Chapter 17

The role of precautionary motivated science in addressing scientific uncertainties related to GMOs

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1. Introduction

Implementing a precautionary approach (as for instance specified in Article 1 of the Cartagena Protocol on Biosafety) might require a renewed look at the science underpinning risk assessment and management of GE and GMO release. Hence, in this chapter I will argue that the implementation of the Precautionary Principle may have implications on scientific practice. For instance, implementation of the Precautionary Principle requires that indications of adverse impacts are being documented in some way, and that risk-associated research is initiated. Such precautionary motivated research might initiate debates concerning the quality of risk-related scientific advice. Furthermore, it may identify areas where scientific understanding is lacking by investigating various models of risk and initiate basic research that concedes or rules out risks of ecological harm. Precautionary motivated science needs to be built on a basic research agenda; it involves broadening the scientific focus, reflexivity and allows for interdisciplinary approaches.

2. Scientific uncertainty with GE use and GMO release

Several reports have been written on the science-based concerns related to the use and release of GMOs (see for instance ESA 2004; NRC 2004; The Expert Panel of the Royal Society of Canada 2001, and in this book see especially Chapters 8–15). The uncertainties described in these reports can be placed in two categories: scientific uncertainty due to (a) lack of scientific understanding, and (b) scientific dissent.

2.1. Lack of scientific understanding with GE use and GMO release

Lack of scientific understanding with regard to the proposed benefits and the potential adverse effects of GE use and GMO release may be due to (see Chapters 4, 8 and 9):

- The new properties that are introduced by genetic modification of a plant, animal or micoorganism.
- Secondary effects of the introduction of the transgenes.

The lack of scientific understanding may be due to the novelty of GE and GMOs, in which case scientific uncertainty may be reduced by conducting more risk-associated research and by collecting more empirical data. In other cases, the lack of scientific understanding may be due to the variability or complexity inherent in the system under consideration. This form of lack of knowledge may be *irreducible* since it originates in the inherent randomness of ecological systems.

There is a need for more comprehensive studies of ecological effects of GMO utilisation, for instance with regard to potential secondary effects of GMO release on environmental processes and adverse effects on human and animal welfare. Experimental testing of carefully elaborated risk hypotheses may result in a solid basis for the avoidance of potentially harmful GMOs (see Chapters 8–15). A more holistic approach to GMO risk issues involves appreciation of uncertainty and implies assessment of time and complexity of ecological aspects. However, the initiation of such risk-associated research involves some challenges to the scientific work since it questions the traditional conduct of science, i.e. with regard to reliance on methods, and the choice of hypothesis. These issues will be further elaborated in the remaining part of this chapter.

2.1.1 Reliance on models and methods

Models are often used in scientific research with the purpose of corroborating a hypothesis, by offering evidence to strengthen what may be already partly established through other means. Models can also be used to elucidate discrepancies in other models or for sensitivity analyses – for exploring 'what if' questions – thereby illuminating which aspects of the system are most in need of further study, and where more empirical data are most needed. Thus, the primary value of models is heuristic; models are representations, useful for guiding further study, but they are not subject to proof.

There is at present uncertainty with regard to the choice of methods and models to investigate the consequences of GMO use and release. This scientific uncertainty results from not fully understanding interactions among variables and the relevance of models used to predict the behaviour of multivariable systems. For instance, the potential for gene flow to the agricultural and natural environment is a new concern for regulators and scientists. This concern includes both a) economic and legal concern with regard to how to ensure coexistence, and b) environmental concern with regard to potential adverse effects on biodiversity.

When controls on field trials have included monitoring of horizontal gene transfer (HGT), the frequency has often been considered to have a low impact or to be insignificant. However, in two recent papers (Heinemann & Traavik 2004; Nielsen & Townsend 2004) it is argued that current techniques for sampling and monitoring of HGT from GM plants to soil microorganisms are too insensitive and that rigorous monitoring may be the only realistic way to detect HGT. Further, they highlight that the frequency of HGT is probably marginally important compared to the selective forces acting on the outcome. The two papers agree that new methods are needed to study HGT. However, while Heinemann and Traavik suggest a new method for studying HGT that is based on detecting iterative short-patch events, Nielsen and Townsend suggest a population-based approach. The fact that the two research groups suggest two different methods for solving the same problem is interesting. When conducting their research, scientists make assumptions and inferences based on the paradigms they are trained under, which in turn influence the scope and choices of methods and models to increase their scientific understanding. Furthermore, differences in training and other forms for socialisation may also have impacts on the choice of hypothesis and the threshold for significance of evidence.

2.1.2 Hypothesis testing: Type-I errors versus Type-II errors

In the practice of statistical testing, researchers often formulate a null hypothesis (H_0). The H_0 is usually stated in terms of 'no adverse effect'. If the outcome of a statistical test warrants the rejection of the H_0, the scientist will normally accept the alternative hypothesis H_1 – that there is an adverse effect. Hypothesis testing operates on the basis of limiting Type-I errors (which erroneously predict an adverse effect when there is in fact none), to ensure that the observed result supports the H_0. Hence, Type-I errors occur when one rejects a true H_0. In contrast, a Type-II error is made by not rejecting a false H_0, i.e. there is an ecologically adverse effect, and the H_0 is wrong (Table 17.1).

Table 17.1. Type-I errors and Type-II errors in ecological studies. Null hypothesis H_0 = There are no adverse effects.

Reality Test results	H_0 is true	H_0 is false
The investigation does not show adverse effects	Correct (1-a)	Type-II error False negative (ß)
The investigation shows adverse effects	Type-I error False positive (a)	Correct Statistical power (1-ß)

According to the traditional scientific norm, one ought to have complete and supportive information before claiming a cause-effect relationship. Consequently, the statistical significance of the result must be strong enough to allow only a small probability (p) that the result is due to chance or has been based on speculation. By convention, in a Type-I setting the probability of this error being made is determined by the significance level of α – often at 5%. Hence, if there is less than 95% confidence that there is an effect (1 in 20), the H_0 is not rejected. In such situations, scientists are prone to assume that the evidence is not strong enough to reject the H_0.
The conservative scientific demand of statistical significance before rejection of the H_0 is adequate if the statistical power is high. Statistical power, (Sp)=1-β (the risk of Type-II error), refers to the probability of correctly rejecting H_0, i.e. statistically detecting an effect if it exists. The risk of committing a Type-II error increases if the power of the data set decreases; i.e. there is limited scientific understanding and there is a scientific hypothesis of adverse effects. Minimising Type-I errors is necessary and adequate when doing laboratory research, as the parameters and variables are few, the results are in most cases reliably identifiable or quantifiable, and the purpose is to gain new understanding and avoid spurious results.

However, exploratory and monitoring research entails a practice that avoids making Type-I flaws (Lemons et al. 1997). Complex interactions in open systems cannot be adequately predicted; hence achieving complete and supportive information before claiming a cause-effect relationship may not be possible. This means that risks to society, health and the environment may remain obscured, because a bias towards avoiding Type-I errors discourages research into risk-associated aspects. In this context, the power of studies to detect relevant risk becomes important. In general, this is often overlooked, leading to a false sense of security from negative studies that fail to find a risk (Andow 2003). For instance, Lövei & Arpaia (2005) claim that power analysis is rarely considered in laboratory tests on the impact of GM plants on arthropod natural enemies. Hence, they argue that in future studies of non-target effects, power analysis needs to be employed since this may help research planning (for example, giving indications of sample size and duration of project) and contribute to clarifying the interpretation of the results.

2.1.3 Systematization of uncertainty may enhance quality and direct further research
The notion that uncertainty is only a statistical concept or represents insufficient data may leave out many important aspects of uncertainty when performing risk assessments (Giampietro 2003; Wynne, 1992). For instance, uncertainty with regard to GMO release and use can be presented at the level of uncertainty or that of ignorance.

Uncertainty refers to situations where we do not know or cannot estimate the probability of hazard, but the hazards to consider are known. This may be due to the novelty of the activity, or to the variability or complexity involved.
Ignorance represents situations where the kind of hazard to measure is unknown, i.e. completely unexpected hazards may emerge. This has historically been experienced with, for instance, BSE, dioxins and pesticides (EEA 2002). With regard to GMOs, unprecedented and unintended non-target effects may emerge. Non-target effects include the influence on and interactions with all organisms in the environment, and may be direct or indirect. Direct effects concern, for instance, ecotoxic effects on other organisms, while indirect effects concern, for instance, effects on health, contamination of wild gene pools or alterations in ecological relationships.

Employment of model-based decision support, such as the Walker & Harremöes (W&H) framework (Walker et al. 2003), may help to identify the types and levels of the uncertainty involved. The W&H framework has been developed by an international group of scientists with the purpose of providing a state-of-the-art conceptual basis for the systematic evaluation of uncertainty in environmental decision making. One of the main goals of the W&H framework is to stimulate better communication between the various actors in identification of areas for further research and in decision processes. In this framework, uncertainty is recognised at three dimensions:

1. Location (where the uncertainty manifests itself, (e.g. if it is contextual (ecological, technological, economic, social and political), if it is in the expert judgement, or in the models used (model structure, model implementation, data, outputs, etc.))
2. Nature (the degree of variability which can express whether uncertainty primarily stems from inherent system variability/complexity or from lack of knowledge and information)
3. Level (the severity of uncertainty that can be plotted on a gradual scale from 'certain knowledge' to 'complete ignorance').
4.

For instance, Krayer von Krauss et al. (2004) have demonstrated and tested the W&H framework with the purpose of identifying scientists' and other stakeholders' judgement of uncertainty in risk assessment of GM crops. In these studies the focus was on potential adverse effects on agriculture and cultivation processes by release of herbicide resistant oilseed crops. Krayer von Krauss et al. interviewed seven experts in Canada and Denmark. To identify the experts' view on location uncertainty, the authors presented a diagram showing causal relationships and key parameters to the experts. To identify the level and nature of uncertainty, the experts had to quantify the level and describe the nature of uncertainty on the key parameters in the diagram. By asking the experts to identify the nature of uncertainty, it was possible to distinguish between uncertainty that may be reduced by doing more research and ignorance that stems from systems variability or complexity.

Approaches that define and systematise the uncertainty involved, such as the W&H framework, may help in using scientific knowledge more efficiently, in directing further research and in guiding risk assessment and management processes.

2.1.4 The unpredictability of complex systems
The study of complex systems is about understanding indirect effects and problems that are difficult to solve because the causes and effects are not clearly related (Chu et al. 2003; Gundersen & Holling 2002; Scheffer et al. 2002). Under such circumstances, the normal scientific approach of trying to produce a best estimate or final answers will not be useful, since it may not necessarily reduce uncertainty. This is because uncertainties regarding the behaviour of complex systems have nothing to do with a temporary insufficiency in our knowledge; it has everything to do with objective, structural properties of complex systems. Putting pressure on a

complex system at one place can often have effects in another place because the parts are interdependent. Hence, one needs to be aware that there will always be an inevitable gap between limited experimental conditions and reality, where the consequences of an activity can never be fully predicted. For instance, in observational studies of complex, poorly understood systems, errors in the independent variables, errors arising from choice of the wrong form of the model used to analyse and interpret the data, and biases from the way the study was conducted may arise (Kriebel et al. 2001).

With regard to GE use and GMO release, unanticipated effects may arise due to interaction between the introduced transgenes(s) and the recipient genome, or unanticipated interactions between the GMO and the ecological system. Designing adequate human and environmental models for determination of risks and identification of unpredictable effects are difficult tasks. Present approaches need to be supplemented with methods that study whole systems. This involves a perception that the dynamics of human and environmental systems cannot solely be described by the parts, as genes and proteins, but concern interaction with each part of the system. Some suggestions for how to study whole systems are presented in Chapter 10. In addition, it is crucial that methods for detection and monitoring are initiated with the purpose of following up the performed risk assessment, to map the actual health and environmental effects and to detect unanticipated effects. Long-term monitoring provides baselines against which to compare future changes and gives input data to improve regulation systems (Cranor 2003).

2.2 Scientific dissent with regard to impacts of GE use and GMO release

In a situation of lack of scientific understanding, analogies from well-known areas of research are often invoked. With GMOs the different scientific disciplines that are involved use competing analogies and models for basic assumptions to frame the scope for further research. For instance, agricultural biotechnologists refer to the practice of conventional plant breeding, while ecologists refer to the experiences based on the introduction of exotic species to make up for the lack of anticipatory knowledge. Since the principles and paradigms of the different scientific disciplines differ, they have no common ground to discuss means for gathering new scientific understanding. There are, for instance, divergent opinions among scientists about the relevance of various potential adverse effects, about the definition of potential ‘adverse effects’, and what action to take to prevent potential harm (Myhr & Traavik 1999; 2003). From this perspective, the demand for ‘more research’ is not sufficient to reduce scientific uncertainty, since the incapacity of science to provide a unified picture of the environment contributes to the uncertainty.

Sarewitz (2005) argues that scientific dissent in the case of highly complex and difficult to assess risk situations are due to different backgrounds/disciplines. The scientists’ backgrounds may affect choice of hypothesis, methods and models, which gives conflicting data and causes disagreements among scientists. What Sarewitz denotes as ‘excess of objectivity’ refers to the observation that available scientific knowledge can legitimately be interpreted in different ways to yield competing views of the problem and how society should respond. Hence, the challenge is to manage the uncertainties that are characteristic of each field so that information of the highest possible quality can be obtained (Funtowicz & Ravetz 1990).

Reflecting on the role of scientific disunity in the interpretation of scientific uncertainty related to GE use and GMO release, the question arises as to how enhanced dialogue between competing disciplines can contribute to make explicit those values, interests and implicit assumptions that represent the frame for each discipline’s approach to scientific uncertainty. For instance, an enhanced dialogue can be facilitated by involvement of a wide base of scientific disciplines as well as independent scientific institutions in the gathering of scientific understanding. Involvement on a wide basis of scientific disciplines will: (1) assist in the exploration of alternative problem framing and alternative indicators that can be used in risk assessment; (2) function as a source of knowledge, data and information – including information on uncertainties – that may be of relevance for risk assessment; and (3) assist in the evaluation and critical review of assumptions used, method, process, and results. This will ensure diverse consideration of both mainstream and minority opinions, and cause avoidance of abuse of science by scientists biased to a specific agenda. Hence, the different methods and models representing the different disciplines may be seen as compatible providers of information and models for studying the problem or the system. With more diversity in the approach, more data will be generated and more responses will be available to understand complexity and changing conditions.

3. Conclusion

In this chapter I have argued that there is a need to achieve wise management of uncertainties with regard to potential adverse effects of GE use and GMO release. This challenge has to be met by scientific conduct and approaches that aim to manage risk and uncertainty, taking into account the complexity of the ecological systems that the GMOs are to be released into. Broad risk assessments of GMOs should include appreciation of uncertainty and complexity, and involve communication of early indications of harm. In this context, scientists and decision makers should become comfortable with making decisions based on the weight of evidence according to an approach that strives to reduce Type-II errors. A change to a more integrative risk assessment, where the Precautionary Principle has an important role may make science more accountable to public concern.

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