to trace and label GMOs and to trace food and feed products produced from GMOs. *Regulation 641/2004 on the detailed rules for the implementation of Regulation 1829/2003. Directive 90/219/EEC, as amended by directive 98/81/EC, on the contained use of genetically modified micro-organisms (GMMs)* regulates research and industrial work activities involving GMMs under conditions of containment. This includes work activities in laboratories. The guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming were adopted by the Commission as a Recommendation on 23 July 2003, C(2003).

In January 2002 the Commission adopted a *Strategy for Europe on Life Sciences and Biotechnology: COM(2002)27 final*. The first and the second Progress Report were adopted 2003 and 2004: *COM(2003)96 final; COM(2004)250 final.*

[44] Bock, A.-K. et al., *Scenarios for co-existence of genetically modified, conventional und organic crops in European agriculture,* European Commission, Joint Research Centre, Institute for Prospective Studies, Sevilla 2002.

[45] Villar, J. L., *GMO contamination around the world*, Friends of the Earth International, Genetically Modified Organisms Programme, 1st ed. 2002, 2nd ed. August 2003. On Mexiko: Quist, D., Chapela, I., *Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico,* Nature 414, 2001, letters. Hirn, G., *Mexiko: Mais trotz Moratorium gentechnisch verunreinigt*, Bauernstimme 12, 2003, p. 10.Mexico has the largest diversity of maize plants in the world, with 56 different types and 16 000 varieties. The international maize and wheat research center (CIMMTY) in Mexico houses the most comprehensive maize gene bank. The US companies evidently accepted the contamination of this sensitive area without disapproval. Varieties were found in the native maize that are only approved in the USA as feedstuffs (StarLink).

[46] The most comprehensive investigation so far, into the effects of GMO on biodiversity is the farm-scale evaluation conducted by the British government. It showed overwhelmingly negative results. Burke, M., *GM crops-effects on farmland wildlife*, 2003, www.defra.geor.uk/environmental/gm/index

[47] A study based on German Ministry of Agriculture data has shown that the use of GMO in the USA led to a 22,500 tonne increase in the use of pesticides. Benbrook, Ch. M., *Impacts of genetically engineered crops on pesticide use in the United States: The first eight*

*years*, BioTech InfoNet, Technical Papers 6, 2003, www.biotech_info.net/technicalpaper6.html The International Plant protection convention (IPPC), one of the regulatory bodies for plant health and risk prevention recognised by the WTO is working on an international regulation for the treatment of "Crop varieties with special environmental risks", which makes provision for risk assessments ("Pest Risk Assessment") for products of biotechnology: www.ippc.int/IPP/En/events.jsp

[48] Concerning the findings of Prof. Hans-Hinrich Kaatz (Institut für Bienenkunde der Universität Jena) cf.: http://www.transgen.de/Aktuell/History/00_05_raps-bienen.html. In horizontal gene-transfer genes from one organism pass to another without a cross being necessary. Some micro-organisms can pick up DNA directly from their environment (transformation) or vectors (often viruses) can transfer DNA from one organism to another (transduction). The previous state of research was that examples of successful horizontal gene transfer were extremely rare in eukaryotes. Hankeln, Schmidt, *Transgene Tiere in Forschung, Medizin und Landwirtschaft*, Brandt, P. (ed.), *Zukunft der Gentechnik*, 1997, 117 pp. However, those examples in which horizontal gene transfer is suspected are particularly relevant to the safety debate. Several investigations have shown that transposable genetic elements (transposons) have probably passed by horizontal gene transfer from one species to another. Beesten, A. v., *Gentechnologie und Ernährung*, Umwelt-Medizin-Gesellschaft 16:3, 2003, pg. 177-187. Ho, M.-W., Ching, L. L., *The case for a GM-free sustainable world*, Independent Science Panel, London 2003, 31pp., 40 pp. on horizontal gene transfer.

[49] Expert report by Eimer, M. et al*., „Agrogentechnik" in den EU-Beitrittsländern*, Öko-Institut e.V. (ed.), Freiburg 2004, www.oeko.de

[50] Veronika Mora (Hungarian Environmental Partnership Foundation in Budapest) states at the *hearing of the COE Committee*: „Even where GMO legislation exists, the lack of enforcement appears to be a universal problem. In most cases it is attributed to the lack of administrative capacity and expert knowledge on the side of administrators – many countries have assigned maybe only one (or half-time) person to deal with GMOs in the Ministry of Agriculture, and no one elsewhere. The lack of state funding hinders the establishment of proper networks to sufficiently monitor imported seeds, feed and food products. Without public pressure there isn't much hope for improvement in this field."

[51] AGRAR-EUROPE 23/04, 7 June 2004.

[52] Anonym Genet-news 2000. Kruszewska, I., *The situation with genetically engineered crops and food in Eastern Europe and the former Soviet Union*, ANPED (The Northern alliance for sustainability), 2001, www.genet-info.org/-documentsBauernstimme.pdf. Online 12.11.2003 Schweiger, T., *EU-Enlargement - The introduction of GMOs by back door of EU accession*?, Friends of the earth and ANPED (ed.), 2003.

[53] Initiatives to create a trans-border zone in the alpine-Adriatic area of Slovenia, Italy (Friuli-Julian Venetia and Austria (Carinthia): see www.genfood.at Zarzer, B. 2004, Geht die Gen-Saat im Osten auf (Is the gene seed sprouting in the East)? 13.08.04 at www.heise.de

[54] Ho, M.-W., Ching, L. L., *The case for a GM-free sustainable world*, Independent Science Panel, London 2003, pg. 37-39.

[55] ibid., 31 pp., 40 pp.; quotation below cf.: pg. 48-50.

[56] Ibid.:“Glufosinate ammonium is linked to neurological, respiratory, gastrointestinal and haematological toxities, and birth defects in humans and mammals. Gyphosate is the most frequent cause of complaints and poisoning in the UK, and disturbances of many body functions have been reported after exposure at normal use levels. Glyphosate exposure nearly doubled the risk of late spontaneous abortion, and children born to users of glyphosate had elevated neurobehavioral defects. Glyphosate causes retarded development of the foetal skeleton in laboratory rats. It inhibits the synthesis of steroids, and is genotoxic in mammals, fish and frogs. Field dose exposure of earthworms caused at least 50 percent mortality and significant intestinal damage among surviving worms. Roundup causes cell division dysfunction that may be linked to human cancers.”

[57] Ewen, S., Pusztai, A., *Effects of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine*, Lancet 354, No. 9187, October 16, 1999, pg. 1353-1354; for Pusztai’s full rebuttal to his critics see also http://plab.ku.dk /tcbh/PusztaiPusztai.htm. Jeffrey M. Smith described the processes in detail in his book on the health risks of GMO. Smith, J. M., *Trojanische Saaten*, München 2004, pg. 17-68. The German edition contains a footnote by Christine von Weizsäcker. The American original edition was published under the title *“Seeds of Deception”*, Fairfield, IA (USA) 2004. Many scientists and journalists have had the same experience as Pusztai. The extent of manipulation and campaigns to destroy professional reputations which have been documented are extremely worrying.

[58] According to the Frankfurter Allgemeine Sonntagszeitung, 12 Sept. 2004, No.37, p.65 Pusztai expressed the following criticism: Companies would produce irrelevant data mountains that only caused confusion. In truth the dossiers almost always contained no fine microscopic data on the gastrointestinal tract, although this was the first thing to come into contact with the GM vegetable. Also, the rats tested were usually too old to discover minimal differences in growth such as he found at that time. “With the tests used, only catastrophic differences could be discovered”, said Pusztai. But nobody expects those, it’s more a question of unexpected chronic effects. The authorities simply did not exert sufficient pressure on the companies to use new methods to obtain genuine answers to decisive questions on the safety of genetically modified foods. The requirements of Mae-Wan Ho and colleagues for the design of future studies were based on Pusztai’s study. Ho, M.-W. et al. 2003, pg. 47.

[59] According to the *EU Novel Food Directive* of 1997: foods containing live genetically modified organisms, or products isolated or processed from GMO, but also substances with new types of chemical structures, products from non-traditionally used raw materials, products from foreign culture groups and traditional foods treated or processed using new technical methods.

[60] Beesten, A. v., 2003, 178 pp.: “With the release and feeding of genetically modified organisms with no previous investigation by long term studies, an uncontrolled experiment is instead being conducted on the whole of humanity, animals and the ecosystem.”

[61] For transgenic cattle, there is no risk of cross-fertilisation in Europe, since wild forms of cattle (urus) became extinct in the 17th century, but it is possible in Africa and Asia since there are potential mating partners (water buffalo, yaks, gaur). For sheep and goats the situation is similar, because potential partners (moufflon, bezoar goat) now occur in very

few areas of the world. For domestic pigs, there is the possibility of cross breeding with wild boar.

[62] In Australia at the end of the 80s, there was an explosion in the population of wild rabbits that had developed resistance to the myxomatosis virus. The effects on the ecosystems concerned were serious.

[63] Several million farmed salmon from aquaculture systems in Canada, Iceland, Ireland, Norway, Scotland, USA and the FaroIslands have escaped in this way in recent years. The farmed salmon are a threat, as a result of transfer of parasites and pathogens, to the stocks of wild Atlantic salmon which have existed for decades. These populations, which are well adapted to their environment, are subjected to “contamination” of their gene pool from the farmed salmon genome, if negative characteristics are bred in.

[64] Muir, W. M., Howard, R. D., *Possible ecological risks of transgenic organism release when trangenes affect mating success: sexual selection and the Trojan genes hypothesis*, Proceedings of the National Academy of Sciences USA 96, 1999, pg. 13853-13856; Muir, W. M., Howard, R. D., *Fitness components and ecological risk of transgenic release, a model using Japanese medaka (Oryzias latipes)*, The American Naturalist 158 (1), 2001, pg. 1-16; Muir, W. M., Howard, R. D., *Assessment of possible ecological risks and hazards of transgenic fish with implications for other sexually reproducing organisms*, Transgenic Research 11, 2002, pg. 101-114; Potthof, C., Teufel, J., *Biologisch unsicher: Transgene Fische*, Gen-ethischer Informationsdienst GID-Nr. 17:3-6, Gen-ethisches Netzwerk e.V., Berlin 2003.

[65] Breton, B., Uzekova, S., *Èvaluation des risques biologique liés à la dissémination de poissons génétiquement modifiés dans les milieux naturels*, C. R. Acad. Fr. 86 (6), 2000, pg. 67-76. Maclean, L., Laight, R., *Transgenic fish: an evaluation of benefits and risks*, Fish and Fisheries 1, 2000, pg. 146-172.

[66] A fifteen-day study with transgenic cichlids in eleven volunteers in Cuba: Guillén, I. et al., *Safety evaluation of transgenic tilpia with accelerated growth*, Marine Biotechnology 1, 1999, pg. 2-14.

[67] Various investigations have found that transgenic fish lines have a modified physical make-up compared with non-transgenic control groups. Differences have often included increased water content, modified amino acid composition, reduced fat content and increased protein content. The nutritional effects of these modifications have not yet been investigated.

[68] Brem, G., Müller, M., *Large transgenic animals*, N. Maclean (ed.), *Animals with novel genes*, Cambridge 1994, pg. 179-233.

[69] Pandian, T. J. et al., *Problems and prospects of hormone, chromosome and genemanipulated fish*, Current Science 76 (3), 1999, pg. 369-386; Dunham, R.A., *Utilisation of transgenic fish in developing countries: potential benefits and risks*, Journal of the World Aquaculture Society 30 (1), 1999, pg.1-11.

[70] Varga, G.A., Kolver, E.S., *Microbial and anomal limitations to fiber digestion and utilization*, Journal of Nutrition 127 (Suppl.), 1997, pg. 819S-823S.

[71] Tappeser, B. et al., *Untersuchung zur tatsächlich beobachteten Effekten von Freisetzungen gentechnisch veränderter Mikroorganismen*, Öko-Institut Freiburg e.V. (ed.), Freiburg 2000.

[72] Natsch, A. et al., *Impact of Pseudomonas fluorescens strain CHA0 and aderivate with improved biocontrol activity on a culturable bacterial community on cucumber roots*, FEMS Microbiology Ecology 27, 1998, pg. 365-380. Experiments to minimise survival capability with "suicide genes" have not proved reliable. Dresing, U. et al., *Peresistance of two bioluminescent Rhizobium meliloti strains in model ecosystems and in field release experiments*, Kalinowski, J. et al., *Abstracts of the annual meeting of the genetic society 1995 in Bielefeld*, Köln 1995, pg. 18; Tappeser et al., 2000.

[73] In the field of organisms there are three different mechanisms of horizontal gene-transfer, transformation, conjugation and transduction. Transformation is the uptake of free dissolved DNA and its integration in the genome of an organism. This mechanism can be natural, if no further treatment is needed, or induced, if the cells have to be submitted to chemical or physical treatment in order to perform transformation. Conjugation is the transfer of DNA between one cell and another, necessarily requiring direct cell to cell-contact. This mechanism plays an important role in nature as well as it is a useful tool for scientific investigation. Intraspecies conjugation is the transfer of DNA between two cells of the same species while interspecies conjugation is the transfer of DNA between two cells of different species. The transfer of DNA between two cells without the need of cell to cell-contact is refered to as transduction. The DNA is transferred between the two cells within lifeless envelopes, which can be provided by viruses for example.Ludwig, A., *Gentransfer im Cyanobakterium Synechocystis sp PCC6803*, Wien 2002. summary under: http://www.arcs.ac.at/dissdb/rn037419

[74] Emmert, Handelsman 1999.

[75] ibid. Just recently it was discovered that a potential biopesticide has a vancomycin resistance pattern similar to that of resistant Enterococci (gut bacteria). This has possible consequences for resistance development in human pathogenic organisms. Patel, R. et al., *The biopesticide Paenibacillus popilliae has a vancomycin resistance gene cluster homologus to the enterococcal VanA voncomycin resistance gene cluster*, Antimicobila Agents and Chemotherapy 44, 2000, pg. 705-709.

[76] Sauter, A., Meyer, R., *Risikoabschätzung und Nachzulassungs-Monitoring transgener Pflanzen - Sachstandsbericht.*TAB-Arbeitsbericht Nr. 68, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Berlin 2000.

[77] Cf.: *Report* GeneWatch UK.

[78] US regulations see on http://www.aphis.usda.gov/ppq/biotech/pdf/pharm-2002.pdf.

[79] *Report* GeneWatch UK, p. 28 recommends that: 1. physical containment (in green houses) or reliable and proven biological containment (to prevent gene flow via pollen) must be required for testing and production of therapeutic compounds in GM plants. 2. only non-food crops should be used. 3. research on environmental impacts must be undertaken urgently. 4. the government must review the use of GM crops for drug production, including their safety and likely efficacy in relation to other desease control methods. Its aim should be to produce clear standards by which the industry would be expected to

operate.

[80] OECD, *Safety evaluation of foods derived by modern biotechnology: Concepts and principles*, Organisation for Economic Cooperation and Developement, Paris 1993; FAO / WHO, *Strategies for assessing the safety of foods produced by biotechnology*, World Health Organisation, Geneva 1991; FAO / WHO, *Biotechnology and food safety*, FAO food and Nutrition Paper 61, Food and Agriculture Organisation of the United Nations, Rome 1996. FAO / WHO, *Safety aspects of genetically modified foods of plant origin*, World Health Organisation, Geneva 2000; FAO / WHO, *Evaluation of the allergenity of genetically modified foods*, Food and Agriculture Organisation of the United Nations, Rome 2001.

[81] Bock, A.-K. et al., *Scenarios for co-existence of genetically modified, conventional und organic crops in European agriculture,* European Commission, Joint Research Centre, Institute for Prospective Studies, Sevilla 2002.

[82] Pickardt, A., Fluri, P., *Die Bestäubung der Blütenpflanzen durch Bienen* (The pollination of flowering plants by bees), Biologie, Ökologie, Ökonomie, Bieneninstitut, Schweiz 2000. Statement of the Deutscher Berufs- und Erwerbsimkerbund e.V. (German Professional Beekeepers Association, DBIB); cf. Also the detailed presentation on agroengeneering and beekeeping, organised with DBIB and the representatives of Demeter beekeepers (Melifera e.V.) on the 29.04.2004 in Berlin (below quoted as: *technical discussion*, DBIB) http://mellifera.weitblick.de/fix/docs/files/GVO%20Statement%20CDU.pdf

[83] In response to my written question on this subject, the Parliamentary Secretary of State Gerald Thalheim made the following statement: "The European Commission commented on the problem at a meeting of the standing committee on food safety and animal health on 23 June 2004 in Brussels. The Commission pointed out that honey is regarded as an animal product and is therefore not subject to the labelling requirement. This is clear from regulation 2001/110/EC of the Council dated 20 December 2001 concerning honey. According to this, honey is the natural sweetener produced by bees of the species Apis mellifera, bees collecting nectar from plants or the secretions of living parts of plants or secretions found on living parts of plants by insects that feed on plants, convert this by combination with their own specific substances, deposit it, dehydrate it and store it in the combs of the beehive and allow it to mature. The Commission further stated that exception from the labelling requirement under Directive 1829/2003 applies to pollen, if its presence is accidental or technically unavoidable and the content is below the threshold value of 0.9%. Pollen from GMOs that are neither approved nor tolerated in the EU, exclude honey from distribution.

[84] German gene technology legislation, on which the legislative process is presently concluded, at present makes no provision for compensation if products are not subject to the labelling requirement or become subject to this legislation as a result of contamination with GMO. The right to protection and compensation is regulated in § 36a Gentechnik-Gesetz (gene technology legislation) (definition of fundamental impairment) and relates to the requirements of §§ 1004, 906 BGB on neighbourhood rights and therefore transfers the principle of fault-free liability to the application of gene technology in agriculture. The plaintiff does not have to prove which of his neighbours is responsible for the contamination. The prerequisite of a neighbourhood relationship, however, presumably does not apply between the grower of GMO and the beekeeper who sets up his hives somewhere in the countryside. Even if users of gene technology were to contravene the

regulations on “good specialist practice” (legal directive on this subject is so far merely announced), the beekeepers have absolutely no right to any claim for compensation.

[85] Information from Genescan Analytics GmbH, Freiburg, quoted from: *technical discussion*, DBIB.

[86] Süddeutsche Zeitung on 02.07.03: only 8% of those questioned by Greenpeace did not give this promise. See also Greenpeace shopping bag.

[87] Study by the National Research Council (USA) in 2001, quoted from: *Environmental Effects of Transgenic Plants*, The Scope and Adequacy of Regulation, National Academy Press, Washington 2001, pg. 224-225.

[88] Report on coexistence between genetically modified crops and conventional and organic crops was adopted by the European Parliament on December 4$^{th}$ 2003. (2003/2098 (INI)) A5-0465/2003 final. The most important requirement is the labelling of seed at the limit of technical detection (0.1%).

[89] *Technical discussion,* DBIB: “The LD-50 method is completely inadequate in this case and also for crop protection agents, firstly since this investigates the damage to adult bees only, and only with regard to mortality and not to social and group behaviour etc. and the effects on the brood. For these risks, broad-based long term investigations are necessary.”

[90] Agriculture is sustainable when it is ecologically sound, economically viable, socially just, culturally appropriate, humane and based on a holistic approach. Cf.: Ho, M.-W. et al., 2003, pg. 53-92. There are a lot of studies as well as scientific research papers documenting the successes and benefits of sustainable agricultural approaches, including those of organic farming, which have been reviewed recently by the FAO and ISIS: *Organic Agriculture, environment and food security*, Scialabba, N.-H., Hattam, C. (eds), FAO, Rome 2002; Lim, L.C., *Organic Agriculture fights back*, Science and Society 16, 2002, pg. 30-32.

[91] *Genschäden nicht versichert* (Genetic damaged not insured) Bauernstimme 01/2004, pg. 14; Gen-ethischer Informationsdienst 160, Okt./Nov. 2003, pg. 34.

[92] In relation to biotechnology, the Cartagena protocol which has so far been signed by 107 states (including the EU) as part of the UN Convention on Biological Diversity (CBD) provides for regulation of liability. At the first conference of the treaty states in February 2004 in Kuala Lumpur, the states expressly agreed a procedure for the concretisation of liability in biotechnology by 2007.

[93] German Federal Government sustainability strategy see: www.bundesregierung.de/Themen-A-Z/-,11405/Nachhaltige-Entwicklung.htm

[94] Concerning the situation in Canada cf.: Hall, L. et al., *Pollen flow between herbicid-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers*, Weed Science 48, 2000, pg. 688-694; Beckie, H.J. et al., *Impact of herbicide-resistent crops as weeds in Canada*, Proceedings Brighton crop protection Conference – Weeds, 2001, pg. 135-142; Orson, J., *Gene stacking in herbicide tolerant oilseed rape, lessons from the North American experience*, English Nature Research Report 443, 2002, www.englishnature.org.uk

Concerning the case of Percy Schmeiser cf. Beesten, F. v.: *Patente auf Leben: David gegen Goliath*, Umwelt-Medizin-Gesellschaft 17, 2004, pg. 43-45.

[95] Mishra, S., *Genetically engineered rice? Take a look at farmers' varieties*, Hindustan Times, IndiaDecember 12th 2002. General information concerning seed offers the campaign SOS (safe our seeds):

www.saveourseeds.org

[96] After a long lasting controversial debate in Germany, the Directive will be regulated in national law in the immediate future. The compromise settled is not satisfying, because it only applies to requests for patents in Germany.

[97] Farmers' privilege: Farmers are entitled to use part of their crop of seed of a variety protected by law for resowing; breeder's privilege: protected varieties may be used to breed new varieties without paying a licence fee for this or seeking permission from the original licence holder.

[98] A recent example of this practice is the "plants" patent issued on 21 May 2003 by the EPO (EP 445 929). The patent holder is Monsanto. The patent covers wheat with a particular baking quality. The reason for the special quality of the wheat lies not in gene manipulation but in a naturally occurring combination of genes. This results in a certain reduction in the proportion of protein in the grains. This makes the wheat suitable for particular items of bread and confectionery. Originally wheat with this characteristic was bred in India. Now Monsanto have a monopoly over growing, breeding and processing of wheat with this special inherited characteristic, because the genetic sequence was decoded in the laboratory. The EPA has now revoked this patent. After the objection of Greenpeace the patent has been withdrawn by the EPA, although it still remains valid in the USA, Canada, Australia and Japan.

[99] Aerni, P., *Public acceptance of genetically engineered food in developing countries: the case of transgenic rice in the Philippines*, IAW/ ETH Zürich Publications 1998, Ernährung sichern – mit allen Mitteln? MISERIOR 2003.

[100] Spangenberg, J. H., *Gentechnik und Welternährung: Versprechen machen nicht satt*, Umwelt Medizin_Gesellschaft 16, 3, 2003, pg. 188-192.

[101] Konrad Ott at the *hearing of the COE Committee*.

[102] Information and references on this section from: *Transgene dürre- und salztolerante Pflanzen*, Gentechnik-Nachrichten Spezial 15, Öko-Institut e.V., Freiburg, February 2004. (Available in an English version.) Particularly affected by water shortage at present are some of the southern developing countries (14 countries in Africa, large parts of Asia), but also the southern states of the USA have suffered water shortages due to drought in the past four years. Problems with salty soils are particularly great in China, India, Thailand, Indonesia, Australia and a number of regions in Central Asia. Naturally occurring saline soils are often found in coastal regions. In some countries such as Egypt or Israel saline ground water makes the cultivation of crops difficult.

[103] Schmitz, G., Schütte, G., *Plants resistent against abiotic stress*, Hamburg 2000. A relatively great deal of attention has been paid to the production of a transgenic type of

tomato by the US American scientist Eduardo Blumwald and his team of researchers. By a scientifically induced increase in the AtNHX1 gene, increased salt tolerance was achieved due to the increased formation of a transport protein. The transgenic Tomatoes can store the salt in the cell vacuoles of their leaves, while the salt concentration of the fruits remains low. (Zhang, H.X., Blumwald, E., *Transgenic salt-tolerant tomato plants accumulate salt in foliage but not in fruit*, Nature Biotechnology 19, 2001.) Contrary to the widely held assumption that stress tolerance in plants can only be achieved by modifying several characteristics, here a high level of salt tolerance was possible by modifying only one characteristic. The same approach was successfully transferred to greenhouse tomatoes and release trials were applied for in 2003. (Moffat, A. S., *Finding new ways to protect drought-stricken plants*, Science Magazine, May 2002. In the meantime the company Seaphire International based in Phoenix (USA) has acquired the licence to the biotechnological method used in this connection. The aim is to develop agricultural production systems with salt-tolerant crops. In dry coastal regions the plants would be irrigated with sea water, possibly in combination with aquaculture. The company's employees are currently experimenting in Arizona und Mexico. http://www.gene.ch/genet/2002/Jul/msg00043.html

[104] See http://www/transgen.de/dgg/Proto_runde2/DP_Sonnewald_vanAken.pdf. The specific risks of transgenic plants in this area are associated with the fact that abiotic environmental conditions (water supply, salt content, nutrient supply, cold, heat or toxic metals) have a major influence on the geographic distribution of plants. Ecological risks from stress-tolerant plants could therefore arise from the colonisation of new ecologically valuable areas and the displacement of rare species, there has been almost no research into risks to date. Basically it may be said in relation to these plants that the potential for their proliferation as weeds increases in proportion to their level of stress tolerance.

[105] *Western GMO opponents threaten efforts to feed world' s poor.* http://www.un.newsedgeweb.com

[106] The FAO report entitled *World Agriculture: towards 2015/2030* states that by 2030 sufficient food can be grown for the increasing world population up to 2030.

[107] Pretty, J., Hine, R., *Reducing food poverty with sustainable agriculture: a summary of new evidence*, Centre for Environment and Society, University of Essex, UK 2001. The systems investigated involved a number of different measures to achieve an improved food supply for people under their own regional conditions: e.g. more intensive use of gardens, improved irrigation management, introduction of new elements in an existing agricultural system (fish farming in rice fields or agro-forestry).

[108] Lewis, R., *Using transgenesis to create salt-tolerant plants*, The Scientist, march 2002.

[109] TAB-Brief (German Office of Technical Assessment), Nr. 18, August 2000, pg. 5: from a pragmatic point of view it is argued that there should be a shift in intellectual effort from the level of the general normative debate to the level of practical possibilities for implementation and their promotion. The debate on the normative level continues to be important, but achievement of a "final consensus" in fundamental controversies is a utopian ideal.

[110] Council for sustainable development in Germany, conclusions from the *Snapshot on sustainability and society*, contributions to the progress report on national sustainability

strategy 2004, p. 2: "Direction is the scarcest resource in the sustainability debate."

[111] Ecology, economy and social security are seen as three equally valid pillars standing together. The European Commission gives the view in its sustainability strategy that social, ecological and economic development should go hand in hand, i.e. traditional partial optimisation should be replaced by an integrative approach taking account of interdependencies. The reason given for the selection of this model was that it was the one that best met the targets for satisfaction of the needs of different generations, as contained in the report of the World Commission on Environment and Development. (WCED 1986) *A European Strategy for Sustainable Development (Commission's proposal to the Gothburg European council)*, Brussels 15.5.2001, COM(2001)264 final. See Döring, R., Ott, K., *Nachhaltigkeitskonzepte*, Zeitschrift für Wirtschafts- und Unternehmensethik Jg. 2, Heft 3, 2001, pg. 315-339, 318 pp.: "Emphasising the equal ranking of the three dimensions undoubtedly represents an upward revaluation of environmental considerations by comparison with previous concepts. However, whether the three pillar model can fulfil its own promise of guaranteeing this equal ranking is questionable. In the three pillar model, prioritisation of conflicting objectives with regard to time can be based on pragmatic considerations, decision, balanced judgment or negotiation. The players may negotiate on many aspects. This will, however, call into question the equal ranking of the pillars. It is therefore quite possible, in the context of the three pillar model, to define sustainability as the ecological and social flank of economic structural change. A defect of the pillar model is that it takes the levels of concepts and guidelines in one jump. It pays for its political appeal in the foreground with systematic deficits. This finally also makes it unattractive at the political level, since the exact basis of its advantage over the established areas of economic, social, educational and environmental policy, and the setting of priorities by democratically empowered decision-makers becomes uncertain." On occasion of the *hearing of the COE Committee* Konrad Ott has transferred various aspects of his concept of strong sustainability onto the green biotechnology. The below listed sketches have been taken from the protocol of that session.

[112] *very weak sustainability* implies continuous growth (GDP); *weak sustainability* assumes far-reaching substitutability between nature and man-made capital; *intermediate sustainability* requires conservation of "critical" natural capital, which as such is difficult to define; *strong sustainability*, in addition to conservation of natural capital (omission), also requires investment in natural capital; *very strong sustainability* goes beyond 4., by respecting the inherent moral value of (some) natural entities

[113] Possible rules and guidelines in the concept of stronger sustainability are: 1. Maintain natural capital intact over time. 2. Restore and invest in natural capital if natural capital has been depleted. Release pressure on natural ecosystems. 3. Make the use of cultivated natural capital in agriculture and forestry truly sustainable in ecological, social, and economic respect. 4. Reduce the material throughput in the economic system. Replace non-renewable resources by renewables 5. Stop counting the depletion of natural capital as income 6. Move from the ideology of global economic integration by free trade.

[114] Sauter, A., *Risikomanagement transgener Pflanzen: Nachzulassungs-Monitoring als Lösung?*, TAB-Brief Nr. 20, Juni 2001, 6 pp.

[115] Rip, A., Van der Meulen, B. J. R., *The postmodern Research System*, Science and Public Policy 23, 1996, pg. 343-352. Nowotny, H., *Es ist so. Es könnte auch anders sein – Über das geänderte Verhältnis von Wissenschaft und Gesellschaft*, Frankfurt a.M. 1999.

[116] Nowotny, H., *Sozial robustes Wissen und nachhaltige Entwicklung*, GAIA 9 (1), 2000, pg. 1-2, (socially robust science and sustainable development) in: GAIA 9 (1): p. 1-2, sees a new form of production of knowledge that is problem-orientated, transdisciplinary but also limited in time and in the context of the application.

[117] Hennen, L., *Nachhaltige Entwicklung – eine Herausforderung für die Forschungspolitik*, TAB-Brief 18, 2000, pg. 24-26. The requirement is not only a substantively but a formally innovative concept of research promotion.

[118] Ho, M.-W. et al. 2003, pg. 53-93.

[119] German Federal Government sustainability-strategy (first progress report); *Biodiversity amongst other spheres of action*, www.bundesregierung.de/Themen-A-Z/-,11405/Nachhaltige-Entwicklung.htm

[120] Ott, *hearing of the COE Committee*: "In philosophy, one does not wish to give answers to fixed questions but to reflect upon the way questions are asked. We see two different questions related to genetic engineering: Question 1: "How can we secure (enduring) coexistence? How can we protect organic farming?" Question 2: "How can we ecologize agriculture and which role, if any, could "green" genetic engineering play? It is a pressing problem to answer the first question. In the longer run, the second question is more important."

[121] The fact that stress tolerance is an expensive hypothesis in terms of gene technology is demonstrated by a project with sweet potatoes in Africa, which was much celebrated in advance with great expenditure on PR as a breakthrough by green gene technology in the fight against hunger. The Kenyan Agricultural Research Institute (KARI) had to discontinue the planned three-year field trials because it became clear that the virus-resistant transgenic potatoes were no more resistant to virus than the conventional potatoes but that they gave considerably lower yields. Six million US dollars were invested in the project by Monsanto, the World Bank and the US government. The Scientist, vol.181, no. 2433, 7 February 2004.

[122] In the developing countries most crops have never been subject to breeding processes and a large proportion of the world's food is based on these "orphan crops", for which enormous improvements in yields could be achieved by normal breeding processes in combination with modern biotechnological methods. With conventional potatoes, for example, a 200-fold increase in yield was achieved by comparison with the original Indian tuber. Gene technology is not necessary for increasing yields, and with its extremely high overall development costs would not be justified in the small "orphan crops" markets. For actual projects, see http://www.isaaa.org/projects/africa/banana.htm andwww.bio.org/foodag/statements/20030326.asp.

[123] Weizsäcker, Ch., *Nachwort zu Smith, J. M., Trojanische Saaten*, München 2004, pg. 351-353.