A critique of the "concept of familiarity" as used in ecological risk assessments of genetically modified plants.

Christian Damgaard* and Hans Løkke

Department of Terrestrial Ecology, DMU, Vejlsøvej 25, 8600 Silkeborg, Denmark.
phone: +45 8920 1598
fax: +45 8920 1414
e-mail: cfd@dmu.dk

*Corresponding author

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Abstract

Two different approaches to ecological risk assessment of genetically modified plants are discussed. The first is an intuitive approach of summarising the scientific knowledge on the specific genetically modified plant, called "the concept of familiarity". The other approach is based on the estimation of probabilities of specific ecological scenarios, which we will call "scientific risk assessment". In the conclusion we will advocate that the use of scientific risk assessment for ecological risk assessment is the superior methodology.

The question of whether or not transgenic plants should be used commercially cannot only be decided upon using agronomic arguments. Genetically modified plants (GMP's) are a public concern, and the public wants to know how safe this new technology is - the scientific answer to such a demand is risk assessment.
Risk assessment of GMP's has developed from the first comprehensive review article presented in the late eighties. This review was primarily based on speculations and its focus was primarily on agronomic concerns (creation of new pests etc.) and on the structure of international co-operation. The authors concluded that more interdisciplinary research was needed in order to evaluate benefits and risks of biotechnology. Since then, scientists have gone through a period of optimism concerning the risks of GMP's, exemplified by, into a phase of growing concerns together with the increasing amount of relevant data. In the mid-nineties the discussion was further expanded from a "simple" scientific debate of biological consequences of releases to include ethical considerations. At the same time the regulatory and legal aspect of commercialisation became a major issue. Today we are at a stage where a lot of relevant data has been collected but no internationally standardised and consistent schemes, test procedures and concepts have been fully developed associated with commercial use of GMP's.

In some cases introduction of new species or genotypes to an area is an irreversible process. If a plant is introduced into a natural habitat it may not be practically possible to remove it again. Therefore, it is important to make an assessment of possible ecological risks of a GMP before it is released for commercial growing. Here we will briefly present two different approaches to ecological risk assessment, one, using an intuitive approach of summarising the scientific knowledge on the specific GMP, called "the concept of familiarity", and another, based on the estimation of probabilities of specific ecological scenarios, which we will call "scientific risk assessment". In the conclusion we will advocate that the use of scientific risk assessment for ecological risk assessment is the superior methodology.

**Concept of familiarity**

Generally, risk assessment is based on a comparison of the GMP and its traditionally grown counterpart, and the risks have traditionally been assessed using an intuitive assessment of possible risks, i.e. using the familiarity concept. General experience with the plant and the inserted construct is used to assess possible risks, and if the plant or the inserted construct is well known and unproblematic, the risk is assumed to be low.

The concept of familiarity is explained by the Organisation for Economic Co-operation and Development (OECD) member countries as: "... the knowledge and experience available for conducting a risk / safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment.". The concept is further exemplified by: "Whether standard cultural practices would be adequate to manage a relatively unfamiliar new plant line or cultivar (i.e., the combination of plant and trait is relatively unfamiliar) can be assessed based on familiarity with a closely related line in conjunction with results from laboratory and preliminary field work with the new line.". A high degree of familiarity does not necessarily imply safety. Instead, familiarity is desirable because familiarity with a specific cultivar or trait facilitates a risk evaluation. Thus, the concept of
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familiarity is, according to the OECD, not analogous to a risk assessment, but only a description of the amount of knowledge and experience available.

Nevertheless, in practical risk assessment it seems that the concept of familiarity implies that a cultivar or a trait that has a high degree of familiarity poses less risk than if it had a low degree of familiarity. According to the Directive 2001/18/EC article 7 of the European Commission a GMP may be deliberately released under so-called simplified procedures if an applicant can convince the competent authorities in a member state that the GMP is "familiar", i.e. if sufficient knowledge is present on the non-modified plant concerning risks for human health and the environment. Likewise, it is stated in the principles for the environmental risk assessment in the Directive (Appendix II) that: "Information from releases of similar organisms and similar traits and their interaction with similar environments can assist the environmental risk assessment."

It is important to note that the concept of familiarity does not evaluate the risk of a specific ecological scenario, rather the argument is that since we have not seen any unwanted ecological effects with the use of similar plants and/or inserts we are relatively safe to conclude that we will not observe any unwanted ecological effects in this case. The concept of familiarity relies on scientific knowledge concerning the GMP, which mainly is based on agricultural science, and the ecological consequences of commercial growing of GMP's are studied much less. Until 1999, approximately 1200 applications for deliberate release of genetically modified plants have been circulated in the EU. Most of these applications state that the purpose of the releases is of agronomic interest. 17 applications, i.e., less than 2% of the total number of applications, specify the purpose of the release to be of purely scientific interest, and only 12 applications state that the release will increase our knowledge of the plant in relation to ecological risk assessment.

As an example of the concept of familiarity used in ecological risk assessment is the development of genetically modified sugar beets (Beta vulgaris). Sugar beets have been grown in Denmark for more than one hundred years and the plant breeders claim that the probability of genetic exchange between sugar beets and its close wild relative wild beets (B. maritima) is very low. This statement is based on the long experience with the agronomic characters of sugar beet, which seem not to be influenced by introgression of genes from natural wild beet populations. However nothing is known about the possible gene flow in the other direction, from sugar beet to wild beet, so it is incorrect to conclude that there is no unwanted ecological effects - as the knowledge only include familiarity with crop genomes and not wild species genomes.

Another example of the misuse of the concept of familiarity is when companies from, for example, North America apply to obtain approval for placing a product on the European market. Often investigations performed under North American conditions play an important part in such applications - claiming their product to have no ecological unwanted effects in Europe, although the relevant European environmental conditions might be very
different from the conditions under which the product have been examined.

**Scientific risk assessment**

In scientifically based risk assessment, a risk normally is defined as the probability that a specific event will occur multiplied by the effect or impact of the event (Risk = Probability x Effect). For example, the risk of nuclear melt down can be quantified by the probability that a melt down occurs times the number of people expected to die as a consequence of the melt down. Thus, scientific risk assessment is separated in two parts, estimation of the probability that a specific event will occur, and the adverse effect of the event on the public who is experiencing the risk. Note that an ecological risk or an ecological hazard is perceived by humans and the society not ecosystems.

The methodology of estimating probabilities is well defined and based on concepts that are generally used in the scientific community. However, it can be difficult or sometimes impossible to predict the probability that a specific event will occur. For example, the probability that a gene will become fixed in a population can theoretically be calculated from knowledge of selection forces and population structure, but in a real world situation the parameter values that are needed to calculate the probability are complex and unknown functions of the surrounding biotic and abiotic environment. For a start, it is important to get a detailed account of the data needed to predict the probabilities of different ecological scenarios.

The methodology of estimation of adverse effects or consequences of events is well defined within, for example, health science and within ecotoxicology. Ecological risk assessment may be more difficult, but is feasible when risks to populations of single species are assessed using endpoints such as significant changes of populations growth rates, population stability or even extinction of metapopulations. Such effects may be quantified on the level of plant communities, birds and mammals, insects, soil macrofauna, and soil microfauna. For GMP's the pure presence of the plants and/or the engineered genes in areas outside the cultivated field may be regarded as an unwanted effect. Also the direct or indirect impact of GMP's through foodchains on indigenous organisms within the cultivated field may be quantified as effects, as in the case of insect resistant crops. Additionally, impacts of GMP's on the physical environment may be used as effect parameters, for example, changes in nutrient cycling, changes in the amount of organic carbon in soil, or increased erosion. The assessed value of the effect may synthesise the degree of "unwantedness" associated with the ecological change, because the more an ecological change is unwanted, the higher is the sense of risk felt by people.

In scientific based ecological risk assessment the following three cases describes the options:
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1. The ecological impact can be assessed, but it is difficult or impossible to estimate the probability of the particular adverse effect occurring in a given period of time. In such cases it may be fruitful to assume that the ecological scenario will happen given enough time, i.e., setting the probability to one, and to perform the risk assessment based on the effect assessment only. Additionally, if it is found impossible to estimate a probability of a specific event, then at least you know what you do not know, and future research can be directed towards that question.

2. Both the probability and the adverse impact can be assessed. This is the ideal situation allowing for calculation of a series of scenarios.

3. The probability can be assessed, however the adverse effect is not elucidated sufficient to allow for specific effect assessment. In the case of an invasive plant, the frequency of the modified plant species may be used as the quantitative effect variable, eventually in combination with the yearly costs of removing the plants from specific areas without injury to pristine vegetation.

In conclusion, estimating the probability of a specific event is best performed by scientific methodology, whereas in many cases the estimation of the adverse effect of a certain event on the human society is both an ecologically based and a political judgement, and cannot generally be performed using scientific methodology. Thus, scientific risk assessment has to be performed by an interaction between the scientific community and governmental regulators who implement the chosen policy.

Conclusions

Traditional risk assessment that is based on expert opinions, using the intuitive approach of the concept of familiarity, will in many cases be a fast method for making risk assessment, but since the methodology is based on an intuitive approach there is no way to check and improve the quality of the risk assessment in a formalised way. When the concept of familiarity is used in ecological risk assessment it is not necessary to specify exactly what ecological scenarios are unwanted. Some consider this lack of precision to be a strength of the risk assessment method, because it allows for unanticipated effects of a specific transgene.

We believe that risk assessment questions best are thought of and formulated with specific risks in mind. Only by being precise in the problem formulation it is possible to make full advantage of complementary scientific research, which on the long term significantly will improve both our general ecological knowledge and the ecological risk assessment. Furthermore, if a risk assessment problem cannot be formulated in two parts, a probability part and an adverse effect part, then it might be because the problem is formulated erroneously, and an alternative formulation of the risk would be more productive. For example, studying the invasion process by plant growth measurements at a single density will never allow you to predict the probability of invasion, and this becomes clear if the invasion process is modelled with the aim of predicting invasion probabilities.
Additionally, following the conventional terminology in the rapidly growing science of risk assessment makes it easier to communicate with scientists doing risk assessment in other scientific disciplines.

A promising avenue for estimating probabilities of ecological scenarios is to integrate population biological and evolutionary modelling with empirical investigations. In many cases it will be possible to summarise ecological effect studies, which are traditionally analysed using an analysis of variance, by a probabilistic approach on specific ecological scenarios. For instance, if we are concerned that a GMP may invade a specific plant community and outcompete a specific plant species, the risk of such an ecological scenario can be evaluated by estimating the probability from competition experiments using standard population biological models and Bayesian statistics. In order to ensure that such a modelling approach works satisfactorily it is important that the probabilistic predictions on different ecological scenarios are followed in a monitoring program.

A further advantage of formulating risks using the scientific risk assessment terminology is that ecological risks can be integrated into a general cost-benefit analysis of a GMP, as a cost that may occur with some probability at some point in time. Such an integration of risk assessments and cost-benefit analyses will be a strong tool for weighing different arguments and making political decisions on the commercialisation of GMP’s. Scientific risk assessment relies heavily on good ecological data, which at the moment only is available for a few model systems. It will be a large task to gather the ecological data needed to do a proper risk assessment, but weighed against the possible benefits of GMP’s to the society it will be feasible.

The degree of familiarity with the biological system is important in the initial phases of the risk assessment when the ecological scenarios which may be looked upon as possible risks are formulated, but the actual risk assessment is best done within the framework of a scientific risk assessment.

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