Chapter 7

GE Applications and GMO Release: The Ethical Challenges

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1. Introduction

The term 'genetic engineering (GE)' is very broad, covering an assortment of ways to analyse and manipulate genomes of living organisms. The public supports different applications of GE to different degrees. Genetically modified (GM) medicines and genetic tests, for instance, are considered to carry invaluable benefits, and hence they tend to be accepted. The utilization of GM animals, GM fish and GM crops, however, is strongly opposed. Different levels of support for different GE applications may be explained by the public conception of potential benefits and risks involved. Such risks are related to the potential for unintended adverse health and environmental effects as well as to social and economic aspects.

Different applications of GE and GMO usage represent various types of risk. For instance, with GE medical applications such as a GM vaccine, a GM drug or somatic cell gene therapy, the beneficiary coincidently carries the potential risks. For germ cell line gene therapy, however, diseases may be cured by genetic 'surgery', and the 'improved' genome will be passed on as a new genotype in the next generation. Accordingly, the risk of harm may be transferred to future generations. Issues that present putative risks across generation gaps, raise questions concerning moral obligations. They involve the challenge of balancing the ethical consideration of human needs today against the opportunities for future generations to fulfil their needs. The situation becomes even more complex when society and the environment may experience the risk. For instance, we do not know with certainty if GM crops will promote general welfare by providing more nutritious food or help to ensure food safety. Neither can we be sure that GM crops do not cause unintended effects on non-target organisms or threaten biodiversity. Inevitably, solutions to such dilemmas should be based on ethical reflections such as: How to act when the long-term consequences are unknown? How sure is 'sure enough'? Who are the affected parties? Good answers to these questions demand safety requirements for health and the environment, taking a long-term perspective, consideration for present and future members of society, and a presumption of democratic decision making. To meet these challenges, we will in this chapter argue that:

- A number of ethical issues, as well as choice of perspectives and value commitments, affect risk assessment and management of GE applications and GMOs.

- A more holistic approach to GE applications and GMO risk issues is needed to account for the present lack of scientific understanding and for the complexity of ecosystems.

2. The role of ethics

Decisions to apply new technology and innovations must be based on evaluations of the assumed benefits versus the potential risks of adverse effects to ecosystem, human and animal health. In addition, a decision must include an evaluation of the values that are important to enhance or to protect, which are directly linked to a community or governmental choice of level of protection. In general, the most fundamental distinction in ethics may arguably be drawn between the outcome of a decision (consequence ethics) and the means for taking decisions (deontological ethics) (Box 7.1).

Box 7.1 Consequence ethics and deontological ethics

Consequence ethics are mainly concerned with the outcome of actions, and what is right depends on the benefits achieved or the good outcome. A classical approach is utilitarian, meaning that the morally 'right' action is the one that optimizes the goal for the whole moral community (Bentham 1789; Mill 1871). Utilitarianism is usually an ethical foundation for risk-cost-benefit analyses. Risk-cost-benefit approaches are often used in the evaluation of technology development, introduction and implementation. Accordingly, an activity may be considered ethically acceptable if its benefits outweigh its costs. In deontological ethics, on the other hand, the moral rightness of an action is independent of its actual consequences (Kant 1781). Deontological ethics prescribe that moral rules need to be applied when making decisions. Such rules may prohibit an action irrespective of the best intentions and/or outcome. Such moral rules may include respect for human autonomy and dignity. Some environmental ethicists have argued that rights and duties should be extended to animals and to the environment, and not relate to humans only (Regan 1980).

GE applications and the release of GMOs involve a lot of challenges to the quality of decision making. The differences in perception between governments, among the scientists and within the public are related to the underlying ethical issues, as well as to choice of perspectives and value commitments that affect frameworks of risk assessment and management of GE applications and GMOs. Most often cost-benefit analyses are chosen as the fundament for risk regulatory frameworks. However, a strict application of risk-cost/benefit analyses does not cope appropriately with the current lack of scientific understanding and the complexity of the human and environmental systems that are to become the recipients of the GE applications and the GMOs. Therefore, application of cost-benefit analyses may, for instance, lead to unintended ecological effects such as long-term adverse effects on health, decreased biodiversity and harm to dynamic ecosystem processes being ignored. Such analyses also fail to take into account the deeper ethical bases that shape the scientific and public opinions. Hence, applications of cost-benefit analyses that only rely on quantitative valuations without qualitative considerations may appear to be a too narrow approach to GE application and GMO release decisions, by being 'blind' to natural and cultural values that are difficult to measure (Wynne, 2001). In addition, it is difficult to quantify environmental costs. They are qualitatively different from straightforward costs carried directly by producers and consumers and are often linked to value questions. Environmental costs are difficult to measure, and adverse effects may develop over long time frames. The benefits of reducing environmental costs and

risks are most often of non-monetary value. The environment may hence be neglected in standard practice and the incentives for reducing environmental risk and cost may be absent.

Different approaches grounded in deontological ethics have as a common feature a demand for equality and justice of something that is considered as important (as rights, income, and access to resources) (Dobson, 1998). Deonotological ethics imply that moral rules need to be considered when making decisions. Consequently, issues of risk and benefit distribution must include balanced ethical considerations concerning the needs of the present versus future generations, as well as for animals and the environment. Furthermore, for the purpose of avoiding serious, unintended ecological effects it may be necessary to develop new ethical models as alternatives to the anthropocentrically grounded approaches that are mostly used at the present. There are distinct philosophical differences between giving priorities to protection of human interests, i.e. anthropocentrism, versus preservation of ecosystems, i.e. ecocentrism (Box 7.2).

Box 7.2 Antropocentric versus ecocentric approaches

In an anthropocentric context, the environment is protected to promote human welfare, i.e. for recreation purposes, or as a source for gaining new knowledge. Since ecosystems contain huge amounts of unknown information, and biodiversity centres represent valuable genetic pools for future possibilities for humans, i.e. agricultural and medicinal development, protection might be in humankind's best interest (Daily et al. 2000; Pimentel et al. 2000). Hence, human interests provide a powerful set of motives for protecting the environment against activities that may have severe consequences (i.e. reduced biodiversity) for present and future generations. Ecocentrics emphasize the need for a change from the anthropocentric domination and exploitation of the environment towards a greater respect for the integrity of the animals and the environment (Dobson 1998, Westra 1998). Biocentrics argue that as humans, we must provide rights to species and habitats and hence it is our duty to respect their integrity (Regan 1980). Respect for ecosystem integrity is considered important, and preservation and protection of biological, ecological and genetic processes are necessary, irrespective of the instrumental value to humans.

In an ecocentric context, release of a GMO or a GE vaccine into the environment may be morally justified when it protects the diversity of the species in the community, and does not cause adverse effects to ecosystem processes. Involvement of ecocentric ideologies will legitimize a holistic approach to risk-associated studies. Such an approach may also focus on changes in both biotic and abiotic factors (both physical and chemical factors that are non-living), for instance the effects on soil, water and air. This ideology differs from anthropocentric GMO governance with respect to value commitments and factual beliefs. Hence, ethical issues do affect the significance of frames and approaches in environmental risk regulation. Involvement of ecocentric and biocentric ideologies will, for instance, entail awareness of the complexity of ecosystems and hence legitimize interdisciplinary scientific initiatives and a holistic approach to risk-associated approaches.

3. Risk assessment and risk management

The Cartagena Protocol on Biosafety was adopted in 2000, and 141 countries have ratified it so far. Many countries have adopted national regulations for GMO use and release as well. The international and national regulations do, simply by their existence, acknowledge the risks of GE applications. By extension, authorities have realized the need to employ precaution in order to protect human and animal health and the environment. However, it is necessary to reflect on the fact that the risk assessment and management strategies prescribed through regulations are developed within particular frameworks. They include (as mentioned) values and preferences in relation to the natural environment and the promotion of human health.

Risk assessment includes hazard identification, risk characterization and risk estimation, while risk management comprises value judgements with regard to acceptability, trade-off criteria and adaptation of strategies for coping with the risk aspects identified during the assessment. Risk assessment has been considered a strictly 'scientific' process, while social and political factors are involved at the risk management and communication stage. However, in reality, it is obvious that risk assessment also involves value judgements. They relate to conception and acceptance of consequences that should be avoided, and also to the processes of risk characterization and investigation. Such judgments are most often made before initiation of the risk assessment, and serve as 'lenses' through which adverse effects and lack of knowledge are viewed, perceived and defined. For instance, if the decision makers demand that complete and supportive information or credible scientific evidence is needed before cause-effect relationships are claimed, lack of knowledge may be downplayed or overlooked in situations with high complexity. Waiting for scientific evidence of harm implies postponement of precautionary measures and preventive actions until a product or an activity is proven harmful, or until plausible cause-effect relations are established. On the other hand, in situations characterized by lack of knowledge and complexity, it may not be possible to get conclusive scientific evidence of adverse effects. A reductionistic approach awaiting conclusive scientific evidence may then fail to protect humans and animal welfare. Hence, the quality of a risk assessment will depend on the value aspects considered important to protect, and the harm that needs to be avoided by the scientists and the decision makers involved.

The present GMO risk assessment procedures are dependent on information produced and owned by the very same companies whose products are being assessed. This means that there is a conflict of interest linked to risk assessment. A further obstacle for independent risk assessment is the difficulty in obtaining access to this information (Myhr & Traavik, 2002), since it is often claimed to be confidential business information. Access to information, i.e. the risk assessment performed by the companies that develop GE applications and the GMOs, and accumulation of knowledge via independent peer review is needed in order to ensure transparency and confidence (Nielsen, 2006). In addition, this is essential for identifying lack of knowledge and for directing further research activities in areas of uncertainty and ignorance.

3.2 Scientific uncertainty and complexity

Before releasing any new living organism or genetically modified DNA construct into a new location or ecosystem, important questions concerning environmental and health effects need to be answered. A number of hypothetical effects, both beneficial

and harmful, have different degrees of scientific support, mostly due to lack of relevant research. At present, very little research to approve or reject such hypothetical claims has been carried out. Without hard data that specifically address the issues, it is impossible to assess health and environmental impacts, and more critically, the exposure levels to be recommended. The present lack of scientific understanding is of ethical significance in the context of research that should be initiated and also of how this research should be carried out (see Chapters 4, 6 and 8–15).

3.2.1 The need for early warning research

The report *Late lessons from early warnings: the precautionary principle 1896-2000*, published by the European Environment Agency (EEA, 2001), describes 14 cases where lack of precaution has had human, ecological and economic costs. The most relevant of the cases in our context may be the horizontal transfer (HGT, see Chapter 13) of antibiotic resistance genes, the endocrine disrupting effects of chemical pollutants and the bovine spongiform encephalopathy (BSE) story. In all 14 cases, 'dissident' scientists predicted and had preliminary results indicating the problems that later became evident. Such scientists were marginalized and discredited by mainstream science as well as by the economic stakeholders involved. Recently, we have experienced GE-relevant cases directly, through the histories of Drs Arpad Pusztai and Ignacio Chapela.

The necessity of learning from past failures, and to heed early scientific evidence of risks, is emphasized in the EEA report. The selected cases are analysed historically with focus on the decisions taken (or not taken) at a given time, and correlated to the knowledge at that specific time. The report describes how lack of scientific proof of harm was misinterpreted as evidence of safety both in science and in policy, and that the failure to respond caused human, ecological and economic costs. For instance, throughout the DES (synthetic oestrogen diethylstilbestrol) case there were official assertions of safety, i.e. that there was no risk of transmission to the foetus (Ibarreta & Swan, 2001). DES had been prescribed since 1947 to pregnant women in order to prevent spontaneous abortions. The pharmaceutical industry, the medical scientists and the regulators did not acknowledge the 'early warnings' indicating that DES could cause harm. As early as in 1938, it was reported that DES could increase cancer in laboratory animals. Several subsequent studies proved that DES could cause cancer in the cervix and vagina of rodent species. However, the acceptance that DES could cause teratogenic effects and was a transplacental carcinogen first came in 1971, ten years after the limb reduction effects of thalidomide were revealed. Before that it was generally assumed that the placenta protected the foetal environment from external exposure. The DES case illustrates how narrow risk-assessment frameworks are, and how the choice of null hypotheses may hamper both initiation and acceptance of early warning based research.

The 14 cases in the EEA report have exemplified the risk of bias towards safety conclusions when hypotheses that dominate mainstream science are treated with blind reliance. The DES case had its tragic toll because it was generally accepted that the placenta protected the foetus against hormone-related harms. Hence, no risk-associated studies to confirm or reject this assumption-based hypothesis were initiated.

The DES, and the other cases in the EEA report, highlight the problem of 'omitted research', an expression used for important research lacking intellectual, economic or political incentives for being carried out.

We have experienced the dramatic consequences of ignoring early warnings quite recently. Following the BSE (mad cow disease) scandal in UK, a *Science* commentary asked: '*What happens when the premise underlying a scientific risk assessment is wrong and, as a result, the risk is vastly understated? In the case of so-called mad cow disease, or bovine spongiform encephalopathy (BSE), people die, an industry suffers, and a country panics*' (Gavaghan, 2000). A very highly respected BSE researcher commented: '*From my perspective, unwelcome scientific advice about an epidemic spread of BSE worldwide, and especially about the undeniable possibility of transmission of the BSE agent to humans, was dismissed*' (Manuelidis, 2000). In other words, when harm cannot be proven by science, in part because the kind of scientific research in question has not yet been carried out, the developer and/or proponent of a product maintains the legal presumption that it causes no harm by its action, and the 'public and the environment' carry the burden of proof.

In relation to GMOs, claims are made that early warnings represent 'snap-shots' and 'worst-case scenarios', not reality, and therefore they should not be published (Shelton & Sears, 2001). This issue has recently been exemplified by the controversies arising following the *Nature* report that Mexican maize was contaminated with transgenic DNA from GM maize (Quist & Chapela, 2001). The report caused an extensive debate concerning methods used for detection of GM contamination and with regard to the significance of the preliminary findings (Kaplinsky et al., 2002). A temporary climax was reached by an editorial note in *Nature* (Editors' comment, 2002) claiming 'the evidence available was insufficient to justify publication of the original paper'. In this case, there has been extensive interference in the process by actors (media, the public, non-governmental organizations, and industry) not normally active in the scientific process. The focus has been on the researchers and their context, and very little has been done to confirm or refute the claimed biologically and ecologically adverse impacts. This case illustrates the extent of scientific disagreements, and ethical dilemmas that surface when there are close ties between public and academic science and private enterprise.

Just like early safety proclamations, early warnings may later be proven wrong. It is, however, important to publish them in order to inform other scientists and regulators. This in turn will become the basis for follow-up research designed to confirm or reject them. If such 'early warnings' are not reported, evidence required for the application of the Precautionary Principle may not be known, and governments may end up making decisions in the absence of proper scientific understanding.

3.2.2 Reductionism, scientific uncertainty and complexity

The 'central dogma' (see Chapters 2–4) was the basis for molecular biology and GE. Approaches based on reductionism were both productive and unavoidable in the early developmental stages of GE. Lately, however, a growing acceptance of an unanticipated complexity and unpredictability in the relationships between DNA-RNA-protein has emerged. New techniques, such as genomics, proteomics and metabolomics (see Chapters 4 and 8) have been developed to cope with complex interactions, the cooperation and coordination of multiple genes and the dynamics of

total genomes. This is not to deny that reductionistic approaches may present very fruitful ways to study phenomena, since they will involve few variables under controlled and contained conditions. However, some results of reductionistic assumptions, such as the belief that large-scale behaviour of GMOs can be extrapolated from effects studied in small-scale models, do not hold validity and do not represent reality. To extrapolate from one context to another, i.e. from small to large-scale release, leaves questions concerning the environmental fate of GM plants unanswered (Wolfenbarger & Phifer, 2000).

Interactions with the environment are organized on a higher level than the DNA level. For instance, the same gene may not have the same expression level in different organisms (Bergelson et al., 1998). A transgene may result in other proteins in the recipient than in the donor plant (Prescott et al., 2005). These and other examples show that extrapolation of data from small-scale to large-scale, or from one context to another, does not necessarily represent reality. Growth conditions are geographically and climatically different and may make it difficult to identify the cause-effect relationships of impact. Such extrapolations may therefore, in fact, increase the uncertainty.

Furthermore, unpredictable effects of GMO use and release may arise due to interactions between the introduced transgenes(s) and the recipient genome, or unanticipated interactions between the GMO and the ecological system. Hence, one needs to be aware that there will always be an inevitable gap between limited experimental conditions and reality, i.e. the consequences of an activity can never be fully predicted. This is because uncertainties regarding the behaviour of complex systems may not be directly linked to lack of knowledge, which can be reduced by performing more research. Consequently, resolving uncertainty and complexity requires a) more comprehensive studies of ecological effects by GMO utilization (see Chapters 4 and 8–15) and b) epistemic discourses that involve different scientific disciplines. This will ensure diverse considerations and enhance critical evaluation of methods, processes and results that may be of relevance to risk assessment (see also Chapter 6).

4. GMOs in the Third World

In a Third World context, GM crops in particular have attained a lot of focus. For instance, it is argued that GM crops may enhance global food security, and must therefore be used in poverty alleviation strategies. However, there is a need to consider the implications of the fact that most GM crops are developed and distributed by Western, resource-rich companies with little connection to regional and local realities in the South. For instance, small-scale resource poor farming does not have the same ability to apply management strategies that come with the new technology, as does large-scale farming. Features that distinguish small-scale low input farming from industrial farming (high input) necessitate adoption of procedures for introduction and management of GMOs that are specially designed for such systems. Hence, there is a need to understand the political, socio-cultural and ecological basis for the release of GMOs, not only for large-scale agriculture but also for small-scale, resource-poor farming (Cleveland & Soleri, 2005). Also, internationally recognized strategies for poverty reduction, conservation of biodiversity and sustainability need to be acknowledged when introducing GM crops in poverty alleviation strategies. In

addition, since environmental security is an essential part of successful poverty alleviation, food security strategies have to be environmentally sustainable. In the context of sustainable development, local acceptance and applicability of new farming practices entail that the knowledge and worldviews of local farmers need to have a central role. These needs initialize the development of competence and capacity as well as inclusion and application of traditional knowledge, relating to biodiversity conservation and use as well as to socio-cultural aspects. Broad involvement may also help to integrate different viewpoints and enable wider considerations of risk. This may also enrich the process of scientific investigation by providing knowledge of local conditions and resources. However, many countries in the Third World have yet to implement national regulatory frameworks for regulation of GE applications and GMOs, and many of these countries also lack scientific and administrative capacities to ensure a sustainable introduction of GE applications and release of GMOs. Hence, the need for biosafety capacity building in the Third World is urgent.

5. Implications of a gene ecology approach

Traditional science is challenged with respect to its ability to address complex ecological risk issues, and consequently also the role science plays in policy making. In response, some scientists and sociologists have presented alternatives to traditional scientific activity. Weinberg (1972) introduced the term 'trans-scientific' to describe questions 'which can be asked by science and yet which cannot be answered by science'. Weinberg challenged the authority of science in policy-relevant decision-making processes, and suggested that political and/or additional processes should be essential. Funtowicz and Ravetz (1990; 1993) have introduced the concept of 'post-normal science'. This contrasts traditional and applied science when it comes to responding to uncertainty and inadequacy in quality or 'fitness of purpose' in policy-related research. Post-normal science entails a broad and integrated view for approaching problems in science, by taking into account both the factual and value dimension of the scientific method. This insight rests on two axes, decision stakes and system uncertainty, and the interrelationship between them.

With regard to biotechnology and GE it has recently been argued that there is a need for more comprehensive approaches, such as epigenetics and systems biology, to take into account the inherent complexity. We support this point of view, realizing that the present lack of scientific understanding and the complexity of the recipient ecosystems necessitate implementation of the precautionary principle and precautionary-motivated risk-associated research (see Chapter 17). Such precautionary research is motivated by post-normal science and is a part of what we have defined as the gene ecology approach (Box 7.3).

Box 7.3 Gene Ecology

Gene Ecology is a new interdisciplinary field that is unique in its combination of genetics and biochemistry with bioethics, the philosophy of science, and social studies of science and technology. It builds on innovative work in the areas of genomics, proteomics, food science, ecology, evolution, intellectual property, indigenous rights, participatory technology assessment, and globalization. This systemic approach reverses the trend toward the more reductionistic qualities of the component sciences.

Gene ecology is a central discipline for the comprehensive evaluation of gene-based technologies.

Gene ecology research starts with a list of 'ifs', 'perhapses' and 'maybes' and the objective of the research is to:

- Adopt precautionary motivated research
- Replace uncertain presumptions of risk with science-based comprehension
- Establish experimental models, experimental designs and methods that reflect the ecological interactions and complexity of ecosystems
- Conduct ethical analyses that are closely linked to the understanding of how GE may affect the well being of humans, animals and the natural environment
- Establish a more integrated basis for assessment of the ethical implications of science and regulations related to GE applications.

6. Social robustness

The present concerns of the public with regard to use of GE can be seen as requests for a dialogue with scientists and regulators. This can only be achieved if the public concerns are taken seriously and approached with respect. If this is the case, the debate may attempt to differentiate between specific GE applications and the various arguments for and against a specific GE application. The key determinants with regard to risk perception are distribution of risks and benefits, voluntarism and consent, and degree of familiarity, visibility and control. Perception and acceptance of risk are intertwined, and are influenced by individual as well as cultural and social values (Renn, 1998). Hence, a normative baseline for judging relevance and acceptability of potential adverse effects varies in time and space, and depends on both scientific understanding and other factors, such as social values within a religious, cultural or national context. The public consideration of GE risks represents a broad view that is not exclusively based on scientific risk assessment.

It has been generally believed that gathering more knowledge about technology will reduce the public scepticism. Contrary to this, several reports have highlighted that regardless of the level of knowledge, the public still holds sceptical attitudes towards GE (Gaskell et al., 2000). For instance, the Eurobarometer surveys reveal that high levels of public knowledge do not reduce the demand for more control of GE applications (Eurobarometer, 2006). According to Nielsen (1999), the sceptical group of the public may be separated into two distinct fractions, 'the traditional' and 'the modern', while the proponent groups share characteristics with 'techno-optimists and entrepreneurs'. The proponents of the technology put emphasis on practical benefits, view science and progress as 'a good thing', and estimate risks to be minor and manageable. The 'traditional group' represents 'the blue argument' and voices concern about the rightness of technological intervention and progress on the basis of moral and religious values. The 'modern' sceptics, on the other hand, argue on the basis of a more environmentalist critique and consider present knowledge too limited to allow some GE applications.

GE proponents have assumed that resistance and scepticism to GE applications are based on ignorance and emotions and may hence be labelled 'irrational'. Indeed, it is

possible that over time the present lack of knowledge will be reduced and scientific uncertainty will be either resolved or recognized as 'non-reducible'. Objections related to inherent values, on the other hand, will remain as aspects of GE. Inherent values vary between individuals and socio-cultural contexts. Such 'value-based' arguments are considered the opposite of scientific facts. This view leads to prolonged separation of values and facts, and reinforces stereotypical dichotomies between scientific and public perception of science (Levidow & Marris, 2001).

Differences in perspectives may be considered complementary rather than contradictory. Consequently, value-based arguments should not be underestimated in decision making, and inherent values need to be included independent of their scientific validity. The future of GE may depend on whether the developers and regulators are prepared to increase transparency and involvement of more than just 'scientific facts'. In this case, more awareness concerning scientific uncertainty as well as ethical, cultural and social issues must be raised. It is crucial to recognize that the scientific, economic and social contexts are intertwined with regard to the quality of risk assessment and management. New institutions for participatory processes are needed to strengthen dialogues between stakeholders, with respect to selection of working hypotheses, burden of proof formulations and evaluation of evidence (public participatory methods are further described in Chapter 34).

Conclusion

Ethically responsible decision making must be based on the best available knowledge, but also on the conception of missing knowledge. This requires awareness of the relevant scientific uncertainties and knowledge gaps involved. While it is widely acknowledged that good risk assessment demands uncertainty and ignorance estimations, the common instruments to make uncertainties and scientific ignorance visible are still limited.

Although research on such topics has made significant progress during the last decade, valuable and useful instruments to represent ethical principles need to be established. Furthermore, the reliability of decision making is not only related to the quality of data supporting technical solutions, but also to whether the data are relevant for risk specific goals and conclusions. Ethical aspects relate directly to the scientific description of the risk assessments and management of GE, taking into account the adverse effects and unexpected effects that need to be avoided, as well as the benefits we need to achieve. This may initiate creative thinking about designs of risk-associated research. Truly creative thinking must include proper monitoring of the promised benefits and potential health and environmental risks as well as social, ethical and cultural issues that the communities find important to protect. Adequate evaluation methods can include stakeholder participatory methods: deliberative processes for uncertainty and ignorance assessments, for accommodation of scientific disagreements, and for integration of stakeholder interests and perspectives.

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