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Ecological Impacts of Traditional Crop Plants - A Basis for the Assessment of Transgenic Plants?

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Summary

The risk assessment of transgenic plants, i.e. genetically modified higher plants (GMHPs), pursuant to EU Directive 94/15/EC, is aimed at investigating whether any risk of undesired effects may arise. For this assessment, not the method of production, but the traits of the individual organism are important; therefore, it must be possible to infer the behaviour of a plant from certain of its traits. In order to verify this assumption, a survey has been made of what is known about the ecological impacts from the cultivation of eleven conventional (non-transgenic) crop plants. No restrictions were made a priori with regard to the type of effects. On the basis of three case studies, we investigated whether the criteria in Annex II B of EU Directive 94/15/EC actually cover the surveyed effects.

The results show that it is hardly possible to infer effects directly from the traits. A (limited) correlation can be found in some cases, if the time frame and surface area are defined, and the recipient plant is well known. A reasonable risk assessment for long-life and genetically heterogeneous plants (e.g. forest trees) seems impossible. In agriculture, however, certain practices have a considerable influence on ecological impacts which – due to the shorter time frame – are more easily identifiable, but long-term impacts can hardly be assessed. Those adverse effects, which could be associated with certain traits to some extent, frequently correlate with maladjustment to the local environmental conditions (e.g. climate). Less attention is usually paid to these effects within the scope of conventional risk assessment. The results indicate that some of the premises on which the current assessment of transgenic plants is based must be queried:

- Conclusions with regard to anticipated effects cannot always be drawn from phenotypic traits with sufficient certainty – although this is a prerequisite for the currently practised form of risk assessment.
- The Concept of Familiarity – propagated by the OECD – seems not sufficient for the assessment of genetically modified plants. In order to make definite statements, too little is known about those ecological effects of conventional crop plants that can be attributed to certain traits and are thus accessible for a risk assessment.
- The Exotic Species model does not offer much help in the assessment either, since its general transferability to genetically modified organisms is doubtful, and a prognosis is hardly possible in the individual case. Much rather, the model makes statements on the medium- and long-term effects of introduced species on a statistical basis.
- The significance of the parameters „gene transfer“ and „invasiveness“ is much lower in practice than their importance for risk assessment, where they have hitherto been the main topic.
- Ecological impacts that are of major practical importance, on the other hand, are not taken into account in the risk assessment, because they concern agricultural practice. The reason for this may be that it is difficult to infer effects from the traits of a plant, even in simple cases. Correlations between certain plant traits, agricultural practices and ecological impacts are even more difficult to establish. Moreover, the statements can hardly be verified in practice.
- The limitation of risk assessment to impacts on "natural ecosystems"— i.e. excluding ecosystems that are used agriculturally – leads to a radical limitation of the scope of protection, especially since it is not quite clear what this term comprises.
- Finally, it is highly inconsistent to investigate only transgenic plants, when there is agreement that only the phenotypic traits and not the breeding technique is significant for a possible risk.

The findings indicate that the starting point for a risk assessment of new plants in general – and thus also for transgenic plants – is questionable. Generally, and in view of the rapid innovations in breeding, the current risk assessment appears to be overtaxed as an environmental protection measure that relies on the precautionary principle. Against this background, the following solutions are proposed:

- *In the long term,* the introduction of "ecological" breeding goals in terms of a prophylactic and extensive environmental protection would be an alternative worth considering. However, such goals would have to be clearly defined, since the concept is unclear and interpretations of the term differ. Definitions provided, this would allow more consistent regulations that do not place transgenic plants at a disadvantage, and market forces could be used for implementation.
- *In the short term,* the identified shortcomings could be relieved – despite the associated problems – by including the influence on agricultural practice into the assessment. As a temporary solution, it should be considered to amend the text of Annex II B of EU Directive 94/15/EC as follows

Section B

3. b) Specific abiotic factors affecting survivability (temperature, water, soil and nutrient needs, stress tolerances).

3. c) (new): Genetic homogeneity, genetic adjustment potential.

5. b) (new): Form of utilisation and cultivation.

6. In the case of plant species not grown in agriculture and forestry in the Member States, description of the natural habitat of the plant and the ecosystem in which it is to be grown, including information on natural predators, parasites, competitors and symbionts.

7. In the case of plant species grown in agriculture and forestry in the Member States, potentially significant interactions with the biotic and abiotic environment in the ecosystem in which it is usually grown, and possible changes to these interactions in the ecosystem in which it is to be grown, including information about toxic effects on humans, animals and other organisms.

Section D

9. Has any of the conditions for the interaction with other organisms and the abiotic environment been modified?

9. a) (new): Does the genetic modification allow, promote or require changes in agricultural practice, including possible expansion of the growing area?

Section H

4. Possible environmental impact resulting from potential interactions with other organisms and the abiotic environment.

5. (new): Possible environmental impacts resulting from agricultural practice that has been modified due to the new traits, including possible expansion of the growing area.

In order to implement the proposals, a list of undesirable practices could be considered. With ist help it could be investigated whether the new trait has the potential to promote or repress one or more of these practices. A monitoring, in which established institutions, agricultural consulting and companies could be integrated, should guarantee that the desired effect is actually achieved.

Contents

1 INTRODUCTION

1.1 STARTING POINTS

The risk of undesired effects may result from any cultivation of crop plants.

The cultivation of a crop plant with certain traits may have effects that are desired, such as higher yield, lower losses due to disease, easier processing, better product quality. On the other hand, there may also be a risk of undesired side effects in some cases, such as stronger erosion, changes in ground water level, residues from pesticides, etc. Also, events that affect the natural environment are possible, such as repression of natural species due to the greater competitiveness of invasive cultivated plants or gene transfer through cross-breeding with sexually compatible wild plants, if this produces hybrids with undesired traits. Whether this can actually happen depends largely on certain traits of the plant, such as the reproduction behaviour, resistance to pathogens and parasites, constituents, form of growth, demands on the soil and the climate, etc. Currently, the risk of undesired effects is not assessed in most cases, since the costs appear too high in comparison with the benefits.

In the EU, the risk assessment of genetically modified higher plants (GMHPs) is based on the assumption that there is currently too little experience with such plants to treat them like conventional ones.

Today, it is generally assumed that transgenic crop plants do not differ fundamentally from conventionally cultured plants, and that only the traits matter (OECD, 1992). Even so, genetically modified plants are assessed for possible risks in one way or another in all industrialised countries – even if the fact that they have been modified by genetic engineering is only secondary. In the EU there is a directive that applies exclusively to transgenic organisms (including plants). It regulates the modalities for their release and placing on the market . Thus, the risk of cultivation must be assessed a priori in each individual case. This discrepancy has led to sustained international discussions within the scope of the OECD, particularly with the USA (process- versus product-oriented regulations; Miller, 1995). The reason why the EU considers separate regulations to be necessary is the fact that fundamentally new traits can be introduced by the methods of genetic engineering. Also, in comparison with conventional breeding, more precise genetic modifications are possible. As we do not have more experience with such plants, a risk assessment must always be carried out according to a catalogue of criteria in the form of a questionnaire. This may be considerably simplified for certain well known and frequently used genes and traits.[1] The traits of the recipient plant, which are assumed to be known, and the newly introduced traits that could lead to a different behaviour are of central importance in the risk assessment. Whether the latter may bear a risk depends largely on the environment at the site of release. With regard to placing on the market, which is generally not subject to further requirements, the environmental aspect becomes secondary, since the modified plant can in principle be grown wherever physiologically possible.

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[1] Since some experience has meanwhile been gathered with transgenic crop plants (OECD, 1993 a), Annex II B of the original Directive 90/220/EEC (EC Council, 1990) has been replaced by Directive 94/15/EC (EU Commission, 1994 a), which contains more adequate criteria for plants. In addition, criteria for a simplified procedure for certain releases have been defined in Commission Resolutions 93/584/EEC and 94/730/EC (i.a.).

In the risk assessment of genetically modified plants pursuant to EU Directive 94/15/EC, information on new traits and on the risk that may be expected is required.

For example, item B 7. in EU Directive 94/15/EC, Annex II B (EU Commission, 1994 a) concerns the ecological interactions of the parental plant. Item D 1. requires a description of the modified characteristics and traits, and items D 4. and D 7.-D 9. deal with differences between the parental plant and the recipient plant (i.e. the one into which the gene is introduced). Last but not least, section H deals with comparisons of persistency, competitiveness of hybrids, and ecological impacts to be expected due to the introduced traits, as a result of interactions with target and non-target organisms. The applicant is required to draw conclusions with regard to the possible behaviour of the plants and effects resulting from the type of trait introduced. It is the essence of any risk assessment: the type and plausibility of unknown parameters (effects) are to be assessed on the basis of known parameters (traits).

The OECD has proposed concepts for the risk assessment of genetically modified plants, which are generally followed.

The OECD lists the following risk areas (OECD, 1993 a) for assessment:

- transfer of genetic material to natural cross-breeding partners,
- invasiveness due to competitive advantages,
- direct effects on target and non-target organisms, such as resistance against insects and pathogens,
- genetic and phenotypic variability, i.e. the development of unpredictable traits,
- effects of biological vectors and genetic material of pathogens used for the engineering of transgenic plants (e.g. Agrobacterium, plant viruses),
- human safety (work safety), particularly with regard to toxicity and allergenicity.

Experience with traditional crop plants (OECD, 1993 b) is the starting point for any risk assessment according to the Concept of Familiarity (OECD, 1993 a, p. 28 ff.). All available information about an organism/gene/environment must be used in order to define measures for the handling of transgenic plants. According to this concept, which has considerably influenced risk assessment throughout the OECD, the following information must be taken into account:

- experience with the crop plant, including its flowering and reproduction traits, site requirements, and breeding modifications to date,
- agricultural and ecological conditions at the site of release,
- experience with the specific new trait,
- results of earlier trials releases of the same or another plant with the same (new) trait,
- experience with the large-scale cultivation of varieties of the crop plant that were produced by conventional breeding,
- experience with the large-scale cultivation of plants that were produced using the same technique as the plant under investigation,
- presence of cross-breeding partners in the natural environment and potential for gene transfer,
- interactions between the crop plant, the environment and the trait.

On this basis, adequate measures for small-scale (for test purposes) or large-scale releases ("Scale-Up") are to be defined or, if this is not possible, releases must be banned. If the available knowledge and thus the "familiarity" is not sufficient to answer the ensuing questions, then special precautionary measures must be taken. The Concept of Familiarity is based on agricultural practice hitherto, and the experience with plants, traits and the environment thus gained. Uncertainty in the cultivation of transgenic plants is juxtaposed by the knowledge of established and recognised correlations, as far as they have been investigated. Ultimately, a picture of the possible behaviour of the new variety of a plant is developed by assessing interactions between plant, trait and environment. Possible effects must be determined in order to take adequate measures. This view is also shared by many in Austria (Gaugitsch and Torgersen, 1995).

If there is uncertainty rather than familiarity, on the other hand, we must be cautious, since undesired effects may occur. However, we cannot state in a general way when sufficient familiarity may be assumed, as this depends on the individual case. In case of doubt, an extensive risk assessment must be carried out, whereby lack of experience can be compensated for. The transgenic plant may be investigated in the laboratory, the greenhouse or on the field. Additionally it can be compared with related plants or plants with the same trait in other ecosystems. Ultimately, the concept assumes that plants with certain traits show a certain behaviour under certain conditions, i.e. certain effects are produced and others are not. If a parameter is changed, predictions are more difficult. But they are not impossible, if as close an analogy as possible is drawn and the correlation between trait and effect is established again by approximation.

The individual countries have different opinions on which effects must be taken into consideration for placing on the market.

The assessment of applications for the placing on the market of genetically modified plants within the EU shows that the individual countries interpret Directive 94/15/EC differently.[2] This is also how the EU Commission sees the situation (EU Commission, 1995).

Great Britain and the Netherlands are particularly active in this issue. They take the view that (in addition to toxicity) only possible direct effects should be assessed, in particular gene transfer, invasiveness and, in some cases, effects on non-target organisms. However, this applies only to the natural environment – i.e. to natural ecosystems, and certainly not to agricultural ones, for example. The development of field weeds resistant to multiple herbicides through the transfer of several resistance genes is regarded as a purely agricultural problem in Great Britain. The possibility of gene transfer alone, even if it is a gene that could mediate a selective advantage, does not constitute a reason to reject an application. This holds true as long as negative effects on the natural environment are not to be expected. According to the British opinion, undesired effects are primarily the repression of species.[3] In other words, invasiveness is only regarded as a problem, if it is associated with a clear risk of repression of species in a natural ecosystem. Effects that go beyond the immediate impacts of plants on natural ecosystems are not regarded as subject to risk assessment.

In contrast to this rather restrictive interpretation, the Scandinavian countries, and in particular Denmark, see the mandate of risk assessment as being more comprehensive.[4] Not only the direct effects of the individual plant, but also the effects that result from cultivation of the new breed should be taken into account. These include effects such as the possibility of increased use of herbicides in the cultivation of transgenic herbicide-resistant varieties. Another example may be the occurrence of resistant pest insects as a result of the cultivation of insect-resistant crop plants. This definitely includes effects that could result from cultivation of the plant under consideration, or effects the impact of which could be limited to agricultural ecosystems. The

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[2] The author has statements from some member states.

[3] Results of a workshop in Windsor in October 1993 (Department of Environment, 1993).

[4] Norway, although not a member of the EU, participates in the biotechnology regulations of the EU within the scope of the EEA, and is working towards a most comprehensive assessment.

British, in particular, and the EU Commission object that this opinion would hardly be covered by EU Directives 90/220/EEC and 94/15. They argue that effects resulting from agricultural practice would have to be discussed within the scope of variety or agricultural chemicals licensing, and not within the scope of biotechnology regulations. Even so, Austria has repeatedly referred to the "Danish line" in its statements, since this takes a more comprehensive view of environmental protection.[5] Thereby, long-term effects are crucial, the assessment of which is difficult since there are only very few scientifically tested models. One of these is the Exotic Species model, which is based on documented experience with established species.

The ecological effects of gene transfer and invasiveness are of a long-term nature. The Exotic Species model offers reference points for the assessment of long-term effects from experience with non-indigenous species.

Non-indigenous species may cause considerable undesired effects (US Congress, 1993). An analysis of long-term experience with such species (Sukopp and Sukopp, 1994) shows that the statistical probability of gene transfer or invasiveness effects is low. Often, these do not develop until the habitat or climate changes, which usually happens long after import of the foreign species and cannot be foreseen. Usually, non-indigenous species have less chance of survival than indigenous ones, but some succeed in establishing themselves. In some cases, they are more competitive than indigenous species, and in extreme cases the Exotic Species will even repress these. In transgenic plants, usually only one or few traits have been modified. Non-indigenous species, however, are "exotic" in their entire organism. A comparison is only possible, to a limited extent, if the new traits change the character of the plant fundamentally. Nonetheless, the Exotic Species model still offers a reference point as to which effects may occur after which lapse of time and with which probability, and also which traits could present an ecological risk. The model does not tell us anything about the risk of undesired effects in the individual case, since it makes only general statements and no forecasts on a case-to-case basis.

The Deliberate Release Directive, although it has only recently been modified, will be amended again in future. There is no agreement as to which direction this amendment will take.

Recently, an analysis of the practice of releases and assessments of applications in Europe was carried out (Levidow, forthcoming). It shows that the problems are partly due to differences of opinions on how the Release Directive should be interpreted, and also to the different traditions of risk regulation. These differences will be important for new product applications. A "Working Group on Risk Assessment" is currently trying to set up uniform procedures and parameters for risk assessment, which should be binding for all member states. This Group consists of representatives from the competent authorities and from science and industry in the EU countries. Initial results show that this working group is heading towards the British opinion in major aspects, but is also criticising it from the Danish position. This applies in particular to the environmental concept, which Denmark defines more broadly.[6]

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[5] See the Austrian statement on "Bt-Maize".

[6] According to the protocols of the meetings of the Working Group on Risk Assessment.

1.2 PROBLEM DEFINITION

The adequacy of the criteria in Annex II B of EU Directive 94/15/EC is to be checked in terms of whether they

- allow possible effects to be inferred from individual traits,
- take into account the environmental effects relevant in practice, and
- can appropriately cover secondary effects.

The following issues were considered particularly relevant:

What experience concerning ecological effects due to the cultivation of conventional crop plants is there? Which effects have been observed?

In the risk assessment, the conventional crop plant as the parental organism is to be compared with the transgenic plant. The behaviour of an agricultural crop plant depends on its traits, on agricultural practice, and on the ecological conditions. With breeding, the genetic equipment of crop plants has already been strongly modified and many new traits have been introduced. Therefore, so the idea, it must be possible to investigate the impact on the environment that the introduction of conventionally modified plants may have had. This raises the question which ecological effects of conventional crop plants have been observed in the past that could serve as a reference in the assessment of transgenic plants.

Which effects are relevant in practice? How relevant are the most frequently investigated parameters gene transfer and invasiveness?

In the past, breeding was aimed primarily at securing and increasing yield, reducing the processing costs, and improving resistance to pests and diseases. Impacts that occurred as side effects were seldom explicitly documented, although this does not imply that there were no such effects. However, they are obviously either difficult to identify, or no special attention was paid to them hitherto. Possibly, such side effects also concerned effects that were not regarded as a problem. They were more than made up for by a change in plant cultivation, a change in variety or fruit cultivated, or by increased use of production resources. Therefore, it was necessary to determine which environmental impacts resulting from the cultivation of crop plants have been documented, whether they are influenced by certain inbred traits, and how they were assessed. Since direct effects from gene transfer and invasiveness are currently the main issue in risk assessment for transgenic plants, it was necessary to determine to what extent such effects are documented, whether they caused changes in natural ecosystems, and whether they were regarded as negative in agricultural practice.

Can individual effects be attributed to certain traits? What are these effects and traits?

The Concept of Familiarity may identify areas of uncertainty. In order to take adequate measures, it is not sufficient to simply observe this. On the basis of the new traits, effects must also be predicted that may occur with a certain probability. The Concept of Familiarity therefore requires a risk assessment that establishes correlations between traits and effects, in order to permit meaningful statements. Whether it is actually possible in practice to infer effects from new traits is doubtful. Therefore, the question whether (and which) empirically determined effects can be attributed to certain traits of the plants was investigated.

Can effects be assessed in terms of whether they have been caused by the traits of the plants or by the cultivation conditions?

If correlations between the observed effects and individual traits of plants are to be established, we must ask to what extent these effects are caused directly, i.e. by the plant itself (e.g. through gene transfer and invasiveness of hybrids), or by agricultural practice (e.g. through maximum utilisation of the potential of a variety). In this way, it may be possible to compare the various interpretations of EU Directive 94/15/EC (see Chapter 1.1. Starting Points).

To what extent do plant traits determine the cultivation conditions?

On the other hand, such a distinction might not be possible, since cultivation methods and plant traits are mutually dependent on each other. It reminds of a "chicken-egg problem", where cause and effect are inseparably linked. Crop plants are usually bred according to specifications that are determined by the conditions of industrialised agriculture; only in this context do new varieties produce the desired yield and can environmental effects be elicited.

To what extent is it useful to take secondary effects into account in order to avoid a negative environmental impact?

If a negative environmental impact of any kind is to be kept as low as possible, it makes no difference whether we are dealing with direct or secondary effects. Direct effects are for example those of gene transfer or invasiveness,[7] secondary effects those from the cultivation of plants and the relevant agricultural practice.[8]

1.3 PROJECT OUTLINE

1.3.1 Procedure

Two institutes were commissioned to investigate the ecological effects of the cultivation of conventionally bred crop plants by expert interviews and a literature research: The department of agricultural research and biotechnology of the Austrian Research Centre Seibersdorf and the Austrian Institute of Ecology for Applied Environmental Research. The Austrian Federal Environment Agency, on behalf of which the study was carried out, expected different accents from the two groups of researchers, especially in the interpretation of results. The Institute of Technology Assessment of the Austrian Academy of Science was to attend the project meetings as moderator, head the planned workshops, and draw up a final report.

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[7] According to one view also taken by the EU-Commission, the issue is not gene transfer itself, but the effects thereof, which are regarded as undesired — in fact, these are also secondary effects, but in this case agricultural practice is of little importance.

[8] However, in order to take these into account a clear political will is necessary, since the assessment of secondary effects is problematic, agricultural practice difficult to anticipate and to control. As a reference, the assumption of status quo is realistic, i.e. the conditions of industrialised agriculture with the compulsion to maximise yield — although opposite tendencies towards a more „ecological agriculture", have recently been observed particularly in Austria (Lindenthal, 1993). See also the policy statement by the Austrian Federal Government of November 1994.

Preliminary surveys resulted in a "guideline" for the subsequent interviews, and the definition of plants for case studies. Subsequently, leading experts in Austria were interviewed in order to audit the status of knowledge with regard to breeding, cultivation, traits and ecological effects. In order to provide an opportunity for assessing the results of the other group and adjusting for possible inaccuracies, the reports were exchanged and commented on. Finally, summaries and interpretations of the results were prepared. A separate expertise was commissioned on the issue of spruce cultivation.

The reports, comments and summaries were sent to a number of Austrian and foreign experts, who were asked to comment. All results were discussed at a workshop and served as the basis for further procedure. Finally, we investigated whether the criteria in Annex II B of EU Directive 94/15/EC were suited for the assessment of the environmental impacts found. Three fictitious cases were assessed on the basis of these criteria. Deficiencies were found that went beyond the individual cases and certain modifications to the criteria appeared necessary, for which proposals were drawn up.

1.3.2 Selection of crop plants

As a working hypothesis, the following traits were postulated to have environment-relevant impacts (the order does not say anything about the relative importance of the individual traits):

- tendency to cross-breed
- invasiveness, especially persistency
- repression of varieties and cultivars
- constituents, especially toxicity, allergenicity
- resistances
- susceptibility for disease (need for plant protective), e.g. through high performance, growing habit or the importation of pests
- stress tolerance, especially resistance to cold, and early maturity or need for warmth,
- high demands with regard to water and nutrients
- root formation and influence on the micro-ecology

It was not clear from the beginning whether it would be more sensible to investigate different-species or traits. On the one hand, only environmental impacts that can be documented were to be investigated. An investigation by varieties seemed more sensible, since the effects usually did not result from the individually modified traits. On the other hand, there were drastic modifications to traits that also caused such effects (example: OO-rape). The investigation of effects that are generally known could, however, cover up others that are not so prominent. The question of whether species or trait should be more important could not be decided. Thus, the selection was made according to whether at least one trait that has shown an ecological impact can be examined with any given species.

A clear documentation of effects was also more important for the project goal than the geographic distribution and thus the economic importance of the plant. Therefore, "exotic" plants that showed obvious effects and were well investigated (e.g. Topinambour) were also included. Last but not least, effects that are caused by the traits of the plant were not to be differentiated from those that had occurred as a result of cultivation practice. For the final selection, the following categories were set up:

- **Agricultural crop plants**: maize, potato (also providing an example for the effects of imported pests) and oilseed rape proved to be very productive for the purpose of the study. Barley was regarded as worth investigation due to its monogenic resistances, soft wheat appeared to be of more general interest (good documentation, problem of stalk length).

Grasses such as cocksfoot, and field forage plants such as clover and alfalfa are often rather neglected, therefore they ought to be included. Although alternative cultures are not economically important and therefore not very widespread at present, some of them are well investigated. They show traits that appear important in the context of the study. Topinambour was chosen rather than hemp because of the available data.

- **Forest trees**: Issues of spruce cultivation are very complex, so that this tree seemed to be interesting, but problematic. The Robinia – like the spruce – is not very developed in terms of breeding, but it has generated environment-relevant changes. The cause of problems is easier to identify (root system, nitrogen fixation) and therefore more accessible for analysis. With the poplar, on the other hand, breeding effects and thus problems of crossbreeding are more important, and the situation is similar to that of some agricultural crop plants.
- **Fruit plants**: Due to the good database, the documented effects (for example due to the high plant protective needs) and the large cultivation surfaces, the apple was considered worth investigation. It was given preference over wine due to the numerous forms of cultivation, whereby the cultivation practice has changed completely in recent years. Other fruit trees (plum, pear, cherry) seemed less suitable.
- **Vegetables**: The main alternatives were radish and tomato on the one hand and Brassica oleracea with its many forms on the other hand. The situation of the pumpkin and paprika seems comparable to that of maize and is therefore covered. In addition, the carrot with its sexual compatibility with the wild carrot appeared interesting.
- **Ornamental plants**: In addition to the ailanthus, the rose and golden rod were considered interesting. The choice fell on the sunflower, which is also used in agriculture and the ecologically relevant effects of which are documented.

The species to be investigated were ultimately defined as:
Apple, carrot, cocksfoot, maize, potato, oilseed rape, Robinia, spruce, sunflower, Topinambour, wheat.

2 RESULTS

2.1 ELEVEN CROP PLANTS

The interviews and literature research led to summaries of the plants' biology and agronomic importance. For some of the plants, however, it turned out that the knowledge, in particular with regard to ecologically important parameters, was rather scanty. In general, there were few unambiguous indications of ecological impacts due to defined plant traits, which were supposed to be the main focus of the investigation. In particular, direct correlations between trait and effect could only be established in very few cases. Interesting accents resulted from the relating of certain breeding goals to observed effects. In the following, some of the results are summarised very briefly. For a more comprehensive understanding, please refer to the reports by the Austrian Research Centre Seibersdorf and the Austrian Institute of Ecology (Soja and Soja, 1995 a, 1995 b; Janssen *et al.*, 1995 a, 1995 b), and the report on the spruce (Geburek, 1995).

- **Apple:** Negative impacts may result from increasing genetic harmonisation through varieties that ensure good processing, uniform fruit quality and uniform yield, and that dominate as a result of market demands. However, they are often poorly adapted to the individual growing areas. The predominant use of a rootstock with feeble growth allows highly intensive orchard cultivation that can only be maintained with the help of high use of pesticides. Last but not least, such rootstocks show poorer rooting with lower nutrient absorbency and stability.
- **Carrot:** Ecological effects result primarily from cross-breeding with the wild carrot, which belongs to the same species. Hitherto, this was only a rather annoying phenomenon that could be reduced but not eliminated by suitable measures (distance between fields for seed cultivation and other fields, elimination of wild carrots in the surroundings), however. The views vary on the significance of gene transfer concerning traits of cultured carrot to wild carrot populations. The opinions range from "substantial influence" to "irrelevant, since the traits of the cultured carrot do not enhance competitiveness". In the long term, a considerable gene flow must certainly be expected.
- **Cocksfoot:** Cocksfoot has numerous traits that must be regarded as ecologically relevant, as considerable invasiveness, sexual compatibility, high competitiveness, ability to regenerate, hardiness, and persistence. Therefore, it is all the more remarkable that no effects can be reported. Apparently, either other parameters are also of significance for ecological relevance, or effects were simply not observed – maybe because they were not conspicuous.
- **Maize:** The tolerance of nitrogen (liquid manure) and triazine herbicides has led to ecologically alarming effects. At the same time, maize is productive and competitive in terms of profit. With the expansion of cultivation area due to the market demand, environmental problems have gained importance. Generally, these are the results of plant cultivation measures due to the industrialisation of agriculture. They cannot always be attributed directly to breeding, but would not have been possible without the traits of modern maize varieties.
- **Potato:** Hardly any indications of direct environmental impacts can be derived from an analysis of the cultivation of the potato – except for a few general influences from plant cultivation measures. Only the dependence on the use of pesticides may be environmentally relevant, but the agents that are used are not particularly toxic by comparison. There are a few high-yielding varieties with lowered disease resistance. Their promotion and the restric-

tion to a few varieties as a result of demands by the processors and the market enhances this problem of susceptibility. The introduction of resistances could help, but only for a short time in the case of monogenic forms. Some resistances bred in have resulted in constituents that jeopardise edibility.

- **Oilseed Rape:** With regard to ecological effects, there are only few indications despite the potential invasiveness and cross-breeding tendencies. The only exception is the impact on wild animals that perished after the excessive ingestion of rape without bitter constituents (OO varieties). However, it is unclear how this effect could be classified in terms of risk assessment, since it would hardly have been predictable.
- **Robinia:** Ecological effects result from a strong invasiveness, which is due to the same traits that make the Robinia attractive as a cultivated plant – high competitiveness, easy regeneration from the suckers and nitrogen fixation. As a pioneer tree, the Robinia promotes the proliferation of a regeneration-inhibiting ruderal flora at the edge of woods, on fellings, and on weakened woods in general. With its intensive suckers, the Robinia may have a sustained influence on the vegetation, thus also repressing indigenous species.
- **Spruce:** Pure spruce cultures show a certain lack of species diversity and thus a low browsing supply with a tendency towards browsing damages. Effects on the soil result from rooting habit (at high ground water level low sinkers and danger of uprooting), microclimate in stands (darker and more constant than for other species of trees), and the water-nutrient balance (possibility to neutralise the ion cycle). Genetic differences have not been investigated experimentally, although effects are likely. Thus, conclusions regarding the behaviour of genetically altered forest trees based on analogies to the effects of unmodified trees are difficult to establish. Thus, a risk assessment for transgenic trees on the basis of the criteria in Annex II B of EU Directive 94/15/EEC is of little use at present.
- **Sunflower:** Specific environmental impacts cannot be identified at present, but if the cultivation areas are expanded further, long-term problems with regard to water balance, erosion and the use of herbicides may ensue. A tendency towards genetic uniformity could cause problems with regard to yield and resistances. Little is known about the ecological significance of the early maturity that is being aimed at. It may be assumed that similar effects to those with maize may occur with regard to the expansion of the cultivation area. Due to the instability of temporarily invasive sunflowers and their hybrids, a high ecological significance is not to be expected.
- **Topinambour:** Ecological effects result primarily from the fact that Topinambour is permanently invasive, although not to the extent that could be expected due to its traits. The flora along the banks of rivers can be characterised by invasive Topinambour plants with their high water needs, whereby indigenous species may be repressed – although not very frequently. Secondary effects, such as the digging up of root tubers by small mammals and subsequent erosion damage to the river banks are controversial, but browsing may have effects on the competitiveness of wild animals.
- **Wheat:** Currently, "high-input" varieties that translate high cultivation intensity into high yields are common. These varieties may also be regarded as ecologically relevant since they have helped to create the potential for energy- and pesticide-intensive, and thus "unecological" agriculture. On the other hand, the development of such wheat varieties does not automatically demand a higher input – they also produce good yields in biological cultivation. Short-stalk varieties also serve to guarantee yield by reducing losses. On the other hand, they allow a further increase in yield through heavier ears. Another problem of increased input is the possible susceptibility for diseases due to the conditions of intensive cultivation.

2.2 GENERALISED FINDINGS

In the following analysis, emphasis lies on general statements based on the results, and not on the significance of one or the other single trait, nor on definite answers to the initial questions. It is based on the summaries and interpretations by Soja and Soja (1995 b) and Janssen *et al.* (1995 b) and additional comments by external experts.[9]

2.2.1 Assessing Relations Between Traits and Effects

The selected plants were investigated with regard to invasiveness, cross-breeding and hybridisation potential, resistance against disease and pests, tolerance of abiotic stress factors, constituents and cultivation demands. For a practical assessment of their ecological effects, this classification of traits appears appropriate.

- *Invasiveness* (example Robinia, Topinambour): The major effect is a shift in the range of species. The tendency towards invasiveness is due to, on the one hand, conditions specific to the species (pioneer traits such as persistence and ability to spread, reproduction biology, differences between generalists and specialists), and on the other hand those specific to the environment (according to the factors time and anthropogenic changes). Less domesticated species are more invasive. The risk of invasiveness can be assessed using hierarchically structured criteria. Although there were potentials for cocksfoot (about which little is known), sunflower, rape, wheat and apple, the risk must be estimated higher for Topinambour and for the Robinia.
- The possibility of *outcrossing* can be assessed by similar questionnaires, too. They may contain questions about generative reproduction, related plants in the natural flora, cross-fertilisation, fertilisation by insects or wind, sexual compatibility, flowering period, fertility and the hybrids' ability to compete. Only if the last two traits are given, there is a possibility of outcrossing. This applies to apple, carrot, wheat, and cocksfoot. A negative effect (the repression of indigenous wild species at certain extreme sites) can only be documented with the apple. The potential for hybridisation depends considerably on the observed period of time.
- *Resistances* concern biotic stress factors and lead to different cultivation measures for monogenic and polygenic factors. The balance between parasites and recipient plants depends on the success of breeding on the one hand, and the parasites' capacity for mutation on the other hand. Monogenic resistances are easier to achieve than polygenic ones. They provide complete, but generally only temporary protection, since virulent varieties can overcome a monogenic resistance more easily. The mechanism on which resistance is based, and thus the balance between recipient and parasite, depends on both morphological (e.g. hairiness) and physiological traits (e.g. cellular immunity).
- *Tolerance* of abiotic stress factors determines the local suitability for cultivation. Negative environmental impacts become more marked when the culture reaches the borders of its natural geographic distribution, or if it is maladapted. There may be tolerance, for example, with regard to temperature (cold tolerance and tolerance of low temperature degree sums), and with regard to rooting (dryness and nutrient tolerance, important for the suitability for low-input cultivation). Tolerances are easier to obtain than resistances, since stress factors

[9] Prof. Dr. Heiko Becker, Institute of Plant Cultivation and Plant Breeding, University of Göttingen; Univ.-Doz. Dr. R. Hron, Federal Institute of Agriculture, Vienna; Dr. Elke G. Jarchow, Ciba-Seeds, Basle; Ing. Peter Kunz, Plant Breeder, Triemenhof - Girenbad, Hinwil/Zurich

do not change constantly like parasites do. On the other hand, stress factors are complex and therefore selection is more difficult. Tolerances may already exist in the varieties or be the "by-products" of other breeding goals.

- *Constituents* are certainly relevant if they are toxic or allergenic. They are of ecological importance when they cause tolerances or resistances. Constituents also determine quality features and thus influence the economic value and cultivation area, which is the most important single factor for ecological impacts.

2.2.2 Structural Conditions as a Cause for Effects

Plant cultivation measures are determined by the needs of the individual culture in interaction with the environment, especially by resistances and tolerances. Breeding modifications have led to changes in cultivation conditions and thus had an ecological impact. Without a certain practice, some traits are of no use, e.g. high-input species of wheat and rape, short-stalk wheat varieties, and apple rootstocks with feeble growth. For conclusions based on analogies, cultivation measures and traits cannot be assessed separately, and the biological needs that any of these measures fulfil must be taken into account.

However, a direct correlation between new problems and new breeds can hardly be established. Agricultural practice is very heterogeneous – e.g. the effects of cold tolerance depend on the expansion of cultivation areas and on cultivation measures. Except for maize (early maturity), conclusions with regard to ecological impacts can be drawn from the traits only indirectly. For example, short stalk lengths and stability do not always go together; however, longer stalks may be more competitive against weeds under certain circumstances. This uncertainty is even greater for plants that are long-lived and whose cultivation area is very large. A (limited) correlation can be found in some cases, if the time frame and cultivation area are defined, and the recipient plant is well known. A reasonable risk assessment for long-lived and genetically heterogeneous plants (e.g. forest trees) therefore seems impossible. In agriculture, on the other hand, certain practices have a considerable influence on ecological impacts which – due to the shorter time frame – are more easily identifiable; nevertheless, long-term impacts can hardly be assessed.

Undoubtedly, plant cultivation measures are also subject to socio-economic factors. The assessment of ecological effects of existing breeds queries the general goals of plant breeding. Since breeding is subject to the same structural conditions as agriculture itself, an assessment concerns also the agricultural structure, which is determined by the demand for certain products that must be produced competitively. However, assigning a responsibility for ecologically questionable practices to "market forces" does not lead to any substantial findings and is therefore omitted here.

The following developments may be considered as being ecologically relevant:

- The *increase in yield through high-input varieties* that turn high cultivation intensity into high productivity has increased the potential for an environmentally questionable agriculture. Although high-yielding varieties are not necessarily more susceptible to diseases than traditional ones, the expansion and intensity of cultivation made possible lead to increased infestation stress. However re-orientation towards lower input can be observed recently.

- *Quality goals* according to the demands of processing prefer traits that can be clearly defined chemically. Others that cannot – e.g. taste – must take second place. Breeders define their goals according to the demands of the farmers, processors and the recommendations by international bodies such as the Food and Agriculture Organisation (FAO). Goals have remained basically the same over the time: higher yield, resistance, herbicide tolerance, stability, improved harvesting and homogeneity. Today new, ecologically more acceptable strategies are required. However, standards for the ecological evaluation of breeding goals are still lacking.

- *Lacking adaptation of varieties* to the conditions of the site can partly be balanced by cultivation measures, which may have a negative influence on soil and ground water. This is particularly important in case of a massive expansion of the cultivation area. Too little attention may have been paid to the interactions between plant and soil and the ability of the plants to take up nutrients, so that nutrients are washed out into the ground water. Presently, the adaptation of new varieties to different sites is managed informally, by the exchange of views between breeders, and by seed testing and agricultural counselling.
- The establishment *of monogenic resistances*: The improvement of resistance through breeding is counter-acted by higher disease stress due to more aggressive pathogens. Monogenic resistances are easier to introduce than polygenic, but frequently they do not provide permanent protection, since virulent races are selected and cause epidemic outbreaks.
- The *decline of genetic diversity* in the agricultural ecosystem may have lead to a tendency of one-sided soil use, to higher parasite stress, to the application of more agro-chemicals and, in some cases, to stronger erosion. The tendency is supported by the quality standards required, and by the limitation of breeding efforts to the economically most significant species and traits. However, it would be necessary to define whether this decline refers to the number of varieties within a species (which is doubtful), the varieties in use or the gene pool of the whole species including wild plants and seed banks. Likewise, the time frame the assessment is based on has to be defined.

2.2.3 Ways to proceed

Based in these findings, four alternative ways to proceed emerge:

- In a comprehensive risk assessment, the interaction between genotype and environment, and the retro-action on phenotype and population should be taken into account. Therefore, a risk assessment for long-lived plants such as trees is impossible due to a lack of predictability. Since reasonable and sound risk assessments do not appear feasible for many other plants either, the emphasis should be shifted to monitoring as an alternative.
- Since a precondition for any monitoring program is that it has to be clear from the beginning which kind of effect to look for, this would only shift the problems. Due to the somewhat ambiguous evaluation system, the questionnaire in Annex II B of EU Directive 94/15/EC will always remain incomplete. Therefore it is necessary to develop an entirely new strategy, whereby we must start out from the general definition of goals in plant breeding. Since the assessment of cultivation methods is not possible in the short term, long-term ecological quality criteria have to be introduced.
- However, a "new" questionnaire cannot be implemented easily for political reasons, so at least an additional question about agricultural practice should be included, which could also be integrated in the assessment of new varieties. However, agreement would have to be reached with regard to what is considered a "normal case" in agricultural practice. Deliberations on an "influence on agricultural practice" could result in specifications for monitoring.
- Since no entirely new ecological effects may be expected from transgenic plants, the international trend (especially in the United States) is towards simplified procedures, a direction which Austria should also follow. An assessment of cultivation methods cannot be carried

out within the time period specified by the EU procedure. Therefore, a further question on agricultural practice is not useful. If ecological problems are recognised, they must be discussed in each individual case.

All proposals can be substantiated, although there are doubts as to whether they can easily be implemented. Obviously, there is a choice between two kinds of attitude. On the one hand the current practice of risk assessment could be criticised in general, either because it is inherently flawed (proposal 1), because it reaches too short (proposal 2) or because there is no reasonable relation between costs and benefits (proposal 4). On the other hand, such a criticism would imply that the plan to integrate practice-relevant ecological impacts into the assessment had to be given up. Hence, proposal 3 presents a feasible compromise since the principle of precautionary risk assessment is satisfied. The question is how to implement it in practice.

2.3 ASSESSMENT ACCORDING TO ANNEX II B OF DIRECTIVE 94/15/EC

In order to find out whether Annex II B to EU Directive 94/15/EC would have to be adapted to this end, it was investigated whether the documented effects can be registered using its criteria. As a working hypothesis, it was assumed that the documented effects can indeed be assessed in this way. In a thought experiment, it was investigated using three case studies whether the hypothesis is correct or which modifications of the criteria could be introduced in order to make them fit better. Besides outcrossing and invasiveness, also the effects of various resistances and tolerances were to be investigated, provided they were identifiable. For this purpose, three plant species that appeared to be particularly significant due to the environmentally relevant traits shown in brackets were selected as examples:

- **Wheat** (short-stalk): The ecological significance was not rated unanimously among the research groups.
- **Maize** (cold tolerance): Impacts result from ecological differences between various cultivation areas.
- **Robinia** (invasiveness): Problems may be attributed to competitive advantages due to the nitrogen fixation ability, among others.

After a brief introduction and recapitulation of the main findings, comments to the questions in Annex II B of the directive 94/15 EC are listed as far as they concernd the trait under investigation. Items that are not listed (e.g. A 1. to A 4., B 1., B 7., etc.) could not be applied sensibly or were not considered relevant for the analysis.

2.3.1 Wheat

The first example was a short-stalk wheat variety. A change in fungicide needs in the context of highly intensive cultivation was in the main focus of the results.

A problem frequently encounterd in wheat cultivation is the breaking of the stalks due to an infestation with Circosporella (or on other grounds). The use of fungicides is necessary if a higher yield is to be achieved. However, the increase in yield through higher nitrogen supply has reached a ceiling with conventional long-stalk varieties, since the ears grow heavier and the stalks break more easily. In the past, chemicals that shorten the stalks were applied in order to render the cultivation of older long-stalk varieties less risky. Meanwhile, varieties that have short stalks are available. The trait of "short stalks" leads to increased stability and lower the risk of breaking – the same nitrogen supply provided. Thus, it may lead to a decrease in fungicide application. However, as a result, the nitrogen supply and thus the size of the ears can be increased – until the stalks start to break again. Therefore, short stalks could also be a breeding goal in order to be able increase the nitrogen supply and thus the yield. However, this would also increase susceptibility for disease, and in particular for fungus disease, so that more fungicides would be required. In general, short stalks may lead to higher input – but it depends on the structural conditions, which ultimately have a considerable influence on the impacts.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

(b) Sexual compatibility with other cultivated or wild plant species.

ther is an ability to cross-breed with rye, and also with other species, in the laboratory. A short-stalk rye that may have resulted from cross-breeding with the appropriate wheat variety (e.g. on a fallow field) has not been observed to date.

3. Survivability:

(b) specific factors affecting survivability, if any.

Low competitiveness. Although the cold tolerance of winter and summer wheat differs, the survivability (but not the yield) is similar; therefore cold tolerance must be regarded as a subordinate factor.

7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

Positive Mycorrhiza effects (in deficiency situations) in terms of nutrient uptake disappear with only a little fertilisation. Some fungus parasites (ergot) are toxicologically important. The infestation stress increases with narrow crop rotation and after stalk breakage.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

(Phenotypical description of the short stalk trait.)

2. Information on the sequences actually inserted/deleted:

(Illustration of the cross-breeding technique that produced the variety.)

4. Information on how the genetically modified plant differs from the recipient plant in

(c) survivability.

It is doubtful whether survivability is increased by lower infestation stress.

8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

Less breakage of stalks, since Circosporella-susceptibility is lower.

9. Potentially significant interactions with non-target organisms.

In order to take the information necessary for an assessment of the observed ecological impacts into account, the question would have to be rephrased like: "Modified interaction with relevant organisms?"

The term "target organisms" (and subsequently "non-target organisms") applies only to the case of direct resistances. One example of organisms that should still be taken into account here is Fusaria. For example, it is conceivable that the susceptibility for Fusaria and Septoria was neglected in breeding.

The term is particularly inappropriate if only the conditions for certain parasites have been modified, even if the modification was introduced in order to reduce the harmful effects of the organisms. However, these modifications may still be of ecological importance; therefore data on modified conditions for interaction with other organisms are necessary. Furthermore, it is not clear why only interactions with organisms should be of importance, especially where tolerances are concerned (which is not the case here, however). Therefore, possible interactions with the abiotic environment should also be indicated.

Short stalks may lead to higher input, which raises the question of to what extent high-input cultivation is necessarily linked to this trait, and whether short-stalk wheat is also suitable for low-input cultivation. The effects on cultivation measures and on agricultural practice should therefore be included, particularly with regard to possible distribution of the organism and the effects on agricultural input.

As for the rest, D 9. is closely related to H 3. and H 4.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

Persistence and invasiveness are not considerably influenced.

2. Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant.

Under natural conditions (e.g. in ruderal flora) a short-stalk cross-breed with rye would hardly be able to survive.

3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).

With the changed conditions for Circosporella-reproduction, a reduced use of fungicides may be expected.

4. Possible environmental impact resulting from potential interactions with non-target organisms.

In order to fight other fungi, however, an increased use of fungicides is possible, since there is greater infestation stress due to the shorter stalks.

Questions H 3. and H 4. should be rephrased, in order to relate better to D 9.

Due to the difficulties in answering some questions (e.g. D 9. and H 4.), sections D and H should be restructured and supplemented. Section D should deal with modifications that concern interactions – and their conditions – with other organisms and with the abiotic environment, and agricultural practice. Section H should deal with the individual ecological effects of these modifications.

2.3.2 Maize

In the second case study, effects like erosion and herbicide needs resulting from the maize's high demand for warmth were of main interest, as well as the repression of (older crop plant) species.

As a "C4-plant", maize is a good example of an originally Exotic Species. Due to maladjustment to our latitudes, the vegetation period is rather too short for maize. Maize cultivation requires a soil that remains open for a long time, in order to make up for the initial competitive weakness of maize compared to various weeds. Therefore, early maturity and cold tolerance were the primary goals of breeding. The maturation phase is no longer a limitation with utilisation primarily as maize for feeding purposes (development of silage maize). As a result of this and the adjustment to colder climates, the cultivation areas were expanded to the north and to higher altitudes. Old forage plants such as clover, etc., which were better adapted, were repressed.[10]

Ecological effects from the repression of (economically) competing fruits are due to the fact that the negative impacts of their cultivation are lower. Although maize can be processed mechanically and produces a high yield, negative impacts still result from the late juvenile growth (erosion through late closing of the soil, herbicide needs through low early competitiveness). With cold-tolerant varieties that have a faster juvenile growth, these effects may occur to a lesser degree through earlier closing of the soil. Since the cultivation of cold-tolerant varieties has been expanded to cooler, i.e. even less suitable regions, however, similar problems to those observed in the original cultivation areas will certainly ensue. In warmer climates, on the other hand, maize also causes erosion, which is due to the relatively big spacing. Regardless of climate, the erosion risk is obviously inherent to maize cultivation, unless a mixed culture is planted.[11]

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

A cold tolerant variety has an advantage compared to a conventional variety at the same site, since, through early closing of the rows, the erosion risk is reduced and the earlier shading lowers herbicide needs.

4. Information on how the genetically modified plant differs from the recipient plant in
(b) dissemination,
Although the maturation index may depend on cold tolerance, an influence on survivability is not to be expected.

7. Information on any toxic or harmful effects on human health and the environment arising from the genetic modification.

Fungus diseases (that may result in toxic products) do not occur until late and are not influenced by cold tolerance, since this concerns only juvenile growth.

9. Potentially significant interactions with non-target organisms.

Changed conditions may have an impact on cultivation practice; a "dragging along" of other organisms in the course of expanded cultivation is possible.

9. a) Does the genetic modification allow, promote or require changes in agricultural practice, including possible expansion of the growing area? (New question!)

When expanding the location to cooler climates as a result of the new trait, the same practices (and problems) must be expected as are common in the ecosystems in which conventional varieties are grown. In the new ecosystems, a practice that is adjusted to the new

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[10] However, before cultivation of green fodder on the same areas that are planted with maize today, corn and potatoes were planted for subsistence use. They were first repressed by clover and this in turn by maize.

[11] This was originally common in tropical and subtropical regions and is still practised in biological agriculture.

trait (and possibly with ecological improvements) must be expected. Since the effects might well differ considerably, the potential to expand the cultivation area is an important piece of information. Since it is not clear a priori whether an expansion of location falls under "agricultural practice", question 9.a) should be modified accordingly.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

4. Possible environmental impact resulting from potential interactions with non-target organisms.

Environmental impacts of "dragged along" organisms are not to be expected.

5. Possible environmental impacts resulting from agricultural practice that has been modified due to the new traits, including possible expansion of the growing area. (New question!)

The cultivation of maladapted maize lead to the repression of more adapted competitors. In predisposed ecosystems, erosion and herbicide problems occurred. (The situation should improve in "old" ecosystems, whereas problems must be expected in new ones. Experiences in old ecosystems show that problems are predictable).

2.3.3 Robinia

The third case study, the Robinia, was chosen as an example of a forest tree. The effects of invasiveness and repression of indigenous wild species were of main interest. Due to its marked ability to regenerate vegetatively, it is very difficult to remove the Robinia from a site again. Furthermore, with its special root system it is highly competitive, which may lead to the repression of indigenous species. The Robinia may be regarded as an Exotic Species, so that the entity of traits is decisive (maize is partly comparable in this respect). The main reason for rejection by the forestry sector of the Robinia as a plantation tree in Austria (unlike Hungary, for example) was the expectation that there would be persistency problems and possible repression of indigenous species of trees.[12]

However, the standardisation and the possibility to comprehensively describe an agricultural crop variety is generally greater than with forest trees. For example, the genetic basis of the Robinia is difficult to assess, the variability is high. Probably, there is natural cloning that is not documented. This also applies to other species of trees. Since the genetic variability of forest trees is much greater than that of agricultural crop plants, comparative standards are very difficult to set up and we must ask ourselves whether the questionnaire with its focus on traits is suitable for the assessment of such plants. This is a reason why there are fundamental reserves against the use of Annex II B of Directive 94/15/EC in the existing form for forest trees.

Thus, he selection of a reference point for the case study was a problem. Since the Robinia as a species causes ecological problems, potential genetic modification is not the main issue in the assessment. The questionnaire in Annex II B of EU Directive 94/15/EC, however, refers to comparison of an existing variety with a new variety. Other comparisons were considered,[13] but were not regarded as feasible. Therefore, only a description of traits in compliance with section B ("recipient plant") of Annex II B of EU Directive 94/15/EC was carried out.

[12] This may be an indication for a tendency in forestry, due to the longer time frame, to pay more attention to possible ecological problems than in agriculture.

[13] Robinia in plantations versus Robinia with a modified trait, such as straight trunk; Robinia versus an alternative plant such as the oak; comparison by sites, etc.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:

(etc.)

In principle, such a description is regarded as feasible although the genetic variability is high.

2. (a) Information concerning reproduction:

(ii) specific factors affecting reproduction, if any,

Generative: 40-100% cross-fertilisation, insect pollination mainly by bees. The seeds are basically enduring (see below), the yield depends on variety. Generative reproduction depends on the existence of fire, and is less important in this country. Vegetative: soil wounding stimulates the suckers.

(iii) generation time;

The time of generation until gametes are produced is 5-20 years.

3. Survivability:

(a) ability to form structures for survival or dormancy,

Since the seeds have a hard shell, some survive at least one year. The natural lifetime is one to two years. The seeds are only long-lived under artificial conditions (maximum 60 years, without loss of vitality 10-20 years). Coppice shooting is almost unlimited.

(b) specific factors affecting survivability, if any.

Ability of nitrogen fixation. In order to describe the influence of the abiotic environment on survivability, this item should be better structured in:

- temperature needs
- water needs
- soil needs
- nutrient needs
- stress tolerances

Since information on the genetic basis is not asked for in the questionnaire in Annex II B, a question on this issue should be included under 3.b).

4. Dissemination:

(a) ways and extent of dissemination;

(b) specific factors affecting dissemination, if any.

The flying range of the seeds is less than the height of one tree. Pollen is usually transferred by bees, and to a lesser degree by the wind. The degree of distribution by suckers in the total distribution is significant, but difficult to assess.

5. Geographical distribution of the plant.

The original area of geographic distribution is the North American east; artificially (in cultivation), the Robinia has been spread world-wide in moderate climate zones. Although the form of utilisation and cultivation is not surveyed according to Annex II B, it is important in this case, and therefore a question on this should be included.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plants, including information on natural predators, parasites, competitors and symbionts.

Here (as also in questions 3 and 7), the habitat of the plant and its behaviour in this habitat are to be described. This includes references to symbionts, such as Rhizobium, incompatibility with the birch and beech, mention of the unknown reasons for differing competitiveness and persistency in the native regions compared with Europe, etc. However, according to the intention of the Directive, question 6 applies only to Exotic Species in the narrower sense, i.e. those that are hardly found in Europe. Plant species that are cultivated in one form or another in a member state are excepted – regardless of their ecological impacts. Obviously, the Robinia is a borderline case for which such information would be useful, but which is not "exotic" to the extent that it meets the indicated criterion.

The term "usually" is not very meaningful. It would be better (but not optimal) to use "in agriculture and forestry" instead. Equally, the limitation to "natural" habitat is obviously unsatisfactory. If you follow the wording of the Directive, important information is lost; the original phrasing (in 90/220) was more appropriate.

7. *Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.*

The restriction to "non-plant" is not reasonable (and suggests tailoring for plants with insect resistance). The question should be rephrased analogous to question 6.

Although section B is basically suitable for an adequate description of the parental plant, the question remains how much information on ecology is required for an Exotic Species. The example of the Robinia shows that ecologically relevant effects may be known in an artificial habitat, in which the plant shows other, partly undesired traits than in its native habitat. The conclusion that this is irrelevant because the plant is already grown commercially within the EU (at least to a modest degree in some areas) is certainly not very sensible. The wording of the Directive suggests, however, that information on ecology is not required for this reason.

3 INTERPRETATIONS

3.1 REFERENCE TO PRINCIPLES OF RISK ASSESSMENT

As has been shown in section 2, the interpretation of the research results mainly depended on the overall view of the different actors involved. In order to clarify the options available, we tried to relate the results, in a more general context, to some problems and trends in the risk assessment of transgenic organisms currently under discussion.

3.1.1 The Assessment of Ecological Impacts

A risk assessment – as required pursuant to EU Directive 94/15/EC – is aimed at investigating whether there are any risks of undesirable impacts on the environment. If this is the case, they must be identified in order to prevent or minimise them. Various sides – including the EU Commission – have repeatedly emphasised that the *traits* of the individual organisms are important and must be evaluated in the risk assessment, and not the method of production. In other words, a prerequisite for any risk assessment is the assumption that it is possible to infer the future behaviour of a plant under certain environmental conditions, i.e. the *effects*, from certain traits of the plant. However, even in retrospect this has proved to be very difficult: Possible effects cannot be inferred directly from certain traits, a fact on which everyone involved in the project agreed.

Certainly, the few examples dealt with here are not representative of the multitude of different crop plants and the various traits that new breeds may have. This is particularly true in times of change in plant breeding as a result of new recombinant techniques. However, it is obvious that very few effects can be associated with distinct traits of the plants, even in a very loose way. This points to an unfavourable starting point for the risk assessment of new plants in general. If it cannot be assumed that transgenic plants differ considerably from conventionally bred plants, then this also applies to them, too.

Among those effects that are assessed as ecologically harmful and where a correlation with specific traits could be established were e.g. the slower juvenile growth and erosion danger, the lacking competitiveness and the high herbicide requirements of maize. Such effects are often associated with poorer adjustment to the local environmental conditions (e.g. climate), and were usually not specifically bred. Little attention is generally paid to such complexes of traits and effects within the scope of conventional risk assessment (see section 3.3 on the relevance of gene transfer and invasiveness). Such environmental effects occur primarily under the conditions of intensive agriculture, which are difficult to modify in practice, even if – at least in Austria – a "more ecological agriculture" is being aimed at.

Paradoxically, new breeds with tolerances that could reduce such environmental effects (such as cold tolerance) actually may exacerbate them. This can be attributed to maximum exploitation of the trait in practice, rather than to the trait itself. This is shown by the case of short-stalk wheat, for example. It helps to prevent the use of fungicides through improved stability – as long as the breakage tendency does not increase to the same extent through heavier ears with higher yields. This correlation is even more obvious in the case of cold-tolerant maize. It allows an expansion of the cultivation area to colder sites, until problematic effects such as erosion reach the same degree as at the warmer sites prior to introduction of the new variety. Since the cultivation area is much larger, they may even exceed these. To give an example with another technology: Nobody would release a bridge with a carrying force of 50 tonnes for such a heavy load. The police would demand a safety margin; vehicles that are heavier than

30 tonnes may not cross the bridge. In agriculture, it seems common to exploit the potentials of an organism to its very limits. Perhaps safety margins would be appropriate here, too.

The practice that is made possible by a certain trait is obviously more important in terms of environmental impact than the trait itself. Its significance, on the other hand, lies in the fact that it allows various practices – those that prevent negative effects, and those that merely shift or even enhance them. The correlation is similar to the one observed with the introduction of the anti-wheel-lock braking system in the automobile industry. The gain in safety made possible by the new technology, i.e. a shorter stopping distance, was neutralised in practice by the possibility to leave less safety distance at high speeds. The braking system is not "to blame" for pile-ups, but it does allow a practice that increases the risk of those negative effects (here: serious accidents) that it should actually prevent.

The assessment of a trait without considering the associated cultivation method, therefore, is questionable if ecological impacts that are also relevant in practice are of main interest. Otherwise, only academic questions about possible risks in areas that have proved to be of little impact hitherto are in the focus of attention. It remains to be seen whether Directive 94/15/EC is the right tool. The choice of wording in the demand to specify "possible effects", however, does suggest that practice-relevant issues are meant, rather than academic ones.

3.1.2 The Concept of Familiarity

The OECD Concept of Familiarity should serve as a guideline for assessments in which there is a high degree of uncertainty with regard to possible effects. It should identify areas in which caution is necessary because of lack of knowledge, and in which there is a need for research. On the other hand, those areas in which – on the basis of experience with conventional plants – answers can be given to possible questions, or where there are at least indications, should also be made identifiable. The concept does not say anything about the risk of negative consequences, only about the degree of uncertainty in any given issue. Therefore, it is intended primarily to identify uncertainty and to distinguish areas with high uncertainty from those with low uncertainty. However, in order to obtain answers or indications, it is prerequisite that the relevant questions have already been asked or that the matter has at least been dealt with. In order to be able to match ecological impacts up with traits of crop plants, such questions would therefore have to have been dealt with scientifically – either implicitly or explicitly.

Our results, however, indicate that this hardly appears to be the case. Either the relevant problems have not even been perceived hitherto, or hardly anyone has inquired about them. So far, either certain events that are now considered worth investigating in the context of transgenic plants (e.g. gene transfer) have not caused considerable problems. Another possibility is that the pertaining effects were not regarded as a problem (or, for example, not attributed to gene transfer). The criteria of seed testing for the selection of breeding goals, etc. concerned mainly the yield, various disease resistances, harvesting efficiency, workability (e.g. apple), etc. "Familiarity" therefore refers primarily to the agronomic performance and less to actual environmental impacts, which were only considered in the second instance, if at all – something that may be changing meanwhile (see previous section). Also, the correlation of traits and effects is so difficult that it can hardly withstand scientific analysis and is therefore questionable. We are not dealing with a linear cause-effect structure, and numerous parameters play a role; not least, agricultural practice is decisive.

However, this means that the "familiarity" of correlations between traits and effects is doubtful – basically we do not know very much. This would imply that, according to the Concept of Familiarity, increased caution is necessary with regard to the correlation of traits and effects.

This refers to all issues of risk assessment in which "possible effects" are the subject. However, with regard to traditional crop plants, the opposite can be observed: Usually, nothing negative is known about the possible correlation between trait and effect. Thus, increased caution is not considered necessary. The reason why nothing (negative) is known may be that no-one has ever paid any attention to the question at stake. This is due, among others, to the fact that the issue has not been a problem hitherto, and therefore is not interesting enough for a scientific investigation.[14]

So the Concept of Familiarity as it is presently applied may seem at odds with the claim to a purely scientific assessment. However, one could object that such issues are only of academic interest, if at all. For example, it does not seem too promising to aim for scientifically substantiated findings on the invasiveness of maize in Central Europe. However, risk assessment in general claims to proceed only on the basis of scientifically substantiated data, so that speculations about possible but unlikely effects (e.g. from horizontal gene transfer) are rejected. The same standards would also have to be applied to facts that are generally known but not considered scientifically proven in the narrower sense. Otherwise the claim to "scientific" risk assessment must be given up and general knowledge admitted. This appears extremely sensible, but should be explicitly declared.

In summary, the concept appears suitable as an indicator of whether and where there is uncertainty, but not as a prognostic instrument for possible effects. At a closer look, uncertainty may also arise in areas that initially appear to be unproblematic because there is experience and negative effects have not been observed. However, since different questions are posed today, issues crop up on which too little is known as yet. Here, the Concept of Familiarity is overtaxed.

3.1.3 The Exotic Species Model

The model of non-indigenous species (Exotic Species) is one of the few scientific models that makes long-term statements on the behaviour of non-indigenous plants. Thereby, the importation, utilisation, ability to become sedentary, current distribution and possible invasiveness, as well as the repression of indigenous species, in short the history of a plant in its new habitat is analysed.

The results indicate that non-indigenous crop species are less adapted than indigenous species, even if – like the potato – they were imported several centuries ago. This may be expressed by higher sensitivity to parasites and according plant protective needs and, in the extreme case (e.g. maize), in total dependence on human care. On the other hand, there may also be clear competitive advantages such as with Topinambour and the Robinia. Generalisations are difficult, predictions almost impossible. The possible reasons for a certain behaviour can only be observed retrospectively, e.g. the hardiness of the Topinambour root in comparison to that of the potato as a prerequisite for invasiveness.

This is also acknowledged by the authors of the model. Individual predictions are not possible, only statements on probabilities. "The model of importation of non-indigenous species is a statistical model that allows generalisations on the risk of undesired ecological impacts which could result from the release of a number of genetically modified cultivated plants in the long

[14] A good example is the highly reputed British PROSAMO project. It had to collect basic data on the pollen flying range, colonisation capacity, persistence, etc., of some common crop plants that were required for the assessment of transgenic plants (Crawley, 1992). The results were not surprising, though, but they were not scientifically established beforehand.

term." (Sukopp and Sukopp, 1994). The prognostic possibilities are thus greatly restricted in the individual case – yet that is precisely what the nature and function of the risk assessment from case to case is about. The importance of the Exotic Species model in this context lies more in drawing attention to possible unexpected behaviour or to effects that are not intended. Since it only indicates that negative impacts must be expected after a long time in more or less rare cases, it is not particularly suitable for risk assessment in the individual case.

The model is also rather questionable for practical risk assessment in another way, since it is doubtful whether transgenic plants can be compared with non-indigenous species (even if we restrict ourselves to phenotypic analysis). The fact of genetic modification does not tell us anything about the type of new traits, the behaviour of the plant, and its importance. It is further doubtful – if not impossible – that the transfer of individual or several isolated traits can change the nature of a plant to such an extent that a fundamental change in behaviour will result. The distinction of how high the degree of domestication is, and whether it is a cultivated or a crop plant or not is much more important (Sukopp and Sukopp, 1994).[15]

The Exotic Species model appears to have stood model for some items in the phrasing of Directive 94/15/EC, however. Section B, for example, is basically suitable for an adequate description of the parental plant. Nonetheless, the question remains how much information on ecology is necessary. According to the intention of the Directive, question 6 is obviously required only for Exotic Species in the narrower sense, i.e. for those that are virtually non-existent in Europe. Plant species that are grown in any form in any member state are excepted, even if ecologically relevant impacts may be known, as in the case of the Robinia. The conclusion that this is irrelevant, and that information on ecology is not required because the plant is already grown somewhere within the EU could be covered by Directive 94/15/EC. In view of the special ecological situation in Austria (alpine region, only country of the EU with Pannonian area), this is particularly incomprehensible. If the words of Directive 94/15/EC are followed to a point, significant information is lost.

3.2 RELEVANCE OF GENE TRANSFER AND INVASIVENESS

3.2.1 Significance in Risk Assessment and Practical Importance

The "Safety Considerations for Biotechnology" (OECD, 1992), also provide the basis for the EU Directive 94/15/EC. Here, the OECD sees gene transfer and invasiveness as the most important events that make a risk assessment necessary prior to the release of transgenic plants. In the approval procedure for the placing on the market – after relevant field trials —, these parameters also play a major role. Others are less central: Effects on non-target organisms and undesired effects on target organisms (e.g. development of resistance to insecticides in plants) are rather special cases. Finally, the "development of unforeseen traits" due to genetic or phenotypic variability is unpredictable by definition. In practice, avoiding risks due to foreign genetic material means introducing as few uncharacterised sequences into the genome as possible. Human toxicity is very rarely relevant. Here, the following considerations about the inclusion of environmental factors and agricultural practice apply accordingly as for gene transfer and invasiveness.

[15] Normative Schlußfolgerungen, p. 141. According to these, the degree of domestication and the existence of wild species as cross-breeding partners are used as criteria for the risk of invasiveness of transgenic plants.

If transgenic plants are basically comparable with conventionally bred plants, then gene transfer and invasiveness must also have occurred in conventional plants – and have been observed in individual cases. One example is the gene transfer from the wild carrot to the cultured carrot. Although the effects disturb seed production, they do not cause any problems for the environment. The *practical* significance of this phenomenon – contrary to the effects on target and non-target organisms – is fairly low. Negative effects of invasiveness were also observed in very few cases only (e.g. in one out of 1000 imported species, from Sukopp and Sukopp, 1994).[16] Undoubtedly, this includes repression of the crab apple by invasive domestic apples in some very specific habitats. However, it remains unclear why this happened there and nowhere else; i.e. such effects can hardly be predicted. Moreover, long periods of time lapse before they become manifest.

The selection of case studies for this project (only ten species) is not representative, and the results therefore cannot claim to be generally valid. However, the effects of gene transfer seem to be minor problems in practice, and those of invasiveness are problematic only in relatively few cases. This mainly refers to hardly domesticated and non-indigenous species, and to species that are little developed in terms of breeding. At least the short-term relevance of gene transfer and invasiveness is therefore lower than would appear judging by the complexity and emphasis of risk assessment pursuant to EU Directive 94/15/EC.[17]

3.2.2 Time Frame

It must be assumed that, in time periods relevant to evolutionary biology, events such as gene transfer and invasiveness will occur in one form or another. Based on experience with non-indigenous species, phenomena may also occur in the medium term that cannot be registered using short-term assessments. According to the Exotic Species model, predictions in the individual case are not possible. In the step-by-step procedure hitherto used, only short-term effects are therefore investigated in relatively few individuals. It is thus not surprising that it has hardly been possible to document associated negative effects so far. These could only be surveyed by intensive monitoring during broad utilisation as may be expected following the placing on the market – provided one knows what to look for. The licensing procedure for placing on the market generally does not specify any further requirements, however, including a monitoring obligation.

In this context, the difference between rotation time and the lifetime of agricultural crop plants and forest trees is significant (Geburek, 1995). Whereas the former are usually monocyclic (except fruit plants), the productive life in forestry may be several centuries. These are definitely relevant periods for events such as those described in the Exotic Species model. However, as already pointed out, such events cannot be predicted in the individual case. Equally, the demands on the plants (and on the product) at the time of harvesting in thirty or fifty years can hardly be predicted at the time of planting. This refers also to changes that could affect the climate or the water balance, which is one reason why the breeding efforts with forest trees

[16] Approx. 1% of the imported species are permanently invasive, 0.1% cause undesired effects. The results of the OTA (US Congress, Office of Technology Assessment, 1993) are similar: Approx. 15% of the invasive non-indigenous species cause undesired effects.

[17] A recent review on the possibility of gene transfer from transgenic plants to wild relatives on the basis of those released to date indicate that 100% pose minimal or no risk. Thus, according to the authors, regulators and companies have acted responsible to environmental concerns (Goy and Duesing, 1996).

have been rather modest to date. In view of such a long time frame, the ability to adjust that is guaranteed by genetic heterogeneity has priority over optimisation with reference to a certain yield parameter.

These differences in time frame are not taken into account by the criteria of Directive 94/15/EC. From this, we could infer that the long-term aspects must be taken more seriously in the above Directive, which would probably meet with problems in practice, however.

3.2.3 Environmental Influences on Gene Transfer and Invasiveness

In reality, other effects than gene transfer and invasiveness have a greater ecological impact. These are characterised by the local cultivation conditions and individual agricultural practice, which varies depending on climate and environment, and which is strongly influenced by socio-economic parameters such as grant specifications. Gene transfer and invasiveness, however, also depend to quite some extent on the local environment – and thus on the cultivation conditions.

Gene transfer requires cross-breeding partners, the distribution of which varies locally. The seed producers of a variety (including transgenic ones) basically aim at the broadest distribution possible (world-wide). Licensing is being harmonised more and more; the mutual recognition of data between the USA and the EU is a political goal of the OECD. Therefore, it must be expected that transgenic varieties will also be cultivated in areas in which cross-breeding partners exist. To ask whether gene transfer will ever be possible therefore makes little sense at the time of placing on the market in one country – it will almost certainly happen somewhere.

Invasiveness is the result of interaction between a (hybrid) species and the ecosystem; it cannot be reasonably assessed by analysing the traits of one (parental) species alone, without taking the environment into account. However, this is precisely what is required in the evaluation of applications for placing on the market. Experience with prior field tests must necessarily refer to only a few (mostly very similar) ecosystems and therefore cannot be generalised.

Agricultural practice – as part of the environmental factors – also has an influence on the frequency of gene transfer. For example, the probability of contact between hybridisation partners depends on the field edge surface (edge effect). Therefore it is not unimportant whether an agricultural system has larger or smaller fields.[18] The type of neighbouring plants, the use of herbicides, etc. also have a major influence. Equally, the possibility of invasiveness depends on the removal of volunteers, crop rotation, the existence of a fallow, or ruderal sites, among others. Therefore, even if we were to restrict ourselves to the parameters gene transfer and invasiveness, and to assess the probability of such events, agricultural practice cannot be excluded from analysis.

3.2.4 Limitation to "Natural Ecosystems"

Risk assessment raises the question of what the ecological risk really is, in other words: which undesired environmental impact is to be prevented. According to an interpretation currently propagated in the EU, which is based mainly on British proposals, this is almost exclusively

[18] The small average size of fields in Norway compared with the EU mean, and thus the greater probability of cross-breeding and in consequence of gene transfer was recently mentioned in a Norwegian comment on application for the placing on the market of a transgenic rape strain (Nielsen, personal communication).

the repression of species in natural ecosystems. Events that have an effect on agricultural ecosystems (e.g. the development of multiple resistances) cannot be taken into account, since they cause only agricultural problems. The fact that these may also be environmentally relevant should not play a role in the evaluation in this context, since they may only be indirect effects. Their probability cannot be assessed with sufficient certainty.

However, it is not immediately clear what is meant with the term "natural ecosystem". If it refers only to those ecosystems that are hardly touched by human activities, then such areas (with the exception of a few nature parks) are very rare in many countries of Western and Central Europe. Natural, "functioning" ecosystems, on the other hand, that are hardly used for agricultural purposes are more common. This is particularly the case in Scandinavia and also in parts of Austria (e.g. in the Alpine and Pannonian regions).[19] One example for how a more comprehensive view could gain ground is the term "seminatural ecosystems" that has been coined by environmental research in the field of air pollutants. The unclear definition of what is meant by "natural" ecosystems could limit the scope of the Directive considerably, because influences on ruderal sites and small islands of distribution would be hardly included. Therefore, we must ask ourselves whether the complex risk assessment for transgenic plants is adequate with regard to the possible effects that shall be avoided.

[19] Equally, national parks account for a small but significant share of the total surface area in the USA.

4 OPTIONS

4.1 ALTERNATIVE ROADS TO FOLLOW

Two alternative conclusions could be drawn from the above considerations:

- On the one hand, the currently common practice according to EU Directive 94/15/EC, which is formally based on the precautionary principle, is considerably exaggerated and obsolete. It could be replaced by a registration procedure (possibly supplemented by a brief informal assessment) that does not present any obstacles to release and placing on the market a priori. The tendency of international regulations also seems to be moving in this direction. However, the precautionary principle would have to be given up completely with such regulations.
- On the other hand, the originally more comprehensive intention of Directive 90/220/EEC, which generally aimed at preventing possible negative impacts of genetically modified organisms on the environment, could be taken up again. The view that only "natural ecosystems" should be considered, whatever that may imply, is not comprehensive enough, and the assessment of possible effects on agricultural practice should be integrated in an evaluation. However, problems must be expected because conclusions with regard to observed effects from known traits – even without the integration of agricultural practice – are problematic.

In summary, should risk assessment (as it seems now) be strongly restricted and given up in the long term? Or should ecological reserves – according to the precautionary principle – be taken seriously, thus also satisfying the public need for risk prevention? In the following, this decision will be discussed on the basis of two alternatives.

4.1.1 Restriction to Repression of Species in Natural Ecosystems

This alternative consists in adhering to the currently common interpretation and considering only the "genetic pollution" of "untouched nature" by genes not present in the gene pool so far. However, this should only be assessed if there is a high probability that it could trigger the repression of indigenous species in such natural ecosystems (even if this cannot be quantified). Furthermore, the notorious problems of assessment and the necessary inferences from traits to effects will hardly allow the investigation to gain a significance that would be recognised by e.g. a court. The current practice required by Directive 94/15/EC is considerably exaggerated for this very unlikely case, however – were it not for the principle of precautionary environmental protection.

Advantages: Long-term effects basically cannot be assessed; they can only be expected with a low probability in the short term and, should they be identifiable, they are practically not very significant. Hence, one could reason in favour of considerable simplification, if not elimination of complex risk assessment and licensing. This would also be consistent with the current agricultural policy aimed primarily at increasing productivity, and would lead to savings in administration. Politically, this perspective would be economy- and technology-friendly. In addition to the anticipated savings, a clear relief for seed breeders may be expected, who would thus have incentives to develop new breeds using modern technology in Europe. This would also have positive effects on the relevant branches of science, which could reckon with more orders from industry. Generally, a policy coined by the concept of sustaining site quality that is competitively oriented would be possible.

Disadvantages: In this restricted perspective, the ecologically most relevant risks would probably be overlooked. The limitation to "natural ecosystems" de facto excludes the greater part of the surface area in Europe (which is covered by agricultural ecosystems) from assessment. Furthermore, it is very difficult to draw the line: we would have to define the traits of a "natural ecosystem" first, whereby differences of interpretation must be expected. Moreover, it is obvious that considerable national differences would ensue. Political disadvantages result from the fact that public trust in official risk assessment and prevention of harm can generally be lastingly undermined, if it is limited to such restrictive criteria or de facto abolished. After all, the function of safeguarding public trust is one of the officially confirmed main functions of the regulation (Verrips, 1995). A softening would undermine its raison d'être in the Directive.[20]

4.1.2 Ecological Relevance – Regardless of the Cause of Effects

If we want to prevent "environmental harm",[21] we must ask which negative impacts are really meant. If transgenic plants are comparable with conventional plants, then "environmental harm" by conventional plants should be analysed, which has been done in this project. Thereby, it was found that, in practice, particularly those effects were ecologically relevant that are currently not or only marginally investigated in the risk assessment. If we really want to register important environmental impacts, a much broader approach would be necessary. In particular, this must include the influence on agricultural practice that can be derived from the phenotypic traits of the individual variety. In addition to the "canonical" parameters gene transfer and invasiveness, these include in particular all tolerances and resistances that bear the potential for expansion of cultivation.

Advantages: This perspective corresponds with the original intention of Directive 90/220/EEC. It could contribute towards a reduction of sustained risks for the environment, since all parameters that could have an influence on the environment could be discussed. This would even be of advantage if they do not play a role in the final decision because their significance is assessed as too low – at least this would create problem awareness. Politically, such a perspective would be of advantage because it meets the public expectation of comprehensive risk assessment and thus the requirements of credibility. Surveys indicate that the concept of risk is currently regarded much more comprehensively by the public than by many important commissions and authorities dealing with the assessment of release applications. There would be another advantage, at least in terms of comprehensive environmental protection. By comparing with conventional plants, more attention would be drawn to the omissions and inconsistencies of conventional agricultural policy with regard to the ecological consequences.

Disadvantages: The comprehensive perspective would theoretically be possible according to current EU law. However, it is contradictory to practice inasmuch as the Commission has repeatedly declared itself in favour of a clearly more restrictive interpretation.[22] Moreover, risk assessment according to this more comprehensive view would have to include non-transgenic

[20] The proponents of comprehensive environmental protection could see a further disadvantage in the fact that there would be no grounds any more to work for ecological goals in agriculture with reference to the special nature of transgenic plants. However, this opinion is likely to become obsolete in the near future.

[21] From the preamble to EU Directive 90/220/EEC on the intentional release of genetically modified organisms in the environment (EC Council, 1990).

[22] On the other hand, this opinion is obviously not shared by all member states.

plants, in order to be consistent. However, this would be a serious interference in the current practice of variety licensing. Due to the number of plants to be investigated; such regulation would hardly be feasible. Politically, an extensive investigation of new varieties is unrealistic. Since such an investigation would only make sense in the general evaluation of new varieties, the latter had to follow the criteria of comprehensive environmental protection. This would require a considerable change in certain aspects of agricultural policy. In view of the existing adjustment problems within the European agricultural system, such a modification would be an obstacle to the intended increase in efficiency. It would be difficult to overcome as long as efficiency is viewed in purely economic terms.

4.2 PROPOSALS

With regard to the problems lined out, Soja and Soja (1995 b) and Janssen *et al.* (1995 b) discuss some possible strategies for dealing with the identified shortcomings. They draw up different proposals for a kind of „third way“:

4.2.1 Integration of Ecological Goals in Seed Breeding

On the basis of their research, Janssen *et al.* (1995 b) came to the conclusion that risk assessment pursuant to EU Directive 94/15/EC ultimately meets with insurmountable difficulties. As an alternative, they propose more intensive research in order to reach better possibilities for drawing conclusions with regard to effects from traits. Furthermore, ecological perspectives should be included in the formulation of breeding goals that should sensibly be included in the seed testing.

Advantages: This proposal would lead to a consequent and consistent regulation in terms of comprehensive environmental protection, regardless of the technology used for breeding, and would be a radical implementation of the precautionary principle. The breeding goals could be included in specifications for the development of new varieties fairly easily. Since there are already approaches towards the implementation of such goals (e.g. the goal of "low-input" suitability), the existing tendencies would be reinforced. In this sense, a political contribution to long-term shifts towards more ecological agriculture would also be made. In the short and medium term, the compulsion for action towards an ecological reform of the entire agriculture would be reinforced, for the individual departments of agriculture on a national level as well as for the EU Commission.

Disadvantages: This approach requires that there is consensus on the concept of the term "ecological goal" – an assumption that is probably unrealistic in the near future. In order to be able to define traits in accordance with such goals, it must be possible to draw clear conclusions from traits (that are to be achieved) to (ecologically desirable) effects. In most cases, one cannot wait for the results of intensive technical research required to establish these correlations. Basically, this is just as problematic as in risk assessment, where conclusions with regard to possibly undesired ecological effects are drawn from existing traits. Incentives, for example to use varieties that are suitable for low input, would have to be provided through suitable structural conditions for agriculture. Such a new framework, however, requires substantial re-orientation in the definition of priorities – i.e. it is not the means but the goal. Politically, there could be disadvantages for the environmental departments, since competencies would be shifted to the agricultural departments or to DG VI of the EU Commission, which is responsible for agriculture.[23]

4.2.2 Taking into Account the Agricultural Practice

Although the problems of risk assessment were generally acknowledged, it appeared that causal correlations can be discussed in certain cases. The practical application of the questionnaire in EU Directive 94/15/EC, however, showed that certain significant environment-relevant effects resulting from agricultural practice could not be covered. Thus, the introduction of additional questions was proposed by Soja and Soja (1995 b) and also by Janssen *et al.* (1995 b).

Advantages: Such a regulation would render it possible to deal with effects that are ecologically important in practice and that have been (or had to be) neglected so far. Additionally, the current structure could remain basically the same. This means that the well-tuned mechanisms of risk assessment can be maintained in general, and that implementation would not be confronted by too many problems. However, the time frame for the assessment of a single case specified by the EU is probably too short. The applicants would have to be induced (voluntarily?) to calculate a lead time of about 6 months. Meanwhile, the fundamental data (excluding competitive data) of the prepared application could be published in order to allow discussions on the implications. Politically, this proposal conforms with the current views both in Austria and in other EU member states such as Denmark. It is basically also in the interest of the environmental departments of these member states and possibly of DG XI at the EU Commission, which is responsible for environmental protection.

Disadvantages: The greatest problem is that agricultural practice is difficult to assess and regionally very varied. Thus, the required information is necessarily unreliable and hardly verifiable. The basic problem of inconsistency also remains, since the regulation only applies to transgenic plants. Furthermore, it is doubtful whether there will really be a ban, should a commission or authority come to the conclusion that significant risks must be expected. Political problems could result from the fact that the signals of EU biotechnology policy currently point more towards deregulation and simplification. Particularly member states like Great Britain, France, the Netherlands and Germany would hardly support such a regulation. It must further be expected that such a regulation could have an alibi character in the light of the short time provided for the required information to be obtained. It remains to be seen whether it is realistic to trust on the collaboration of the applicants. Moreover, interpretation differences are probable, particularly between the individual member states, so that the somewhat ambiguous situation that we have today would not be clarified.

4.2.3 Modification of the Questionnaire

In the long term, the introduction of "ecological" breeding goals (which must be clearly defined) may be the better alternative in terms of a precautionary and comprehensive environmental protection. This solution leads to consistent regulations and does not put transgenic plants at a disadvantage. Basically, it makes market forces available for implementation. However, it is still a long way until the introduction of such goals on a broad level. Currently, the inclusion of

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[23] This also meets with resistance from many groups active in environmental protection, since traditionally quite different parameters are to the fore in seed testing. Therefore, many people consider a proper implementation to be doubtful.

agricultural practice into the assessment, despite all problems, could at least ensure a broader horizon that would pave the way for broader ecological breeding goals in the long term.

For such a strategy, some of the items in Annex II B of Directive 94/15/EC will have to be amended, which are listed below. The discussion is based on the three case studies (wheat, maize and Robinia) in Chapter III.

Section B

This section describes the recipient (parental) plants; it provides important information about the starting point of the genetic change. In order to be able to assess future traits, information about the behaviour of the plant in the environment is necessary. However, it is not quite clear how much information on the ecology of the plants is necessary.

Question B 3 is important for a general assessment of the plant. In order to describe the influence of the abiotic environment on survivability, question B 3.b) should be better structured in temperature, water, soil, nutrient needs and stress tolerances:

- *B. 3. b) Specific abiotic factors affecting survivability (temperature, water, soil, nutrient needs, stress tolerances).*

Since information on homogeneity of the genetic basis can currently not be collected, question 3.b) should be amended to include information on the genetic adaptation potential:

- *B. 3. c) Genetic homogeneity, genetic adaptation potential?*

Especially for plants with a longer rotation time or lifetime, such as forest trees, amendments would be necessary to comply with the long-term nature of the assessment. Question B 5. should be amended to include questions on the form of utilisation and cultivation:

- *B. 5. b) Form of utilisation and cultivation.*

In question B 6, (like in questions B 3 and B 7), the habitat of plants and their behaviour in this habitat is to be described. This includes information symbionts, incompatibilities, reasons for different competitiveness in the native country and in Europe, etc. However, according to the intention of the Directive, question B 6. applies only to Exotic Species in the narrower sense, i.e. for those that virtually do not exist in Europe. Plant species that are grown in any form in a member state – regardless of their ecological effects – are excepted. The Robinia, e.g., is a borderline case in which such information would be useful but which is not "exotic" to such a degree that it meets the specified criteria. Thus, the wording "usually" is not very meaningful. It would be better to use the expression "in agriculture and forestry" instead. If the wording of the Directive is followed, important information is lost. Equally, the restriction to "natural" habitat is obviously unsatisfactory, but will be retained. Question B. 6. could be:

- *B. 6. In the case of plant species not grown in agriculture and forestry in the Member States, description of the natural habitat of the plant and the ecosystem in which it is to be grown, including information on natural predators, parasites, competitors and symbionts.*

The limitation in question B. 7. to "non-plant" indicates that it has been tailored for applications for plants with insect resistances, and is therefore very specific. The question should be rephrased analogous to question 6:

- *B. 7. In the case of plant species grown in agriculture and forestry in the Member States, potentially significant interactions with the biotic and abiotic environment in the ecosystem in which it is usually grown, and potential changes in these interactions in the ecosystem in which it is to be grown, including information about toxic effects on humans, animals and other organisms.*

Sections D and H

Whereas section D includes questions about modified conditions for interaction with other organisms or the abiotic environment, and agricultural practice itself, section H deals with the individual ecological impacts of these modifications. Sections D and H must be amended in this sense.

The term "non-target organism" in question 9 ("Potentially significant interaction with non-target organisms") applies to direct resistances, at the most. The term is particularly inapplicable, if only the *conditions* for certain harmful organisms have been modified, even if the modification was introduced to reduce the detrimental effects of the organisms. These modifications could be important though, therefore information about modified conditions for interactions with *other relevant organisms* is necessary. Furthermore, it is not clear why only interactions with organisms should be of importance, especially where tolerances are concerned, so that possible interactions with the *abiotic environment* must also be indicated. For more general application, the question should be rephrased:

- *D. 9. Has any of the conditions for the interaction with other organisms and the abiotic environment been modified?*

Impacts on plant cultivation measures and on *agricultural practice* must be included, especially with regard to the possible distribution of an organism and the effects on input. The effects of an expansion of the cultivation area may be considerable, therefore this possibility is also important piece of information. However, it is not clear a priori whether such an expansion falls under "agricultural practice", therefore question 9.a) should be phrased accordingly:

- *D. 9. a) (new): Does the genetic modification allow, promote or require changes in agricultural practice, including possible expansion of the growing area?*

As a complement to question D 9, question H 4 is aimed at the ecological relevance of the information:

- *H. 4. Possible environmental impact resulting from potential interactions with other organisms and the abiotic environment.*

In question H 5 – as a complement to question D 9 a) – the ecological relevance of the information, e.g. soil problems due to over-fertilisation, could be dealt with:

- *H. 5. (new): Possible environmental impacts resulting from agricultural practice that has been modified due to the new traits, including possible expansion of the growing area.*

4.2.4 Implementation

The inclusion of additional questions on agricultural practice poses some problems, however. Besides political opposition, such a strategy would meet some serious questions concerning its implementation. The following ones appear to be crucial:

What kind of agricultural practices or application of agro-chemicals should the assessment deal with?

Since we are dealing with an assessment of environmentally relevant facts, those experiences that ideally refer to concrete, clearly identified and scientifically tested environmental impacts are important. However, as was shown, a direct inference from measures to environmental impacts is just as difficult as the conclusion from plant traits to ecological effects. Even so, there seem to be certain practices of which we definitely know that they have undesired effects, e.g. over-fertilisation, use of long-life herbicides, letting the soil open for long times, etc.

- *A list of undesirable practices should be considered. Thus, it could be investigated whether the new plant – compared with the parental plant – has the potential to promote or repress one or more of these practices.*

Such a list could accelerate assessment considerably, but could also mean that other effects not related to one of the listed practices are no longer considered – thus turning the risk assessment into a formal exercise.

Does an assessment of the possible distribution on the market (economic competitiveness, distribution potential) provide reasonable information?

The most important parameter for the extent of ecological impacts is the cultivation area, therefore information on this point would be useful for the assessment. However, such information would have to be very speculative. We are dealing with an assessment of market potentials, which the individual companies are quite likely to carry out but will certainly not publish. They are quite rightly considered as a strategic company secret. On the other hand, such market research can hardly be carried out or controlled by third parties within the short time available. Furthermore, the consequences are unclear: what is to result from such information? Should plants with a high market potential be subject to more stringent safety requirements? This would probably restrict their market potential, thus eliminating the reasons for the safety requirements again, etc.

- *Useful as such information may appear, it will probably prove to be just as problematic in practice.*

How can breeding goals and their ecological advantages be presented?

If "ecological goals" in seed production are to be realised, it would be necessary first to define what this means. Generally, it would be possible

- *to follow on from the list of undesired practices proposed above, and to define traits that could reduce or prevent them.*

However, the requirements are much higher here. Initially, the main issue was to find out whether a certain undesired practice could possibly be promoted. Here, a negative statement would have no consequence. Unless there was reason to assume that such a practice would be supported, there would be no misgivings about the plant assessed. If, however, it is not certain whether an active contribution is made towards prevention, the goal of introducing such a trait cannot claim to be "ecological". Furthermore, we have the tiresome problem of identifying correlations between trait and effect. If we want robust data on such correlations, the trait of the plant would have to have been investigated. This would require that it already exists in the plant – although the breeding goal is to introduce this trait. Therefore, such goals must be defined very cautiously. Information can certainly be provided in a very general way, but usually more in a negative form: the trait should not promote certain practices. For specifications beyond this, the knowledge base is presumably missing.

Which requirements are adequate and how can they be controlled?

Adequate requirements fulfil their purpose, and can be complied with and controlled at reasonable cost. There are doubts about to what extent agreement can be reached on both the purpose and the cost. If the purpose of requirements is to restrict the practices mentioned in the list, this could initially serve as a common basis. However, an agreement must be reached with regard to the list, which has to be modified depending on environmental, climatic and socio-economical conditions.

- *Control of whether the desired effect is actually achieved has to be guaranteed by monitoring, in which established agricultural consulting should be integrated.*

This could also be done in collaboration with the producers of seeds, who should be interested in proving that their products are ecologically superior to conventional products. Thus, it all depends on using existing consulting and control channels for this purpose. However, just how compatible this would be with the sovereign functions of the authorities, namely licensing subject to requirements and their controls, remains a point for discussion.

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6 ANNEX II B OF THE DIRECTIVE 94/15 EC

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute).
2. Name, qualifications and experience of the responsible scientist(s).
3. Title of the project.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:
   (a) family name,
   (b) genus,
   (c) species,
   (d) subspecies,
   (e) cultivar/breeding line,
   (f) common name.

2. (a) Information concerning reproduction:
   (i) mode(s) of reproduction;
   (ii) specific factors affecting reproduction, if any,
   (iii) generation time;
   (b) Sexual compatibility with other cultivated or wild plant species.

3. Survivability:
   (a) ability to form structures for survival or dormancy,
   (b) specific factors affecting survivability, if any.

4. Dissemination:
   (a) ways and extent of dissemination;
   (b) specific factors affecting dissemination, if any.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plants, including information on natural predators, parasites, competitors and symbionts.

7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

C INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name of donor organism(s)) and intended function of each constituent fragment of the region intended for insertion.

D INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/deleted:
   (a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP,
   (b) in case of deletion, size and function of the deleted region(s),
   (c) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination,
   (d) copy number of the insert.

3. Information on the expression of the insert.
   (a) information on the expression of the insert and methods used for its characterisation,
   (b) parts of the plants where the insert is expressed (e.g. roots, stem, pollen etc.).

4. Information on how the genetically modified plant differs from the recipient plant in
   (a) mode(s) and/or rate of reproduction,
   (b) dissemination,
   (c) survivability.

5. Genetic stability of the insert.

6. Potential for transfer of genetic material from the genetically modified plants to other organisms.

7. Information on any toxic or harmful effects on human health and the environment arising from the genetic modification.

8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

9. Potentially significant interactions with non-target organisms.

10. Description of detection and identification techniques for the genetically modified plant.

11. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Purpose of the release.

2. Foreseen date(s) and duration of the release.

3. Method by which the genetically modified plant will be released.

4. Method for preparing and managing the release site prior to, during and post-release, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Any precautions taken:
   (a) distance(s) from sexually compatible plant species,
   (b) any measures to minimise/prevent pollen or seed dispersal.

2. Description of methods for post release treatment of the site.

3. Description of post-release treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant.

3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).

4. Possible environmental impact resulting from potential interactions with non-target organisms.