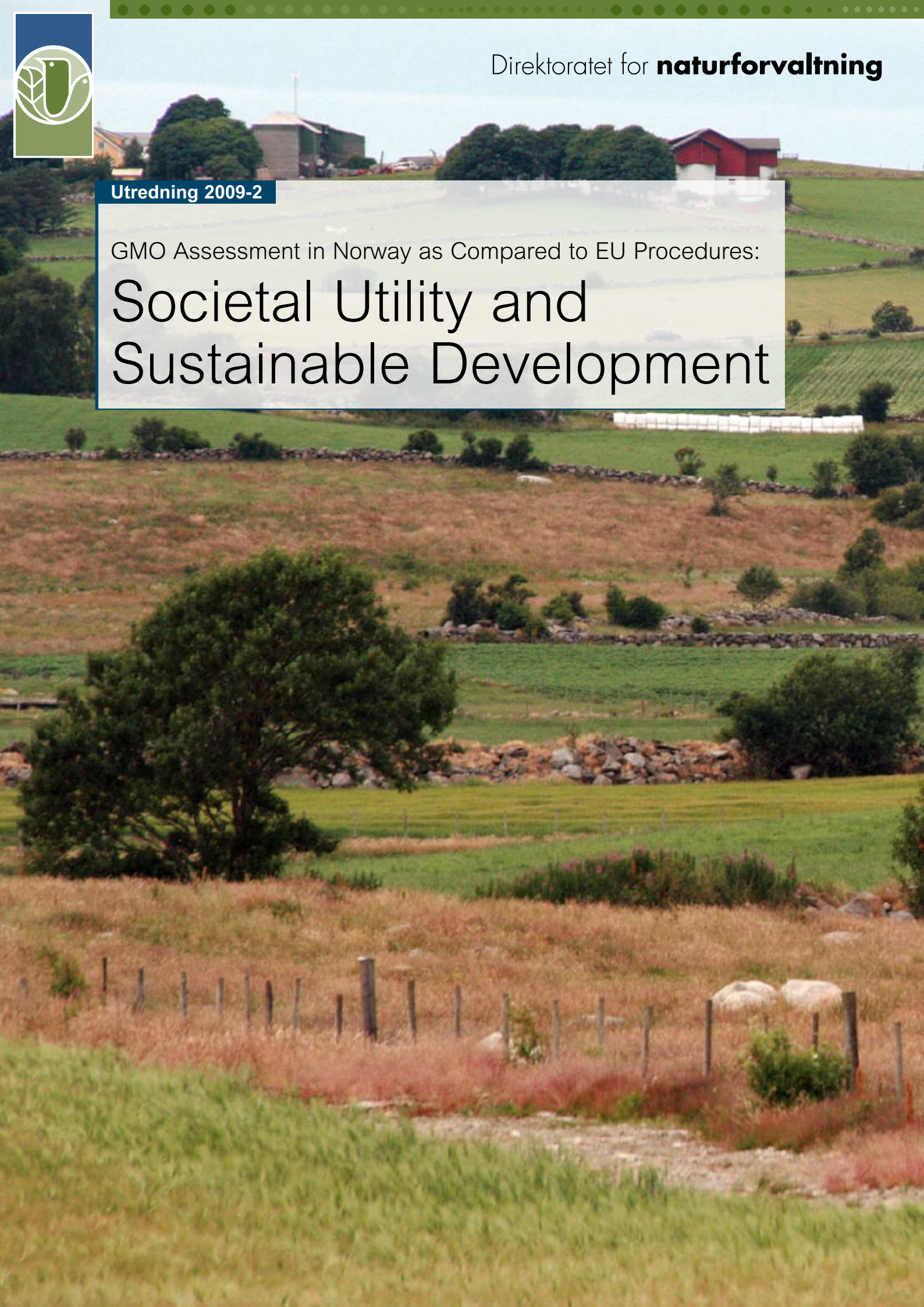

Direktoratet for **naturforvaltning**

Utredning 2009-2

GMO Assessment in Norway as Compared to EU Procedures:

Societal Utility and Sustainable Development

GMO Assessment in Norway as Compared to EU Procedures:

Societal Utility and Sustainable Development

Vurdering av GMO-søknader i Norge sammenliknet med EU: Samfunnsnytte og bærekraftig utvikling

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Anne Ingeborg Myhr og G. Kristin Rosendal. DN-Utredning 2009-2

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Ekstrakt:
Mandatet gitt fra Direktoratet for naturforvaltning var å levere en vurdering av i hvilken grad dagens søknader til EØS-området om markedsføring av genmodifiserte organismer (GMO) oppfyller kravene om samfunnsnytte og bærekraft i den norske genteknologiloven. Forfatterne identifiserte følgende fire hovedtema for utredningen: a) beskrive hvordan norske myndigheter kan benytte seg av prosedyrene i EU systemet; b) diskutere hvordan konseptene bærekraftig utvikling og samfunnsnytte kan anvendes i et bredere perspektiv; c) evaluere den vedlagte dokumentasjonen for to utvalgte GMO-markedsføringssøknader med fokus på egnethet for vurdering av bærekraft og samfunnsnytte; og d) gi anbefalinger angående vurdering av bærekraft og samfunnsnytte. Utredningen er basert på en vurdering av tilgjengelig litteratur og dokumentasjon.

Abstract:
The overall mandate of the study was to assess how and to what extent marketing applications for GMOs fulfil the criteria of sustainable development and societal utility in the Norwegian Gene Technology Act. The authors identified four objectives: a) elaborate how the Norwegian authorities can use the procedures implemented in the EU system; b) discuss how the concepts of sustainable development and societal utility can be applied in a broader sense; c) evaluate the information provided in two given GMO marketing applications, with a focus on the adequacy of the supplemented information; and d) develop recommendations concerning the assessment of sustainable development and societal utility. The report is based on a desk study of available literature and documentation.

Forord

DN har et sentralt forvaltningsansvar knyttet til norsk vurdering av søknader om utsetting av genmodifiserte organismer (GMO) i miljøet. Norge må, som følge av EØS-avtalen, ta stilling til alle GMO-søknader som sendes til medlemsland i EU. I Norge behandles søknadene i henhold til lov av 2. april 1993, nr. 38 om framstilling og bruk av genmodifiserte organismer m.m. (genteknologiloven), og søkers dokumentasjon vurderes i henhold til forskrift av 20. august 1993 om konsekvensutredning etter genteknologiloven.

Norge og EU har tilsvarende krav mht dokumentasjon av helse- og miljøeffekter ved utsetting av en GMO, men til forskjell fra genteknologiloven stiller ikke EUs regelverk krav til vurdering av produktets innvirkning på bærekraft og samfunnsnytte. Dermed må norsk forvaltning ta stilling til søknader som ofte har mangel på dokumentasjon egnet for å vurdere kriteriene bærekraft og samfunnsnytte.

DNs mål med utredningen var å få innspill til hvordan norske myndigheter på en bedre måte kan benytte seg av søknadsprosessene i EU til å ivareta de norske kriteriene mht bærekraft og samfunnsnytte. To reelle GMO-søknader er undersøkt for å belyse tilgjengelig informasjon i søknadene og påpeke mangler. Utredningen er utført av Anne Ingeborg Myhr fra GenØk – Senter for biosikkerhet og G. Kristin Rosendal fra Fridtjof Nansens Institutt.

Utredningen peker blant annet på fortsatt behov for operasjonalisering av de norske kriteriene bærekraft og samfunnsnytte, og viser til forvaltningens utfordringer i forhold håndtering av manglende informasjon i søknadene. Antallet søknader om utsetting av GMO øker årlig, noe som vil aktualisere problemstillingen ytterligere i årene fremover.

Yngve Svarte
Direktør Artsavdelingen

Foreword

The Directorate for Nature Management (DN) has a central role regarding the regulation of genetically modified organisms (GMOs) in Norway and assessment of notifications for release of GMOs into the environment. In accordance with the EEA Agreement Norway must evaluate all GMO-notifications received by EU member countries. In Norway, the notifications are evaluated according to the provisions in the Act of 2 April 1993 No 38 regarding the production and use of genetically modified organisms (Norwegian Gene Technology Act) and the information provided in the notifications must be in accordance with the Regulations relating to impact assessment pursuant to the Act.

Procedures for release of GMOs in Norway and the EU are fairly similar with regards to the required health and environmental risk assessments. However, contrary to the Norwegian Gene Technology Act the GMO-regulations in the EU do not require assessment of the impact of GMOs on sustainable development or benefit to society. This often results in a lack of relevant documentation for assessment of the Norwegian criteria, thereby complicating the task of the Norwegian regulatory authorities.

DN commissioned the report with the aim of receiving input on how Norwegian authorities can make better use of the GMO-procedures in the EU to fulfil the Norwegian criteria of sustainability and benefit to society. Two GMO-notifications have been used as case studies to identify information of relevance and pinpoint the gaps. The report is written by Anne Ingeborg Myhr (GenØk – Centre for Biosafety) and G. Kristin Rosendal (Fridtjof Nansen Institute).

The report points, amongst others, to a need for continued development of the criteria sustainable development and benefit to society and makes note of the challenge faced by Norwegian authorities on how to deal with lack of information in the notifications. As the numbers of GMO-Notifications increase yearly these issues will be even more relevant in the years to come.

Yngve Svarte
Assistant Director General

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A report to the Norwegian Directorate of Nature Management on:

GMO Assessment in Norway as Compared to EU Procedures:

Societal Utility and Sustainable Development

Anne Ingeborg Myhr (GenØk) and G. Kristin Rosendal (Fridtjof Nansen Institute)

Sammendrag

Utredningen omhandler hvordan søknader om markedsføring av genmodifiserte organismer (GMO) oppfyller kravene i den norske genteknologiloven til bærekraftig utvikling og samfunnsnytte. Gjennom EØS avtalen er det norske GMO regelverket tett knyttet til GMO lovgivningen i EU, og det er mange likheter mellom Norge og EU i vurderingsprosessen – både forvaltningsmessig og i praksis. Norge og EU legger mer eller mindre lik vekt på kriteriene etikk, helse og miljø. Et overordnet funn i utredningen er det brede spekteret av praksis og rådgivning som karakteriserer GMO politikken på regionalt nivå og i de enkelte medlemsland innen EU.

Norge er det eneste landet med krav til en utredning om bærekraftig utvikling og samfunnsnytte. Det kan derfor ikke forventes at industrien leverer slik informasjon, og det er også tilfellet. Dette setter Norge i en vanskelig situasjon da det ikke vil være riktig for norske myndigheter å akseptere en endring av bevisbyrden; manglende informasjon fra industrien vedrørende bærekraft og samfunnsnytte kan ikke være norske myndigheters ansvar. En løsning for å oppfylle lovens kriterier er å investere i ytterligere forskning på området, da det vil kreves mye dokumentasjon for å gjennomføre kriteriene i praksis.

I sin gjennomgang av beslutningsprosessene og vurderingsprosedyrene viser utredningen til en av de største forskjellene mellom Norge og EU sine GMO vurderinger: eksemplene med antibiotika resistens. Utredningen diskuterer også grunnlaget for GMO vurderingene som foretas, altså dokumentasjonen som vedlegges søknadene. Våre funn viser til at dokumentasjonen kan være problematisk på flere områder: manglende åpenhet da store deler av dokumentasjonen er konfidensiell, i strid med Århus konvensjonen; det finnes mange ulike tolkinger av de vitenskapelige funnene; et stort volum, som vanskeliggjør en grundig gjennomgang og vurdering; ikke i samsvar med god vitenskapelig praksis da det i hovedsak er søkers egne vitenskapelige avdelinger som fremskaffer den; og, til sist, er det en mangel på dokumentasjon vedrørende bærekraft og samfunnsnytte.

Deler av vår analyse er en evaluering av egnetheten av søkers dokumentasjon for vurdering av bærekraft og samfunnsnytte, og det følges opp med en diskusjon om hvordan kriteriene kan benyttes i et bredere perspektiv ved å vurdere dem opp mot to GMO plantesøknader. I forhold til kriteriet bærekraft fant vi at søkers informasjon var av stor relevans i forhold til å besvare konsekvensutredningens spørsmål om global påvirkning og økologiske grenser. Disse aspektene krever for øvrig en videre tilnærming, for eksempel vurdering av sosio-økologiske effekter ved introduksjon av GMO, og de undersøkte GMO søknadene bidro ikke med relevant informasjon på det området. Videre fant vi heller ikke informasjon egnet til å vurdere aspektene menneskelige grunnbehov, fordeling mellom generasjoner, fordeling mellom rik og fattig og økonomisk vekst.

Vi vurderte også hvordan de to søknadene oppfylte kriteriet om vurdering av samfunnsnytte. Informasjonen var manglende og dårlig underbygget og vi fant at vurderingen krever en bredere analyse. Viktige aspekter inkluderer vurdering av faktorer som i hvilken grad teknologien er egnet til stor- eller småskala landbruk, effekt på sysselsetting, matvaresikkerhet, landskapsestetikk, human- og dyrehelse og velferd, og en vurdering av hvem som drar nytte av teknologien.

Det er stor internasjonal interesse knyttet til praksisen som utvikles i Norge på dette området. Dersom norske politikere og byråkrater ønsker å demonstrere en oppriktig interesse og omtanke for bærekraft og samfunnsnytte kriteriene ved bruk og utsetting av GM-vekster, vil det være nødvendig å vise til en mer konstruktiv bruk av de juridiske verktøyene. I siste del av dokumentet presenterer vi en rekke anbefalinger knyttet til vurdering av bærekraft og samfunnsnytte aspektene. Vi peker også på en rekke forskningsbehov egnet for å identifisere hvordan GM-vekster i praksis påvirker bærekraft og samfunnsnytte på global basis.

Summary

The report assesses how applications for marketing of GMOs fulfil the criteria of sustainable development and societal utility in the Norwegian Gene Technology Act. GMO legislation in Norway is closely linked to that of the EU through the Agreement on the European Economic Area (EEA). There are many similarities both regulatory and in practice between Norway and the EU in GMO assessments. Norway and the EU put more or less equal regulatory weight on the criteria of ethics, health and environment. An overall finding in this report is the wide range of practices and advice that characterises GMO policy at the regional and member-state level within the EU.

Norway is the only country to formally ask about sustainable development and societal utility. As a result, industry cannot be expected to, and does not, provide information about such matters. This puts Norway in a difficult position. It would seem inappropriate for Norwegian authorities to accept a reversal of the burden of proof; failure by industry to provide information on sustainable development and public benefits cannot be the responsibility of Norwegian authorities. One way of dealing with the situation according to the legal requirements is to invest in more research on these issues, as a large amount of documentation would be required to substantiate the practical consequences of the criteria.

In examining the decision-making and assessment procedures, the report addresses one of the major differences between Norwegian and EU assessments of GMOs: the cases of antibiotic resistance. It also discusses the basis for the assessments, i.e. the documentation following the GMO applications. We find that the documentation accompanying GMO applications may be problematic for several reasons: It is lacking in transparency as large parts of it is confidential, violating the Århus Convention; there are many different interpretations of the scientific findings; it is huge – making thorough assessment very difficult; it is lacking in sound science as it largely stems from research departments of the applicant itself. Finally, information is lacking about sustainable development and societal utility.

Part of our analysis was to evaluate the adequacy of the supplemented information and follow this up with a discussion of how these concepts can be applied in a broader sense, by testing on two GM plants. With regard to sustainability, we found that information provided by the applicants was of high relevance for questions with regard to global impacts and ecological limits required by the impact assessment. However, these questions entail also much wider concerns as for instance effects on socio-ecological relationships by introduction of GMOs, of which the applications we investigated did not give any relevant information. Further we found no information that can be used to answer questions about impacts on basic human needs, distribution between generations, distribution between rich and poor countries, and economic growth.

We also assessed how the two applications fulfilled the criteria of societal utility. The information was very scarce and not substantiated and we found that the assessment warrants broader analysis. Important aspects would include the consideration of factors such as whether the technology is suited to small or large farming enterprises, effects on employment, food security, landscape aesthetics, human and animal health and welfare and a consideration of who would benefit from the technology.

There is significant international interest tied to the developing practice in Norway with regard to these issues. If Norwegian politicians and bureaucrats are to demonstrate genuine interest and concern for sustainable development and societal utility with the use and release of GM-crops, it will be necessary to apply a more constructive use of the legal instrument. Hence, at the end of the report we present our recommendations concerning assessments of sustainable development and societal utility. We also suggest research needs linked to identify how GM crops in practice affect sustainability and societal utility around in the world.

Mandate

This report has been drawn up at the request of the Norwegian Directorate of Nature Management.
We were mandated to:
Assess how and to what extent marketing applications for GMOs fulfil the criteria of sustainable development and societal utility in the Norwegian Gene Technology Act.

Four objectives were identified:

a) elaborate how the Norwegian authorities can use the procedures implemented in the EU system;
b) discuss how the concepts of sustainable development and societal utility can be applied in a broader sense;
c) evaluate the information provided in two given GMO marketing applications, with a focus on the adequacy of the supplemented information;
d) develop recommendations concerning the assessment of sustainable development and societal utility.

Work on this report has been carried out as a desk study involving three research months.

1. Introduction[1]

This report examines the process of deciding on applications for genetically modified (GM) crops or plants for import or commercial planting in Norway. The focal points of discussion are the specific criteria of societal utility and sustainable development set out in Norway's Gene Technology Act. Our discussion takes as its point of departure an assessment of two GM plants: Pioneer Hi-Bred's 1507xNK603 maize and Monsanto's soy 40-3-2, aka 'Roundup Ready' soy. The European Union Commission announced on 24 October 2007 its approval of 1507xNK603 products for import, food, feed, import and processing. The soy was accepted in 1996 for import, for processing, and for food and animal fodder in the EU. GMO legislation in Norway is closely linked to that of the EU through the Agreement on the European Economic Area (EEA), to which Norway is a party. In line with the EEA, the Norwegian authorities within an almost identical legal framework must separately decide on all GMO applications sent to the EU. In Norway, there has been growing agreement on application of the precautionary principle and increased rejection of applications in the preliminary assessments (Rosendal, 2007). It is an open question whether this is counter to current trends in the EU (Lieberman & Gray, 2006) and, if so, what this implies for Norway's stance.

In the next section, an overview of recent developments in internal assessment procedures in the EU is presented. A brief analysis of Norwegian GMO assessments is offered in section three, where the development of arguments and principles is examined. The main developments are linked to the broad concepts of public utility and sustainable development. Section four follows this up with a discussion of how these concepts can be applied in a broader sense. This includes close scrutiny of legitimacy and participation in relevant decision-making processes and the relationship between science and politics. In addition to the analysis of the written documents that accompany the applications themselves (in Norway and the EU), we have based this discussion on documents pertaining to decision-making processes and practices (hearings, evaluations, articles on the subject), and regional (EU), international (Cartagena Protocol) and domestic legislation (Norwegian Gene Technology Act) and regulations. Impact assessment in Norway is unique in that it requires that sustainable development and societal utility be considered in GMO applications. This is in line with the stated purpose of the Norwegian Gene Technology Act (Section 1): 'production and use of GMOs shall take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development…' This is further explained in Section 10 of the Act: 'In deciding whether or not to grant the application, significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.'

In section five we analyse implications of these criteria and identify some challenges for the assessment, especially since the applicants do not provide any information on sustainable development and societal utility. In section six we operationalise the concepts of sustainable development and societal utility, which we test on the two GM plants: Monsanto's soy 40-3-2, aka 'Roundup Ready' and Pioneer Hi-Bred's 1507xNK603 maize. Finally, section seven presents our recommendations concerning assessments of sustainable development and societal utility.

[1] The project has been supported by the Norwegian Directorate for Nature Management. Thanks to Jan Husby, Peter Johan Schei and Terje Traavik for valuable comments during the process of preparing this report. Any remaining errors are the sole responsibility of the authors.

2. Regulatory Framework for GMO Assessment

Today there is no broad international consensus as to what is at risk from GM foods and crops. Considerable scientific uncertainty attends the effects of GMOs with regard to both the environment and human health. The uncertainties regarding environmental effects pertain to the risk of GMOs affecting or displacing native species and the risk of effects on agricultural practises – such as insect resistance and herbicide resistance development, and cross-contamination of conventional crops.[2] Uncertainties about the potential effects of GM food products on human health include concerns about increased resistance to antibiotics, toxicity and allergenicity development. On the other hand, it is recognised that GM plants may have the potential to benefit the environment by, for example, reducing the need for pesticides while at the same time increasing agricultural yields. Another possible benefit is the great potential for developing new medicines and vaccines. The debate involves legal, trade-related, political, ethical and socio-economic considerations, and has engaged actors at all levels, from the local to the global arenas. In this section we present the regulatory frameworks at the national (Norwegian), regional (EU) and international levels. This debate influences Norwegian policy-making and relates to the development of knowledge, to trade in biotechnological products, and legal frameworks and obligations established in other parts of the world (White Paper, 1991:40).

Five levels of legislation make up the framework for dealing with GMOs in Norway. There is international law, which includes the WTO (SPS and TBT) and the Cartagena Protocol on Biosafety under the Convention on Biological Diversity (CBD), and concerns the right to apply limits, including the precautionary principle. Norway was a pioneer in developing GMO regulations and has remained a very active participant in international processes dealing with this issue, such as the development of the Cartagena Protocol. Second, there is international soft law, made up of the emergent standardisation on the level of protection together with the decisions taken by individual countries on risk assessment and risk management based on the precautionary principle, among other things. For Norway, the EEA brings an additional third level, with legally binding EU Directives and Regulations. This comprehensive system includes Directive 2001/18/EC[3] on Deliberate Release of GMOs, Regulation No 178/2002 on Food Safety Authority, Regulation on traceability and labelling (1830/2003), and Regulation (EC) No 1829/2003 on genetically modified food and feed. Fourth, there is the national level, where Norway's Gene Technology Act (No. 38/1993) is the most important. Finally, also national assessments and decision-making add to the legal body relating to GMOs.[4] For Norwegian policy-makers, EU regulations and the Norwegian Gene Technology Act constitute the 'hard law' that is directly legally binding and must be implemented in decision-making. As diverging obligations following from these two legally binding frameworks are particularly difficult to handle, it is these two levels that will be in focus in this section. However, the EU member states are not uniform in their approach to this issue, so we will also consider the decisions and practices of individual countries in discussing the basis for Norwegian positions on GMO.

Within the OECD sphere, the EU has enacted some of the most restrictive rules in this field, matched only by Norway's GMO legislation. At present, the Norwegian Gene Technology Act represents yet another step towards precaution, with its stipulations that the processing and use of GMOs must take societal utility and sustainable development into account. This implies that while Norway and the EU put more or less equal weight on the criteria of health and environment, Norway must in addition heed the criteria of societal utility and sustainable development. It should, however, be noted that the ethical criterion (article 29), as well as the wording on socio-economic concerns (articles 31 & 7d) of EU Directive 2001/18, may pull in the same direction as the additional Norwegian criteria.

[2] A central example – which is politically and scientifically controversial – is found in Mexico, where genes from transgenic maize were discovered in native maize populations (Quist & Chapela, 2001).

[3] Directive 2001/18 is a revision of earlier Directive 90/220.

[4] Based on the presentation by Ole Kristian Fauchald, Conference on Ecological Risks and Precaution in the Nordic Countries, May 2005, Faculty of Law, University of Oslo.

In comparison, regulatory practices in the USA involve technical experts, who consider the safety of GM crops on a case-by-case basis in line with the concept of substantial equivalence.[5] Furthermore, the US risk-based regulation does not involve social factors in the risk evaluation. Aspects like governance and distributive effects are seen as value-laden issues and hence incompatible with risk assessments (Jasanoff, 2000). For several, but not all, developing or newly industrialised countries, the level of GMO regulations is more liberal than in the EU or Norway.

Although European biotechnology industries have pushed for de-regulation in hopes of getting a level playing field with their counterparts in the USA, the EU's GMO regulations have become increasingly stringent over the past 10 to 15 years (Bernauer, 2003; Rosendal, 2005). The process now involves environmental risk assessment, mandatory post-market monitoring of GM products, obligatory provision of information to the public, and requirements for labelling and traceability at all stages of the marketing process. In practice, the last time the EU member states approved the commercial growing of a GM plant was in 1998, albeit presently several such applications are pending final decision.

This restrictive practice, known as the 'de facto moratorium', prompted reactions from the USA, which argued that the EU was using this for protectionism in violation of the World Trade Organisation (WTO) agreement.[6] The political controversy here revolved around interpretation of the precautionary principle as elaborated within EU regulations as to GMOs and the precautionary approach in the 2003 Cartagena Protocol on Biosafety, as against the greater emphasis on scientific evidence of risk articulated in WTO agreements. At the time, a team of international scholars (science, technology and society) sent an Amicus Curiae brief to the WTO Secretariat/Legal Affairs Division, arguing that assessment of ethical and societal aspects of the EU's GMO regulations and policy was legally outside the scope of the WTO, as risk assessment rests within the legal domain of each nation state and cannot be delegated.[7]

In 2004 the revision of the directives and new legal procedures, Regulation No 178/2002 on Food Safety Authority and Regulation (1830/2003) on traceability and labelling were finalised, and the unofficial EU moratorium was ended. The ending of the 'moratorium' can also be seen as a response to the USA taking the EU to the WTO. Since 2004, EU approval processes have ended in deadlock fourteen times in a row; the EU Commission has granted ten approvals unilaterally.[8] The 'moratorium' has not, however, yet ended for commercially grown GM crops, nor has there been an end to the controversy among EU member states with regard to GM crops. Member states remain deeply divided over whether to accept GMOs or not – a pattern repeated among the new members, where the split is approximately 50/50 (ENDS, 2004). Some individual countries, such as Austria, Hungary and Poland, have invoked domestic bans on EU-approved GM seeds and crops. When the Hungarian ban on MON810 was deemed by the Commission to conflict with Directive 2001/18/EU, Hungary was supported by 22 of the 27 member states in the EU Environment Council, and so the ban was upheld. Only Finland, Sweden, the Netherlands and the United Kingdom voted with the Commission in favour of overturning the Hungarian ban, while Romania abstained.[9] France and Germany have also introduced temporary bans on MON 810 maize, following domestic scientific conclusions that there are 'serious doubts' about its use and safety.[10]

Applications for deliberate release and commercialisation of GMOs follow EU Directive 2001/18/EC and Regulation 1829/2003 on genetically modified food and feed. According to Article 6(8) of 2001/18, the deliberate release of GMOs into the environment can be authorised only by the explicit decision of a Competent Authority. By stating that the 'Member States may take into consideration ethical aspects when GMOs are released' (point 9 in the preamble), this Directive allows for differing national standards based on ethical judgement. For instance, while Finnish law is strictly focused on ecological and health risks, Swedish law permits greater discretion concerning not only the physical effects of the GMO but also societal effects. Ethics is thus an integral part of the EU regulatory framework for GMOs, but the concept has not been strict-

[5] Products considered substantially equivalent to those occurring in agriculture and nature do not require further testing, post-market follow-up or labelling. Accordingly, GM food and GM products that are considered as safe as its non-GM counterpart, will be approved for a limited period (i.e. licenses).
[6] See Lieberman & Gray (2006) on how the beginning and ending of the 1998–2004 de facto moratorium was never legally enacted by the EU.
[7] *Amicus Curiae brief*, April 30, 2004 (WT/DS291,292,293).
[8] *International Environmental Reporter* (INER), 2006, Vol. 29, No 20: 744.
[9] *International Environmental Reporter* (INER), 2007, Vol. 30, No. 5: 118.
[10] http://www.planetark.com/dailynewsstory.cfm?newsid=46350&newsdate=10-Jan-2008 Accessed 22 January 2008.

ly defined at the EU level. The interpretation of what this implies is not a straightforward issue. In the report of the Swedish Riksrevision (the Office of the Auditor General) on domestic GMO assessments, 'ethically sound' is defined to include 'societal utility' (Riksrevisionen, 2006: 89). According to this understanding, a GMO can be allowed only if it involves utility for society. The interpretation formed part of the basis for the conclusion of the Swedish Riksrevision that ethical assessments of GMOs in Sweden are 'underdeveloped and difficult to understand' (p. 89), that the authorities have failed to assess utility against risk, and that, overall, risks are not adequately handled (p. 87). The assessment of utility against risk is an important element with regard to the criteria of the Norwegian Gene Technology Act. However, a thorough assessment would necessitate a much broader analysis than envisaged for this report.

According to Directive 2001/18/EC, the applications and affiliated reports are to be sent to all member countries, which have 60 days in which to raise any questions.[11] A qualified majority vote among the Competent Authorities is necessary for approval of an application. If this fails, the application is returned to the Council of Ministers. If the Council again fails to reach a decision (as has happened in every case), the case goes to the Commission, which takes the final decision. New GMO licences have been resolutely opposed by a 'hard-core' group of EU member states (basically Austria, Denmark, Greece, France, Italy and Luxembourg) with a blocking minority in the Council (ENDS 2003). During the unofficial moratorium, the Commission did nothing under these circumstances; since the moratorium was lifted, the Commission has ruled in favour of the applications (see Lieberman & Gray, 2006).[12] In most cases the Commission's approval of new crops has been based on positive scientific opinions from the European Food Safety Authority (EFSA) and its scientific panel. For this reason, several ministers have been critical to EFSA and urged the scrapping of the procedures that have allowed the European Commission to end the EU's de facto moratorium on new GM crops despite opposition from many governments (ENDS, 2006).

EU Directives and Regulations generally apply to Norwegian assessments of applications for import and trade in GMOs. The applications and affiliated reports are sent to all EU/EEA member countries; at this stage, Norway may also present its own questions and comments. A GMO application that has been approved in the EU will automatically be open to commercialisation in Norway as well, unless the Norwegian authorities decide against it within a reasonable time. The Norwegian authorities may decide not to approve it, if it is deemed to present a risk to health or the environment, or a breach with the other requirements under the Norwegian Gene Technology Act, including those related to ethics, social justification and sustainable development. Norway's Ministry of the Environment is responsible for deliberate release of GMOs and is also the Competent Authority in Norway.[13] The domestic decision-making process is delegated to and co-ordinated by the Directorate for Nature Management. Applications are sent out to expert agencies, including the Norwegian Scientific Committee for Food Safety and the Norwegian Biotechnology Advisory Board,[14] both of which present their recommendations to the authorities. The Norwegian Scientific Committee for Food Safety, the Panel on genetically modified organisms, deals with questions on genetically modified organisms, such as micro-organisms, plants and animals, and genetically modified food and feed including their derived products. They focus on risk assessment of health and environmental effects of GMOs. The Panel's recommendations tend to follow those from EFSA, while the Norwegian Biotechnology Advisory Board is generally more in line with the opposition to approving GMOs among those EU member states who favour application of the precautionary principle in GMO assessments. What then are the trends in Norway's assessments of GMO applications, and how are these assessments affected by the situation in the EU?

[11] The process may be prolonged with another 45 days if members come up with questions requiring additional information from the applicant.

[12] The moratorium was brought to a partial end through the approved import of Syngenta's Bt11 maize (GM pest resistant) – for sale as tinned sweet corn, not for growing, 19 May 2004.

[13] The Ministry of Health, in collaboration with the Directorate for Health and Social Affairs, is responsible for the contained use of GMOs in Norway.

[14] The Biotechnology Advisory Board consists of 21 members, 13 appointed on a personal basis and 8 appointed by nomination from various public organisations. The 13 personally appointed members come from a range of research institutions and the private sector. The 8 are appointed by various interest groups, including environmental, medical, industrial, agricultural and labour organisations. In addition there is a highly qualified secretariat of five members, who provide advice and expertise. Observers from six government ministries also participate in the meetings of the board.

3. Developments in Norwegian GMO Assessments

From the similarities in the legal frameworks in the EU and Norway, as well as the general Norwegian tradition of following the EU lead, we could expect similar trends in Norway's GMO assessments. As yet, no commercial growing of GM crops has been allowed in Norway, but a great many applications are pending. By contrast, within the EU ten applications have been authorised; however, no GM plants have yet been accepted for commercial growing since the end of the 'moratorium' and there are many applications still awaiting final decision in the EU. Hence, the similarities may still be seen to be greater than the differences, not least given the scepticism among roughly half of the EU member states concerning the reversal of the trends in Commission practice.

The main lines of arguments or principles applied in Norwegian assessments when requesting information prior to possible acceptance can be divided into three broad categories: environmental, human health and societal concerns. With the cases that involve antibiotic resistance, the argumentation from Norwegian Biotechnology Advisory Board assessments has evolved over time (Rosendal, 2007). During the early phase (until 1997), the inclusion of this particular feature was not met with complete rejection, but these cases were nevertheless turned down in the final round by the Norwegian authorities. In the post-moratorium phase (2003–) cases of antibiotic resistance have been unanimously rejected in the Norwegian assessments. Another trend is towards a more detailed argumentation, as the specific criteria of public benefit and sustainable development are more widely applied. Arguments now include access to seeds for food security, effects on global agricultural structures, and North–South issues of equity (Rosendal, 2007). This represents an expansion and operationalisation of the special inclusion of 'ethics, societal utility and sustainable development' in the Norwegian Gene Technology Act of 1993. A related trend in terms of the observed broader argumentation relates to the use of the precautionary principle, but this trend is not uniform. While it is significant in the NBAB, the Walløe Commission (NOU 2000a:29) recommended giving the green light to GM food (against a minority), despite its conclusions about the uncertain health effects involved. Typically, the controversy over GMO assessments hinges on whether to apply precaution (in line with multilateral environmental agreements) or, with closer adherence to the WTO system, to rely on 'sound science'. These trends were found in a study of assessments by the NBAB and by a follow-up in terms of interviews (Rosendal, 2007).

The trend in Norway has hence been a reversal of the more liberal approach of the early phase preceding the moratorium, and towards robust agreement in favour of heeding environmental, health and societal concerns. In this sense, Norway's approach to GMOs reflects the view predominant within the EU, as application of the precautionary principle to health and environmental issues has tended to prevail over industry's demands for de-regulation (Rosendal 2005). The final results of GMO assessments may, however, prove different in Norway and in the EU. The Norwegian Biotechnology Advisory Board is mandated to give advice that takes into account specific Norwegian demands as to sustainable development, ethics and societal utility. Norway is the only country to formally include concerns about sustainable development and societal utility – these criteria are not part of EU legislation. As a result, industry can hardly be expected to provide information about such matters – nor does it do so. This tends to put Norway in a difficult position and gives rise to a dilemma: One the one hand, it is commonly expected that Norwegian authorities would prefer to be in line with the argumentation from the EU in such matters (Rosendal, 2007). On the other hand, it would seem inappropriate for Norwegian authorities to accept a reversal of the burden of proof, in the sense that failure on the part of industry to provide information on sustainable development and public benefits cannot in the end be the sole responsibility of the Norwegian authorities. It is, however, an unresolved legal question to what extent the Gene Technology Act places the responsibility on Norwegian authorities for finding and collecting information on sustainable development and public utility. One way of dealing with the situation in line with the legal requirements might be to invest in more research on these issues, as considerable documentation would be required

to substantiate the practical consequences of the criteria. Another option might be to contact the applicant directly and require the necessary information in accordance with the Norwegian Gene Technology Act. In many cases, the Norwegian market may not be worth the extra effort from a cost–benefit analysis, but in other cases, it might be of interest for the applicant in the additional market for specific GM products. It is also worth noting that a negative decision on an application by Norwegian authorities, based on insufficient information, would not represent a precedent for future cases, provided that more information could somehow be provided.

Either way, there would seem to be an inherent contradiction in the expectations regarding the results of the decisions by Norwegian authorities in these cases.

4. Assessment Trends: In-depth Cases

Environmental risk assessment is characterised by the legitimate involvement (access) of a growing number of groups and organisations – including university institutes, applied research institutes, consultancy firms and the research institutes of stakeholders, such as governmental and other public agencies, industry organisations, and environmental advocacy groups (Stokke, 2005). What does 'legitimate involvement' imply? This question is highly relevant to the examination of access to assessment procedures and final decision-making. Legitimate involvement is in fact fraught with stumbling blocks, as the gap between science policy-makers and the general public is widening in the biotechnology sector (Irwin, 1995). Public deliberation has many advantages, such as participant learning, the inclusion of knowledge of local conditions and social values, awareness building and the stimulation of public debate (see also section 5.1.4). Potential disadvantages concern questionable representation, high costs, the readily manipulative agenda-setting and vague conclusions (Mohr, 2002). This also points up the difficulty in classifying some knowledge claims as 'facts' or 'scientific' and others as norm- or value-based argumentation. Where to draw the line? Are some arguments more valid than others? It is difficult to generalise conclusions from many of the peer-reviewed reports on safety studies of GMOs, because they frequently vary in their choice of research material, methodology and analysis, and by the type of harm being investigated (e.g. environment vs. health). Several publications can be said to have found evidence of adverse effects of GMOs, whereas a number have not (see for instance Andow & Zwahlen, 2006; Domingo, 2007; Weaver & Morris 2005; Wolfenbarger & Phifer, 2000). This point is further addressed in section 4.2.2.

As yet another corollary to this understanding, Irwin (2004) points out that it is problematic to focus on regulations at the national level when technologies are decidedly global in origination and application. 'Decisions taken elsewhere by international industrial organisations (with Monsanto as the obvious example) can effectively remove the possibility of nations going GM free (e.g. by mixing GM and non-GM foodstuffs at source)' (Irwin 2004: 63). This supports the contention that Norway's assessment procedures are likely to be affected by parallel processes in the EU and elsewhere.

In this section, we start by briefly addressing access to decision-making processes (4.1). Second, we take a look at the major differences between Norwegian and EU assessments of GMOs (4.2). Third, we discuss the basis for the assessments: the documentation accompanying GMO applications (4.3). The fourth section tackles the question of basic economic interests with a view to GMO use (4.4). In each of these aspects, the application and utility of the concepts of public utility and sustainable use are addressed.

4.1 Legitimacy in assessments and decision making

A study of the GM debate in the UK, Australia and New Zealand found that access to decision-making and the inability to weigh explicit social value judgements with the broad science consensus were the major obstacles to successful deliberative public debate (Walls et al., 2005). For instance, in the New Zealand experience, non-scientific arguments were implicitly marginalised because the questionnaire employed for interest groups made it difficult to use holistic arguments. A 'holistic argument' in this case might imply a concern for the implications for landscape and culture embedded in the agricultural system or consideration of the growing dominance of multinational corporations in the life sciences. These enterprises increasingly decide on options for the development of new medicines and food, they are part and parcel of the GM revolution – but somehow their role seemed 'beside the point' in the questionnaire developed to study the public debate (Walls et al., 2005). A similar view has been further elaborated by Sheila Jasanoff (2005), who points out how science–policy relations in the biotechnology sector are characterised by the growing absence of broad public participation and a lack of democratic institutions to deal with this. However, the situation may be different in Norway, where it is broadly acknowledged that the GMO issue is characterised by a high level of NGO mobilisation coupled with rather weak protests from industry. For instance, in cases where approval is required, the competent authority may decide that public consultations are to be held (more about challenges regarding hearings in section 4.3).

Compared to the public and political criticism raised about EFSA, the Norwegian Biotechnology Advisory Board would seem to enjoy considerable legitimacy among members of the general Norwegian public – a point on which respondents from industry also partly agreed. On the one hand, the Norwegian biotechnology sector realises it does not constitute a strong lobby, being too small and fragmented to have much influence within this policy field (Rosendal, 2007). Moreover, it is the NGOs that have been most active in setting the agenda here: at least, this is the situation at present. On the other hand, the Norwegian biotech industry would clearly have preferred a body more in line with EFSA to assess GMO applications, and it has expressed the wish to exclude ethics, sustainable development and public utility from the criteria applied (Rosendal, 2007). This raises the question of whether 'knowledge' should be restricted to 'scientific facts' – and if so, does this include more qualitative, scholarly findings about societal and socio-economic aspects?

What is held to be acceptable scientific evidence for a decision is a difficult issue. For example, Article 15. Risk assessment (1) of the Cartagena Protocol on Biosafety states:

Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner…. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The references to 'available scientific evidence' and 'scientifically sound manner' can be seen as a predetermined qualitative term, and requiring risk assessments to be undertaken in a 'scientifically sound manner' involves a misrepresentation of the current lack of knowledge and may cause uncertainty, especially if these terms have implications for how Article 10. Decision procedure, (6) of the Protocol is to be interpreted:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

The acknowledgement in Article 10 of the Protocol that there may be 'insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects' reflects an awareness that not only the quantity but also the quality of the scientific information shall be taken into account in the assessment.

Another problem is the term 'lack of scientific certainty' found in Article 10 of the Protocol and in many other versions of the precautionary principle. This term express a strong belief that further research and empirical gathering may achieve scientific certainty. However, the uncertainties encountered in GMO assessments may be of different types and come from various sources, so the challenge becomes to recognise and acknowledge both the qualitative and quantitative types of uncertainties involved (more about scientific uncertainty in section 5.1.2)

4.1.1 Inclusion of scientific developments

Developments within functional genomics and molecular biology, such as a heightened focus on complexity and system thinking, are advancing and will give rise to new scientific knowledge and paradigmatic shifts (ENCODE Project Consortium 2007, Greally 2007; Kapranov et al., 2007; Nature Editorial 2006; Whitham et al., 2006).

The 'Central Dogma' postulated that 'one gene gives one mRNA gives one protein', formed the groundwork for molecular biology and biotechnology. Now the 'Central Dogma'-based concepts of genes organised like 'pearls on a string', with each gene functioning as an independent entity, have been overturned. These concepts formed the basis for the emergence of transgenic engineering techniques during the past 30 years of the last century, as well as for US government/industry claims and EFSA regulations. Approaches based on reductionism were both productive and unavoidable in the early developmental

stages of molecular biology, and may still offer very fruitful strategies for phenomenological studies, since they involve few variables under controlled and contained conditions. Lately, however, there has emerged a growing acceptance of an unanticipated complexity and unpredictability in the relationships between DNA-RNA-protein and the cellular and organismal metabolism (Uhrig, 2006). New methodological toolboxes, such as genomics, proteomics and metabolomics, have been developed to cope with complex interactions, the co-operation and co-ordination of multiple genes and the dynamics of total genomes (for recent reviews, see Traavik & Lim Li, 2007). This will have future implications for biosafety assessment of GMOs and will influence regulatory developments concerning GMOs.

For transgenic GMOs the complex interactions may be illustrated at several levels:

Genomic level:

- The DNA structure of the organisms that is being modified is a complex structure. Not enough is known about how and where a transferred gene integrates with the organism's genome and how the integration influences the chromatin structure and the expression of other genes in the genome (Doerfler et al., 2000; Filipecki and Malepszy, 2006; Latham et al., 2006; Recillas-Targa, 2006). Interactions with the environment are organised on a higher level than the DNA level (Whitham et al., 2006; Matthews et al., 2005). A transgene may result in different molecular versions of proteins in the recipient than in the donor plant (Prescott et al., 2005; Rang et al., 2005; Rosati et al., 2008). The expression of the inserted gene, as well as the level of expression and the time the gene is expressed, may also vary (Zolla et al., 2008).

Organism level:

- A GMO released to the environment will interact with the other organisms in this environment (Whitham et al., 2006). For example, the intention behind insect resistance in Bt maize is to have an impact on the pest population of insects feeding on the plant, but it may also impact non-target organisms, like other insects feeding on the plant, some of which may even be beneficial, as well as other consumer organisms of the maize (Rosi-Marshall et al., 2007; Bøhn et al., 2008; Kroghsbo et al., 2008).

Population level:

- Release of a GMO may cause changes in the natural population of other organisms. The modified organisms can cross with native species and alter the gene pool of that population, possibly leading to change in fitness of the hybrid population.

Ecosystem level

- This can include tri-throphic impacts, like impacts on insects, birds and other animals feeding on insects that feed on GMOs (Hilbeck & Schmidt, 2006; Lövei & Arpaia, 2005). It also includes the impact on consumer health, impacts on soil construction and the possibility of horizontal gene transfer as genes are released through the degradation of decaying GMOs.

Ethical and social implications

- Implications for the development of agriculture and maintenance of local agricultural practices, small-scale agriculture and local plant varieties (which often are aspects of local culture etc.), and socio-economic impacts on local agriculture societies; Also implications for the public's perception of food and ethical considerations as to how humans interfere with other species and the environment.

Moreover, since GMOs are reproductive living organisms, delayed environmental impacts might appear. Hence, some results of the reductionistic assumptions, such as the belief that possible large-scale effects from GMOs can be extrapolated from the effects studied in small-scale models, do not represent reality. To extrapolate from one context to another – from small- to large-scale release – leaves questions concerning scale of effects and therefore the environmental fate of a GMO unanswered (Wolfenbarger & Phifer, 2000; Haslberger, 2006). For instance for GM plants growth conditions are geographically and climatically different throughout the world that may make it difficult to identify the cause–effect relationships of impact, especially when using studies conducted in a different environment as basis for risk assessments. Such extrapolations may in fact increase the uncertainty, also because uncertainties regarding the behaviour of complex systems may not be directly linked to any lack of knowledge that can be remedied by performing more research.

4.2 Different developments in Norway and the EU: The case of antibiotic resistance

When it comes to assessing cases of antibiotic-resistant GMOs, the NBAB bases its argumentation on a decision of the Norwegian Parliament (the Storting), asking the government to ban production, import and sale of all GM products that contain genes coded for antibiotic resistance.[15] Increasingly, it is argued that these types of traits should be avoided altogether, even though antibiotic resistance is a highly efficient tool for practising GM technology. This would seem to fit well with the proposition that scientific developments and arguments enhance the scope for knowledge claims to affect a decision-making process. However, the same learning process does not seem to have influenced EU decisions, as the following example will show.

As a reaction to the EU moratorium, industry has tried harder to find alternative technical solutions, avoiding antibiotic resistance as a technical means to select the right transformation events. However, some of the technical solutions currently in use apply less risky antibiotics, such as those administered in small quantities in Western and Northern societies. This pinpoints an important difference in the EU and the Norwegian assessments, as the NBAB will argue that the use of these antibiotic-resistant genes may lead to an increased resistance to antibiotics in the GM crop-producing country. The Norwegian Gene Technology Act, with its clauses on 'societal utility' and 'sustainable development', comes into play with a view also to health and environmental effects in Third World countries. If GMOs caused antibiotic resistance for these particular types, that would be harmful in poor countries. By contrast, within the EU, the EFSA GMO panel (EFSA, 2004) has recommended an added element in the regulations, by introducing 'divisions of risks' and arguing that antibiotic resistance should be considered problematic only if it has a possible negative effect on health and the environment – and this is interpreted to apply solely to conditions in Europe. This difference is linked to the EU approach to GMOs not grown commercially in Europe. The EFSA 'division of risks' has led the EU to decide that information on environmental concerns is no longer required in such cases, whereas Norway still requests such considerations. As a consequence, these applications do not carry information about environmental concerns, because the application does not concern cultivation in the country applied to. When Norway requests additional information about environmental effects relating to these cases, no such information is forthcoming (more about this in section 4.3). It has been interpreted as a strategy from industry that the applications are mainly for import – and so far seldom for cultivation – of the plants in the EU. This is also relevant with regard to the two applications on maize and soy – as they have not been assessed with a view to environmental effects in developing countries, where most of the cultivation will take place.

This example indicates that Norway might be prepared to be more restrictive than what is generally accepted in the EU, although this acceptance is far from uniform (section 2). That could imply that EU behaviour in fact has scant impact on Norwegian GMO assessments. Any deviant Norwegian decision has yet to be criticised by the EEA Committee, but it is impossible to rule out future criticism and potential pressure.[16] The Norwegian Scientific Committee for Food Safety (VKM, 2005) recommended that Norway accept the EU 'division of risks'. In practice, this may mean that Norway would need to change its Gene Technology Act. As yet, however, the Norwegian authorities envisage no such legal changes.[17]

The example of antibiotic resistance leads us to a further examination of the documentation that accompanies GMO applications. Here we will look into some reasons for why the documentation accompanying GMO applications may be problematic and illustrate some of these problems by one selected GM plant: Pioneer Hi-Bred's 1507xNK603 maize.

[15] The decision came as a response to Stortingsmelding (White Paper) 40, 1996–97 ('Matmeldingen').

[16] The EEA Committee takes the decision on whether new Community legislation is of EEA relevance, with joint participation by the EU Commission and the EEA-EFTA member states. For instance, in the discussion on the use of the precautionary principle in food safety, some of the concerns of the Committee were noted in the EU documents as well. In Norway, the representatives may state their opinions, but there is no voting in the committee. Nor is the government obliged to follow the opinions stated in this body. The government may make its own conclusions before the meetings in Brussels (Melsæther & Sverdrup, 2004).

[17] Interview with representative of the Norwegian authorities, Ministry of the Environment, 24 August 2006.

4.3 Evaluating documents following GMO applications

Aside from the case of antibiotic resistance, there is still considerable scientific uncertainty about the effects of GMOs on the environment and human health. Globally, it has largely been the multinational corporations that dominate the fields of agro-biotechnology and pharmaceuticals that have carried out GMO risk assessments. In April 2006, EU Environment Commissioner Stavros Dimas was quoted that the EU assessment procedures for GMO applications relied too much on short-term industry data.[18] This controversial statement has relevance also in the Norwegian context. As indicated by Commissioner Dimas' statement, it has been held that most of the knowledge is produced within very few arenas, involving a limited number of independent actors (Myhr & Traavik, 2002). The main bulk of scientific assessments emanate from corporate actors with vested interests in the scientific findings about the technology concerned. Most studies on GM plants and products are based on information provided by research laboratories and/or released by industry (Gaskell et al., 2003). This documentation, along with the GMO applications, is provided by multinational corporations that enjoy little trust on the part of the general public, whether in Norway or in the EU (Gaskell & Bauer, 2001). Companies such as Monsanto are seen as part of the globalisation that takes decision-making away from local arenas (Rosendal, 2005). An interesting and important question is why there has been so little research on GMO effects funded by public institutions. One reason may be science policy developments since the 1980s, where science policies and implementation instruments like biotechnology research programmes influenced scientists to work with GM technology, focusing on work on pro-GM research questions, as this was the only way of attracting and securing research grants (Kamara et al. 2008).

The documentation accompanying GMO applications may be problematic for four reasons. The first problem regards transparency and confidentiality. Some of this information is available on the Net, through the European Food Safety Authority (EFSA), but other information is confidential and most is not easily available to the public, which would seem to be a violation of the Århus Convention. The parties to the Århus Convention have agreed to extend the treaty's rules on public participation to all government decisions involving the release of GMOs (ENDS 2005). In particular, governments are to make available 'in an adequate, timely and effective manner' a summary of the request for authorisation for the release or marketing of GMOs.[19] On this point, Norway is followed by similar concerns in the EU, as noted by Commissioner Dimas. Also the Swedish Riksrevision points to similar concerns that the knowledge about secondary 'genetic spread' is lacking (p. 88).

The problem of confidentiality that is linked to the documentation accompanying GMO applications has several implications. Access to peer-reviewed quality data is essential for a 'science-based' risk assessment. In order to gain regulatory approval, commercial developers of GMOs often submit their own test results to document the expected behaviour of the GMO and its products in the exposed system, and hence, its safety. Some experimental data on the safety of GMOs are also available in the peer-reviewed literature. Yet, knowledge gaps are routinely identified during regulatory risk assessment of GMOs. These gaps are often due to missing data (lack of relevant studies) or because the previously published studies have too narrow a scope or have focused on aspects of the biological system with only limited relevance to the biosafety of the GMO itself. Moreover, that there can be many different interpretations of the scientific findings. To address the lack of direct empirical data and studies, a number of substitute approaches and assumption-based reasoning are routinely included in regulatory risk assessment. Often, the concepts of familiarity (with the unmodified parent organism) and substantial equivalence (to the unmodified parent organism) are used to frame the safety investigations of the GMOs in the context of previous experience and current analytical methodology (König, 2004).

Second, the documentation is huge, with numerous files and documents attached to each application. The enormous quantities make thorough assessment very difficult. It has been speculated whether this could be seen as a deliberate strategy on the part of the applicants: to provide information in such great masses as to be hardly penetrable, at least not for non-experts. On the other hand, such a strategy could work both ways, as it would also strengthen the distrust of this type of knowledge producer.

Third, the documentation is supplied with references, but a substantial portion of these references point back to the research departments of the applicant itself, making it hard to see how this should be judged as sound science.

[18] Planet Ark, 'EU vows clarity on GMOs, eyes end to deadlock, 19 April 2006. http://www.planetark.com/dailynewsstory.cfm/newsid/story.htm
[19] *International Environmental Reporter*, 28(12):399.

Let us take a closer look at the third problem with a view to the cases in question, using Pioneer Hi-Bred's 1507xNK603 maize as an example. The application has 55 references. Of these, almost half are references to official documents, such as general OECD and FAO reports and guidelines, none with any direct reference to the case in point. Another third of the references are drawn from the company's own research units and are simply cited as 'unpublished technical report'. Only in two instances do these have any direct bearing on the GM plant for which the application is sought: most are outdated or focus on other species. There are 21 references to peer-reviewed books or articles. However, only five of these are recent enough to have any bearing on current technology. All of them deal with allergies and human health issues only, and do not concern environmental aspects of the GM plant in question.

The fourth problem is in part particular to the Norwegian situation: despite the information overload, important aspects are lacking. Most apparent is the lack of information about sustainable development and societal utility. Revisiting this fourth problem area, Norway's domestic legislation provides for an addition in maintaining its refusal. As no other country makes this demand for information, we have already contended (section 3, last para) that an applicant is unlikely to invest resources in providing such data.

It would seem that gaining Norwegian acceptance of GMO applications is not a particularly high priority among applicants. Their first priority is likely to be acceptance in the EU countries, as the unofficial moratorium is loosening its grip. Similarly, from the EU perspective, it may not be considered worthwhile to follow up any deviant Norwegian decisions with pressure to conform. As noted, the EU member states remain deeply divided over whether to accept GMOs or not – a pattern repeated among the new members, who are also split about 50/50 (ENDS, 2004). The main sign that the moratorium has ended is the Commission's new policy of deciding in favour of GMO applications, also in the face of persistent opposition. In any case, the upshot is that the dispute has become less scientific and more political in nature. This in turn means that we need to look further into the situation of affected actors in this sector. Who stands to gain and who stands to lose from the recommendations issued by the Norwegian authorities concerning GM applications?

4.4 Norwegian interests structure concerning GMOs

So far, the plants applied for marketing within EU (predominantly maize, soy, cotton and rapeseed) have had little practical utility for Norwegian farmers, except for GM rapeseed. This situation indicates that the GM issue is not yet very controversial in Norway, as there are low costs involved for relevant actors in following the results of the assessment procedures. But what would happen with an application for a potato or a strawberry that could flourish with the use of far less pesticides? That might be of great economic interest to Norwegian farmers. Then it might prove problematic for the Norwegian authorities to have a precedent of very strict practice. So far, the likelihood of this scenario has not been great, as Norway represents a rather marginal climatic area for agriculture. However, North America, Russia and parts of Asia certainly have some similar climatic zones and areas, so Norway must expect in the future to get applications that could be of far greater economic interest and relevance for Norwegian agriculture and aquaculture. This could bring new elements into the discussion also with a view to societal utility with arguments 'closer to home'.

On the other hand, the Norwegian farmer might choose to stick to the strategy of using 'GMO-free zones' as its marketing brand. In an open letter to the government (October 2006), the two main Norwegian farmers' organisations together with 13 more environmental, health and women's NGOs urged for a general moratorium on all GM plants in Norwegian fields.[20] The organisations emphasised the environmental and health concerns and the precautionary principle, arguing that it is impossible to control co-existence between GM plants and traditional plants. In sum, whichever way decisions are made on GMO applications, it will involve costs for the Norwegian government: in terms of going against domestic public opinion, or against potential technological development and economic gains as well as the EU.

On a similar note, when it comes to the import of GM products to be used in fodder, the situation illustrates potential future trends. For instance, for animal fodder producers it is becoming increasingly difficult to ensure that they receive feed sources that are free of GM. In 2006, the aquaculture industry used 880, 000 tonnes of feed, of which 40% was based on plant materials, mostly

[20] Press release, 14 October 2006: 'Nei til genmodifisering av norsk landbruk' (No to gene modification of Norwegian agriculture). Open letter on gene modification of Norwegian agriculture, to the Ministry of Agriculture, the Ministry of the Environment, and the Stortinget Standing Committees on Commerce and Industry, and on Energy and the Environment. Oslo, 4 October 2006.

soy, maize and rape. In accordance with Norwegian feed regulations (Norsk fôrvareforskrift) approval was not required for the use of GM-processed feedstuff and additive ingredients in feed below the limit of 2%. As this 'Fôrvareforskrift' is to be harmonised with EU regulations, the Norwegian Food Safety Authority required that all current GM-based feedstuffs to be used had to be reported to the Norwegian Food Safety Authority by 15 March 2006, due to a transition time until implementation of the EU regulations in Norwegian regulations (15 September 2008). On 15 March 2006, the Norwegian Seafood Federation (FHL) did notify the Norwegian Food Safety Authority that they wanted the opportunity to use 24 GM-processed feed-stuffs from maize, oilseed rape, cotton and soy in the production of feed. In November 2007, the Norwegian Food Safety Authority announced that 19 of these products were approved for commercialisation on the Norwegian market (the product is to be labelled if the GM content of each ingredient exceeds 0.9%), until new regulations are in place in September 2008. Then a new notification must be sent for evaluation by the Norwegian Food Safety Authority.

5. Sustainable development and social utility

The main purpose of the Norwegian Gene Technology Act is to enforce the containment of GMOs and control of GMO releases. Furthermore, the Act is meant to ensure that 'production and use of GMOs should take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects to health and the environment'. Hence it is obvious that, for the Norwegian authorities, that contribution to sustainable development should be assessed together with an evaluation of the societal utility in applications for the use and release of GMOs.

5.1 Sustainable development

Since the publication of the World Conservation Strategy, the concept of 'sustainable development' has received increasing importance in most policy areas. A widely used definition of the concept is 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs' (WCED, 1987). The concept represents an improved tool for decision-making, as it brings together social, ecological, and economic considerations (Dovers et al., 1996). Inevitably, this presupposes safety requirements for health and the environment, taking a long-term perspective, consideration for present and future members of society, and the assumption of democratic decision-making. Further, aspects like more equitable sharing of resources and improvement of ecology, e.g., environmental health and quality of life, are important issues of the sustainable framework. It contains within it two concepts: the concepts of 'needs', essentially the needs of the poor to which overriding priority should be given; and the idea of limitations imposed by the state of technology and social organisation on the ability of the environment to meet present and future needs (Kamara & Coff, 2007). Accordingly, the basic normative and ethical ideas of the concept of sustainable development in the WCED report are as follows:

1. meeting needs
2. social fairness
3. maintenance of natural resources and nature
4. sustainable economy

The idea of sustainable development has been applauded, but also extensively debated. The strength of the concept is arguably its broad sense and its ambiguity that may support various agendas (Redclift, 1993). For instance, while environmental risk assessment focuses solely on risk, consideration of sustainability entails provision for assessing both potential environmental risks and benefits. This possibility for more broad impact assessment was also emphasised in the ACRE report (2006) 'Managing the footprint of Agriculture: Towards a comparative assessment of risks and benefits for novel agricultural systems'. The subgroup within ACRE that developed this report noted that a comparative sustainability assessment of GMOs could cause a change in emphasis, from the assessment of risk to an overall assessment of impact with a high focus on how to meet the goals of sustainability.

Critics of the concept of sustainable development have, however, emphasised the limited value of the concept in situations involving the risk of irreversible environmental damage, accumulation of compounds and discontinuities (Norton, 1992). Furthermore, the definition of sustainable development is elusive, and highly varying views persist among both scientists and regulators with regard to what the concept constitutes – evident in the literature as different and contradiction interpretations of the normative values and the ethics behind sustainable development.

The main contested values and practices of sustainable development are: what values are important within sustainable development and how to set priorities between them, and how to achieve maintenance and preservation of nature and biodiversity versus a just society and economic development? (See Kamara & Coff, 2007.) When people recognise that there is a problem – for instance, that feed is a limiting factor for further expansion of aquaculture involving salmonids and that the use of marine feed (fish) is incongruent with sustainable development – they differ on which means should be used to solve the problem.

In the literature, a distinction has been made between weak and strong variants of sustainability (Kamara & Coff, 2007) Weak sustainability places emphasis on the use of risk/cost–benefit analysis and holds that loss of

environmental resources can be weighed against innovation and management adaptation. The distinction between weak and strong sustainability lies in the degree to which the precautionary principle are to be applied to ensure protection of environmental resources. For instance, very strong sustainability favours high emphasis on ecological protection and preservation (Karlsson, 2006).

Some elaborations on the WCED definition consider intrinsic values to humans but are very unclear on whether to ascribe intrinsic value or instrumental value to animals and nature. There are distinct philosophical differences between giving priority to the protection of human interests and to the preservation of ecosystems. A strong eco-centric position involves respect for ecosystem integrity, where adaptation of intrinsic values is independent of human interests or instrumental purposes (Westra, 1998). With regard to sustainable development, it is imperative to examine whether more eco-centric positions are required. Another problem is that the harm that needs to be avoided in a sustainable context is often seen very broadly. It is expected that stakeholders use different conceptual frameworks[21] in identifying values important to protect, thereby affecting what may be considered as sustainability relating to the use of GMOs. Sustainability in introducing and using GMOs also influences such socio-economic values as employment, income, and local economic activity (Poteau, 2000). Hence, an integrated assessment related to sustainability implies the handling of technical facts and social issues that almost always are incommensurable (Giampietro et al., 2006). For instance, an integrated approach would need to answer questions like: 'sustainability of what, for whom, in what time frames, and at what costs' – which represents a challenge to the methods and analysis to be used.

5.1.1 Uncertainty and precaution

The precautionary principle is considered as a key issue within the sustainable development framework. It has been a vital issue in various international environmental treaties as well as national regulations, and the regulation of GMOs in Europe requires that a precautionary approach is to be followed. Basically, the precautionary principle requires commitment to the idea that full scientific proof of a causal link between a potentially damaging operation and a long-term environmental impact is not required for taking precautionary measures. Several different versions of the precautionary principle exist (Foster et al., 2000). In a strong formulation, the precautionary principle may be phrased as follows (Cameron & Abouchar, 1991): 'In order to achieve sustainable development, policies must be based on the Precautionary Principle, environmental measures must anticipate, prevent, and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.'

Interpretation of scientific uncertainty in a sustainable context includes a high focus on environmental protection. Within this context it is important to acknowledge that an environmentally adverse effect may be qualitatively different from straightforward costs borne directly by producers and consumers, and that environmental effects or the environmental 'harm' that needs to be avoided may often be linked to value questions. Environmental costs are difficult to measure; moreover, adverse effects may develop over long time frames to become irreversible. 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 risks and costs may be absent. In standard practice, as with cost–benefit analyses and risk assessments, 'uncertainty' is often defined simply as lack of knowledge that can be reduced by further research. More comprehensive definitions of risk and uncertainty imply acknowledging that uncertainty may be irreducible, as well as that underlying assumptions and framing of hypotheses might create uncertainty. For instance, important observations about uncertainty include the following (based on Funtowicz & Ravetz 1990; Stirling 2001; Wynne 1992):

- Uncertainty is more than statistical error or inexactness of numbers: it is increasingly understood as a multi-dimensional concept involving quantitative and qualitative dimensions. Uncertainty can manifest itself in different parts of the risk assessments (as system boundaries, model structure, parameters, and data).
- Most present-day uncertainty methodologies and practices focus only on quantitative uncertainty in model parameters and input data. Methods to address qualitative dimensions of uncertainty are absent or in an early stage of development. Further research does not necessarily reduce uncertainty: it may often reveal unforeseen complexities and irreducible uncertainty.

[21] A conceptual framework is here defined as a set of basic beliefs, values, attitudes and assumptions creating a frame through which we view ourselves and the world.

- In problems characterised by high system uncertainties, knowledge gaps, and high decision stakes, unquantifiable dimensions of uncertainty may well dominate the quantifiable dimensions.

Scientific efforts have been made to understand lack of understanding in terms of sources and types. For instance, various typologies of uncertainty have been developed with the purpose of contextualising the broader scientific uncertainties found in risk assessments (see Stirling 2001; Walker et al., 2003; Wynne, 1992). A hazard can be related to a specific adverse event, while risk represents the relationship between probability and consequences. Uncertainty is a situation where we do not know or cannot estimate the probability of hazard, but we know the kinds of hazard to consider. Ignorance refers to situations where we do not even know what kind of harm to measure, as with the emergence of completely unexpected and unprecedented hazards. Such situations have historically been experienced, for instance with BSE, dioxin, and pesticides (EEA, 2002). Indeterminacy describes the inevitable gap between limited experimental conditions and reality, where the consequences of an activity can never be fully predicted. In this context, potential long-term effects and cumulative effects by GMOs are of relevance.

In addition, further uncertainty will be the result if one does not acknowledge the conditional nature of scientific understanding and that underlying assumptions and commitments may affect the outcome. By using a method called multicriteria mapping, Stirling and Mayer (1999) studied various judgements from experts that advised the UK government on the regulation of GMO in the late 1990s. Even though the government advisory committees typically represented their collective judgements as precise prescriptive recommendations, it became clear that the underlying individual expert perspectives displayed significantly greater diversity. According to Stirling and Mayer, these contrasting pictures of risk are dependent on how the analysis is framed. Many factors can influence the framing of science for policy, which can lead to radically divergent answers to apparently straightforward questions. This ambiguity arises when there are differing interpretations of the description of a system or a phenomenon, or when there is strong disagreement about definitions of terms.

5.1.2 Scientific dissent with regard to impacts of GMO use and release

Among scientists opinions diverge as to the definition of potential 'adverse effects', the relevance of various potential 'adverse effects', and what preventive action to take. Kvakkestad et al. (2007) report that various scientists, depending on scholarly discipline (ecology, molecular biology, plant breeding), source of funding (public or industry) or whether they work within industry, government or academia, interpret data differently in situations characterised with uncertainty, and thus express a diversity of opinions about risks by GM crops.

Sarewitz (2004) has argued that scientific dissent in the case of highly complex and hard-to-assess risk situations is due to different backgrounds/disciplines that may affect choices of hypotheses, methods and models, in turn yielding conflicting data and causing disagreement. Within the field of GM research, various scientific experts draw or make inferences from their specific academic disciplines to support their views and framing of the risk issues debated, and this influences the scope and choice of methods and models. For instance, agricultural biotechnologists often make inferences about the safety of a GM plant based on the long tradition of use and predicted behaviour and familiarity of conventional crop plants (von Schomberg, 2006). Implicit in this is the assumption that the insertion of genes and genetic material by genetic modification does not substantially alter the genetics and physiology of the GM plant beyond the inserted trait. Some ecologists, on the other hand, refer to experiences from the introduction of exotic species and draw inferences on the lack of knowledge about the GM plant, arguing that the biological characteristics of species are not good predictors of invasive success, and that just a few genes can make the difference between success and failure. They also stress that adverse effects may not materialise until years after cultivation and distribution. Both these views may be plausible, but they refer to a completely different scientific information base and type of research. Hence, scientific advice tends to be based on expertise and not on scientific data, with the implication that the result of the risk assessment becomes uncertain and dependent on the experts in question (Andow & Hilbeck, 2004). This is clearly evident in the current regulative practice where various governmental authorities reach different conclusions on the safety of GM crops although the applications may contain similar data and involve assessment procedures. From this perspective, the demand for 'more

research' is not sufficient to reduce scientific uncertainty, since the very incapacity of science to provide a unified picture of the environment contributes to the uncertainty.

Closer examination may reveal that subjective assessments, value disagreements, bias and conflict of interest also define the agendas for the discourse (Meyer et al., 2005). This in turn would mean that disagreement surrounding scientific evidence could be exploited in a politicised way in order to obtain public and regulatory support for the specific objectives of the actors. The various groups may all present rational agendas given their contrasting risk-benefit perspectives, objectives and values within the dynamic discourse of knowledge formation. Furthermore, differing value perspectives and risk perceptions may influence the framework that scientists and risk regulators consider appropriate for the regulation of GM crops. Those who see no risk would favour a narrow science-based regulatory framework, while those who perceive uncertainty and the value-laden context of risk assessment may demand more broad precautionary approaches and stakeholder involvement in risk assessment and management processes.

This is not to argue that studies of GM plants that indicate adverse effects necessarily prove that GM plants are harmful: some studies claiming adverse effects may also be dismissed. The purpose is to highlight the challenges involved in scientific uncertainty and subjective assessments.

5.1.3 Transparency and participation

Although there are several obstacles to public participation (see section 4 and 4.1), participation is important since this will increase transparency and legitimacy. Public involvement may also enhance learning about the ecological and economic benefits that the public consider important to pursue, and the 'harm' they consider important to avoid. Perception and acceptance of risk are closely related and are influenced by values held at the individual level, as well as by cultural and social values (Renn, 1998). The debate over GMO use and release is not related solely to health and the environment, but also encompasses economics, ethics, cultural and social aspects that may be equally important as the risks to health and the environment (Wynne, 2001). Hence, stakeholder judgements in regard to the necessity of introducing GMOs into any ecosystem or used as food and feed build on explicit or implicit perceptions of risk, social aspects as well as communities expectations of the benefits that may accrue. Identifying and assessing public perceptions on risk related to GMOs involve some obvious challenges. For instance, unavoidable value incommensurability exists between the cost (in terms of possible long-term environmental degradation and reduced biodiversity) and the benefits (increased food production and environmental benefits) of the introduction of GMO (Aslaksen & Myhr, 2006). This will most probably depend on the cultural and traditional context that may vary among countries/ regions, e.g. small-scale traditional agriculture with crop rotation towards a development of large-scale industrial monoculture agriculture. Finding a way to balance competing values and accommodate those different values is a profound challenge. Participatory discourses can be used as a means to identify a country's chosen level of protection, and hence be compatible with the interests and values of the affected parties.

5.2 Norway: the two first notifications received by the authorities

In the following we briefly present two of the first cases received by the Norwegian authorities. The first case concerned experimental greenhouse release of GM-Begonia and the other is a marketing application for an herbicide-tolerant rapeseed. Our intention was to clarify whether the concepts of sustainable development and societal utility were important criteria in the decision-making process, and to discuss the relevance of these processes for the two cases on soy and corn presented later.

5.2.1 Genetically modified Begonia

In 1993 the Ministry of the Environment received its first application for deliberate release of GMO (Case documents). The application concerned deliberate greenhouse release of genetically modified *Begonia x cheimantha Everett* (GM Begonia). The modification was carried out by use of antisense mRNA technique that resulted in inhibited ethylene production by blocking the ethylene-producing enzyme ACC-synthase. Prolonged freshness of the ornamental plant was achieved by this modification. Production of GM Begonia could thus commercially replace plants that usually would have been treated with the chemical argentthiosulfat (STS) for prolonging quality. Selection of the GM Begonia is possible with the marker kanamycin resistance (npt-II). The Norwegian authorities treated the GM Begonia application of experimental release in greenhouses as a deliberate release with some risk management measures in accordance with the

Gene Technology Act, since it did not fulfil the requirements for contained release, and because the legislation of experimental release in greenhouses was under preparation. The Board could see no danger to human health or the environment in connection with deliberate release of the ornamental plant. The majority of the Board believed that the new knowledge obtained through such research could be beneficial to society and thus provide valuable experience with GM plants, and the Board believed that consumers would appreciate such ornamental plants with prolonged freshness. However, a minority of the Board (two members) was not convinced that the GM plant could be considered as a contribution to sustainable development, even if it would involve reduced use of chemicals. The minority also argued that there was a contradiction between natural ageing and prolongation of freshness that could cause consumers to choose another ornamental plant. The Ministry of Agriculture focused on the existing uncertainty concerning ecological effects, and therefore advised the Ministry of the Environment to limit the release to five years and to a restricted area and number of plants. The Directorate for Nature Management and the Governmental Pollution Control Authority commented on the applicant's consequence analysis, which resulted in the conclusion that the GM Begonia could not establish itself in the Norwegian climate; the experimental period was mainly during the cold winter season.

Potential ecological impacts of GM Begonia

The Norwegian Authorities thus concluded that GM Begonia could not establish itself in the Norwegian climate (Case documents). Furthermore, since the approved project would be performed inside greenhouses, the expert committees and the Board concluded that it would be possible to limit any gene transfer and invasion of the plant to surrounding ecosystems. Although the project was to be carried out on a small scale, the Ministry of Agriculture wanted to limit the period to five years to reduce the risk of environmental damage. Harm to human health was not considered as an important issue, most probably since the plant would not be used for dairy purposes.

The reason for the narrow risk assessment might be that the GM Begonia project was seen as basic research. The basic concept in Norwegian legislation is that sustainable development has little relevance to basic research, since the results of such research are necessarily unpredictable. Basic research should be considered as beneficial. This stand is, of course, controversial. Scientific work often takes place at the boundaries between basic and applied research. Today, the time-lag between basic research in biotechnology and gene technology and its application is very short. Furthermore, basic research may run contrary to sustainable development because of its context, as Backer illustrates by referring to how basic research connected with the development of the atomic bomb would have been in conflict with the concept of sustainable development (Backer, 1995). Therefore, it has been argued that the distinction between basic and applied research is flawed, and that scientists have a social and moral obligation to ensure that their information addresses the needs of the public and safeguards the environment.

5.2.2 Genetically modified rapeseed

Norway's Ministry of the Environment received a European marketing application for a genetically modified oilseed rape plant (*Brassica napus L. oleifera Metzq.*) in 1994 (Case documents). The applicant was the Belgian firm 'Plant Genetic Systems'. The plant was genetically modified to tolerate the herbicide glufosinate ammonium (marketed as Basta or Finale). Before the Biotechnology Advisory Board had evaluated the application, highly relevant scientific results were published: a genetically modified herbicide-tolerant rape had transferred its transgene to a weedy natural relative in the course of only two generations (Mikkelsen et al., 1996). In response, the Board advised against marketing, noting that the potential transfer of resistant genes to relatives might create a weed problem and thereby increased herbicide use, possibly leading to a change to more dangerous herbicides. Another concern of the Board was the water-polluting potential of glufosinate. Furthermore, the modified plant carried a kanamycin-resistant gene (npt-II) as selection marker; the release of GMOs with antibiotic-resistant genes was at that time controversial in Norway.[22]

Potential ecological impacts of herbicide-tolerant rapeseed

The Ministry of the Environment declined to permit marketing of the herbicide-tolerant rape plant from 'Plant Genetic Systems' in October 1997. The decisive argument was that the documentation concerning ecological and health aspects did not satisfy the requirements of the Norwegian Act (Case documents). The Board advised against marketing, acknowledging that potential transfer of resistant genes to weeds may create a weed problem and thereby increased herbicide use.

[22] Cases of GMOs with antibiotic resistance have been unanimously rejected in the Norwegian assessments since 2003.

Whether herbicide-tolerant plants represent a more environmentally friendly alternative to conventional agriculture is being challenged. The most common herbicide that GM plants is modified to tolerate is glyphosate, which is considered as having less ecological impact compared to herbicides used in conventional agriculture. The introduction of such modified plants promises better weed control and thereby a decline in the amount of chemicals used, as well as reduced soil loss from erosion. In recent years, however, detailed studies of the economic impact of genetically engineered crops (yield and chemical input) have shown divergent results. In some cases, it has been found that yields of herbicide-tolerant plants were significantly reduced and that the use of herbicides had increased (Benbrook, 2003; FoEI, 2008). On the other hand, there are reports that claims that introduction of herbicide-tolerant plants has reduced the use of agrochemicals (USDA, 2000). As might be expected, the performance of GM crops appears dependent on local conditions, such as cropping patterns, the occurrence of weed varieties and pest problems, and climate and soil types.

With the herbicide-tolerant rape, the decisive argument for the Norwegian authorities was, as mentioned above, that the documentation concerning ecological and health aspects did not satisfy the requirement of the Norwegian Act. We contend that sustainable development was not a major issue in this case either, although it was taken into account to a moderate extent.

The case studies we have chosen to present here were the first case to be approved, the GM Begonia, and the first to be turned down, the genetically modified rape. The Act, although legitimising sustainable development, did not seem to ensure that it was practised. One reason may be that there were no regulations for impact assessment at the time of these first cases. In January 2006, the revised impact assessment regulation entered into force in Norway, and the issues of sustainability, social justification and ethics were lifted into the regulations section 17 and its annex 4. These issues will be further presented in the next section.

5.3 Norwegian impact assessment questions in relation to sustainability of GMOs

In order to guide political decisions concerning GMO and in line with the intentions of the Gene Technology Act, the Norwegian authorities have, on the basis of the Biotechnology Advisory Board's Discussion Paper: *Sustainability, benefit to the community and ethics in the assessment of genetically modified organism*s (2003) elaborated in annex 4 of the Impact Assessment Regulations (see boxed text) several questions that we will discuss in the following.

Appendix 4 to the Norwegian Impact Assessment Regulation:

EVALUATION OF ETHICAL CONSIDERATIONS, SUSTAINABLE DEVELOPMENT AND BENEFIT TO SOCIETY,
CF SECTION 17 OF THE REGULATIONS

IV SUSTAINABLE DEVELOPMENT

A. Checklist

1. Global impacts

Will there be global impacts on biodiversity?
Will there be impacts on ecosystem functioning?
Will there be differences between the impacts of production and use in these respects?

2. Ecological limits

Will there be any impact on the efficiency of energy use?
Will there be any impact on the efficiency of other natural resource use?
Will there be any impact on the proportions of renewable and non-renewable resources used?
Will there be any impact on emissions of global and transboundary pollutants?
Will there be any particular impact on greenhouse gas emissions?
Will there be differences between the impacts of production and use in these respects?

3. Basic human needs

Will there be any impact on the degree to which basic human needs are met?
Will there be differences between the impacts of production and use in these respects?

4. Distribution between generations

Will there be any impact on the distribution of benefits between generations?
Will there be any impact on the distribution of burdens between generations?
Will there be differences between the impacts of production and use in these respects?

5. Distribution between rich and poor countries

Will there be any impact on the distribution of benefits between rich and poor countries?
Will there be any impact on the distribution of burdens between rich and poor countries?
Will there be differences between the impacts of production and use in these respects?

6. Economic growth

Will there be any impact on the use of energy and other natural resources for economic growth?
Will there be any impact on the global/transnational environmental impacts of economic growth?
Will the there be any impact on the distribution of economic growth between rich and poor countries?
Will there be differences between the impacts of production and use in these respects?

B. Comment

An evaluation of whether a project is in accordance with the principle of sustainable development must be based on an overall assessment and discussion of all these questions. However, not all the questions will be relevant in all cases.

5.4 Practical implications

With regard to questions ***1: global impacts*** and ***2: ecological limits***, the risk assessment performed by the applicants is of high relevance and can be used to consider whether the following issues have been taken into consideration:

1. Persistence, invasiveness, possible population and fitness changes linked to selective advantage or disadvantage are key biological characteristics that should be assessed for GM plants prior to their introduction into a new habitat. This includes the need to assess the potential and outcome of: volunteers; the establishment of the GM plant outside fields (or the habitat of introduction); its spread within agricultural ecosystems or in the wild, including possible invasiveness; interactions and influences on other organisms; and persistence and population increase of the GM plant in the environment.
2. Potential for gene transfer. Gene transfer may take place vertically, through sexual crossing to non-GM plants and also to related wild plants in the surrounding environment. There is also the possibility of horizontal gene transfer to micro-organisms in soil, or those living on or next to the GMP.
3. Interaction between GM plants and target organisms. Interactions may cause effects like reduced abundance and diversity of targeted weeds and insects, resistance development in insects and plants as well as increases in secondary pests as a consequence of the absence of their original target organism.
4. Interaction between GM plants and non-target organisms. These interactions include potential impact on biodiversity through the effect of a GM plant, its product, practise or its management on non-target plants and animals. This may involve changes in susceptibility to non-target pests and diseases, as well as other direct and indirect impacts on habitat diversity and biodiversity.
5. Changes in bio-geochemical processes. Such impacts include changes in soil biodiversity (microbial biomass, e.g. changes in symbionts like mycorrhiza and nitrogen fixating *Rhizobium*.) and soil basal respiration, soil fertility, including the nutrients available to plants, and may lead to reduced plant health.
6. Changes in cultivation patterns. The introduction of new GM plants may cause changes in farming practices (e.g. amount and type of pesticides used, change in application of fertilisers, tillage, and crop rotation) and may increase the energy input needed.

These issues can have both direct and indirect impacts on the environment. The various aspects may not be applicable to all GM plants, and need therefore to be considered on a case-by-case basis. This should be done in relation to the characteristics of the inserted genes, the expression of new traits, and combined with an evaluation of possible effects on the receiving environment(s). The documentation received from the applicant is therefore important, but should always be evaluated with a view to existing local or national knowledge, e.g. regarding the local agricultural system, existing monitoring or surveillance programmes, and the basic local knowledge about the crop in question and the possible impacted environments: all this is information and knowledge rarely available to an applicant.

Risk assessment focuses on risks: no consideration is given to evidence of any potential environmental benefits, such as reduced herbicide use, which may lead to reductions in the direct and indirect CO_2 emissions arising from herbicide manufacture, transport and field operations. Global impacts and ecological limits include broader assessment of the use of the GMO in question, taking into account the possible benefits as well. GM crops holds prospects for both environmental problems and solutions. Environmental goods and services to be considered may include:

7. Water balance, which includes the effects of a GMO or its management on the quality of water and the amount of fresh water required producing a given yield of the product.
8. Energy balance, which concerns the amount of renewable and non-renewable energy used in the production of the GM crop compared with the energy output used to produce a non-GM crop of the same species on the same acreage.
9. Latency / cumulative effects, where latency represents the delay between cause and effect, and cumulative effects are those that accumulate steadily over time until a critical threshold is passed, whereupon effects manifest themselves.

In the Norwegian impact assessment it is emphasised that both global impacts and ecological impacts are to be assessed with regard to whether there will be differences between the impacts of production and use of the GMO in question. This is related to the effects on socio-ecological relationships by production of GMOs.

Social-ecological resilience has three defining characteristics: The amount of change the agricultural system can undergo and still retain the same controls of function and

structure, or still be in the same state, within the same domain of attraction; the degree to which the system is capable of self-organisation; and the ability to build and increase the capacity for learning and adaptation. Resilience can be understood as the capacity to recover after disturbance, absorb stress, internalise it and transcend it. Resilience is the capacity to conserve options and opportunity for renewal and novelty (see Berkes et al., 2000; Holling, 1973; Holling et al., 1995; Gunderson 2000). Resilience refers to both ecological and cultural resilience, of individuals, of ecosystems, and of local communities. An important precondition for resilience is to apply local and traditional knowledge and practice, in practice often coinciding with adaptive management of resources and ecosystems. Resilience entails quite different issues with regard to large-scale and small-scale agriculture, which challenges the notion of a single, statistical, universal assessment for use of GMOs for all environmental and social agriculture conditions. Unlike the case in the main GMO-growing countries, agriculture in Europe is on a relatively small-scale level, in close contact with surrounding natural habitats. Hence resilience may serve as a good yardstick for assessing whether GM crops may affect socio-ecological relationships. However, at present, not enough is known of how GM crops may affect resilience. Here it is important to recognise that the introduction of GM crops into small-scale farming systems involves new challenges:

- The small size of the farm creates obstacles for having sufficient protection in the field to slow down resistance development, e.g. using refuges, where a percentage of the crop planted is not GM, so as to avoid development of resistance to the Bt-toxin in target insects (Cleveland & Soleri, 2005).
- The small size of farms may limit the possibilities of farmers to choose not to plant GM crops, because pollen spread and seed dispersal from nearby fields containing GM crops may 'contaminate' conventional and organic crops, making it difficult to distinguish and segregate between GM and non-GM varieties (Binimelis, 2008)) (more on coexistence under economic growth p.29).
- Initial success may lead farmers to abandon alternative crops varieties in the field as well as alternative livelihood strategies (Cleveland & Soleri, 2005), which may reduce the resilience of the social ecological system due to loss of diversity in social and agricultural systems (not spreading the risks) (Berkes et al., 2003).
- Because the GM seeds are patented property, owned by the companies, farmers become dependent on external institutions for providing seeds.
- Seeds have to be renewed every year; moreover, they tend to be more expensive than conventional hybrid seeds, making the farmer more dependent on regular cash inputs.

Accordingly, there are several features that distinguish small-scale, low input farming from industrial farming (high input) which necessitate adoption of procedures for introducing and managing GMOs that are specially designed for such systems.

With regard to questions ***3: basic human needs***, ***4: distribution between generations***, ***5: distribution between rich and poor countries***, and ***6: economic growth***, there is no information in the documents that accompany the application. However, these questions are highly related to the normative basis for development and use of GMOs.

Basic human needs

The UN Millennium Development Goals (MDG) prescribes globally agreed basic standards for human existence in term of targets to be met by the year 2015. An important challenge to meeting the MDG is to strengthen food security. One direct approach to combat food insecurity is to increase food production; another is to increase incomes. GM crops may be relevant to both elements of food security, and have hence been promoted as an important tool by the biotech industry. The potential benefits include improved crops that would be more nutritious, higher yielding, resistant to pests and disease, tolerant to physical stress such as saline soils and drought, and more environmentally sustainable (FAO, 2004).

Food security is strongly linked to consumers' rights to explicit information on food safety. In a recent review Domingo (2007) asks: where is the scientific evidence showing that GM plants/ foods are toxicologically safe, as assumed by the biotechnology companies involved in commercial GM foods? He reviews available published scientific literature concerning potential toxic effects / health risks of GM crops and concludes that experimental data in the peer-reviewed literature are very scarce. Domingo finds that most investigations correspond to short-term toxicological studies where the focus has been on nutritional parameters: hence they contain very little toxicological information. Here is a crucial need for long-term studies. Domingo he criticises the relevance of substantial equivalence to be used in safety studies of GM plants, and argues that investigating the same nutritional capacity between a GM and a non-GM plant does not prove that they have similar health risks. Genetically modified plants might contain other toxic substances, or

might not be substantially equivalent in genome, proteome and metabolome compared with unmodified crops (see also section 4.1.2). In addition is this point: Basic human needs are closely related to section 6 on social utility.

Distribution between generations

Intergenerational ethics raises the issue of how uncertainty affects our moral responsibility to future generations, and to what extent moral agents can be held responsible for activities that inflict risks on generations to come (Jonas, 1979). It has been argued that our moral responsibility to posterity is limited because our ability to foresee how present decisions and activities will affect future generations is limited. GM plants hold promise of benefits that are based on expectations that may be realised in some parts of the world but may be the opposite for others. Hence, this is a situation of ignorance regarding the pace and direction of future scientific and technological developments as with regard to the development of adverse effects. This ignorance reduces responsibility in a temporal dimension because in most arenas it is impossible to predict the resources needed of future generations.

The starting point for assessing the distribution of benefits and burdens between generations is to assume that human beings in the future will have the same physiological (physical and biological) needs as we have. According to Regan (1983), the consequences of alternative courses of action can be graded on the basis of how the harm will affect more or less vital interests. In this context we may distinguish between vital human interests, connected to physical health and survival and autonomy on the one hand, and non-vital interests, such as the wish to improve individual welfare beyond vital interests. Hence a decision that affects human interests has more serious consequences than a course of action that can affect non-vital interests. Ekeli (2004) argues that it is immoral to impose risks upon future generations in cases where the following conditions are fulfilled: (1) the risk poses a threat to the ability of future generations to meet their physiological needs, and (2) the risk assessment is supported by scientifically based harm scenarios. 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 the risks may involve society and the environment. For instance, we do not know with certainty whether GM crops will promote the general welfare by providing more nutritious food or help to ensure food safety. Neither can we be sure that GM crops will not cause unintended effects or threaten biodiversity.

Another important aspect is irreversibility: a GMO is in most cases released as 'live' plants and micro-organisms and animals. This means that, out in the environment, they may multiply and spread, becoming impossible to control or recall. As yet, however, no studies have been carried out to ascertain the long-term benefits and risks.

Distribution between rich and poor countries

Agricultural GM technology is applied in many developing countries, and it is expected in the near future that the area devoted to GM crops will exceed that in developed countries (James, 2006). GM plants have a potential to be most useful for the Third World by providing nutritional and food security. For instance, insect and pest attacks cause heavy crop losses that might be restricted by introducing insect-resistant crops. Hence, GM crops have been promoted, especially by the biotech industry, as an important tool to address hunger and poverty in the South. However, decisions on how to ensure 'food security' involve not only questions of how to provide food supply, but also how food should be equally distributed. Another important aspect is that GM plant development has so far concerned the transfer of a restricted number of genes, especially herbicide- and insect-resistant genes, into a handful of the most important agricultural plants, based on applications in industrial countries. Little attention has been paid to such basic Third World food crops as cassava, cowpea, millet and sorghum, which are critical for food supply and livelihoods. There are exceptions, such as rice modified to provide vitamin A and iron to combat food deficiencies leading to blindness (Ye et. al., 2000). It is planned that the plant will be available free for farmers whose annual earnings fall below a certain threshold.

As in Europe, most agriculture in poor countries is carried out at the small-scale level in close contact with surrounding natural habitats and wilderness. Hence resilience may be a good yardstick for assessing whether GM crops may affect socio-ecological relationships in poor countries. However, as yet not enough is known of how GM crops may affect resilience. Also here it is important to acknowledge that introducing GM crops into small-scale farming system creates new challenges, as shown in our case studies. Furthermore, agriculture in poor countries is more vulnerable to changes in economic and social structures that provide livelihoods in the rural areas (FAO, 2004; Nuffield Council on Bioethics, 2004). For instance,

a recent report initiated by the UN and World Bank (IAASTD, in press 2008) discusses many issues pertinent to achieving sustainable global agriculture production. In many respects the report is directly opposed to the optimistic GMP promises expressed by the biotechnology industry. Small-scale agriculture in poor countries is very different from industrialised farming: fields are small and farming is carried out with low or no external inputs like chemical fertilisers, pesticides and hybrid seeds. Food production, consumption, breeding of plants, and seed conservation are integrated activities, and the fields contain great crop diversity (Pretty, 1995; Cleveland & Soleri, 2005). Small-scale farming is important for food production but also for conserving plant genetic resources and socio-cultural diversity (Bhagavan & Virgin, 2004).

Accordingly, introducing GM crops into small-scale farming systems creates further new challenges:

- Seeds may be very expensive for the farmer.
- Farmers have limited access to information about potential risks of planting GM crops and limited participation in risk management.
- If crop yield improvement is not continuous over time (e.g. through resistance development), this can mean that the strategy of using GM crops as a poverty alleviation strategy in the long term leads to increased poverty.

The issues of uncertainty and lack of knowledge regarding potential hazards and risks of GM crops in poor countries, together with the need to strengthen capacity building, are elaborated in the report by the UN Secretary General *Promoting the application of science and technology to meet the Developmental Goals contained in the Millennium Declaration* (UN, 2004). The report states that many developing countries lack scientific and administrative expertise and that implementation of safety regimes may encounter difficulties due to lack of capacity. Hence, a major issue in connection with implementation of the Cartagena Protocol is appropriate capacity building and technology transfer that can enable developing countries to fulfil their obligations under the Protocol. In addition, it is expected that the Cartagena Protocol will be of central relevance in the process towards developing domestic biosafety regulations. Successful implementation of the Cartagena Protocol hinges on the active development and use of both scientific and local knowledge. Article 26 of the Cartagena Protocol specifies that countries may take socio-economic considerations into account when making decisions about GM crops. The World Resource Institute (2005) has followed up this by recommending 'public agricultural institutes should base their biotechnology research decisions on socio-economic assessments that identify the need of the poor'. According to the Millennium Ecosystem Assessment (MA), degradation of our ecosystems is a barrier to achieving the MDGs and poor people are the ones that are hardest hit by degrading ecosystems (Millennium Ecosystem Assessment, 2005). The MA recommends that food production and agricultural development programmes aiming at poverty reduction and improved livelihoods should be ecologically as well as socially and economically sustainable, if they are to succeed as poverty alleviation measures.

Economic growth

Economic sustainability concerns primarily the economic benefits or costs to society and benefits of the use of a GMO or its product or practice and associated mitigation strategies in comparison to current technologies. In a cost–benefit analysis of GM crops in Europe, Wesseler (2001) has analysed the benefits of GM crop adoption in terms of reduced pesticide use and its positive impact on human health, as well as the effect on groundwater quality and on biodiversity. Use of herbicide-tolerant crops may give more cost-effective production with higher return to farmers through more efficient weed control and thereby more predictable harvests. However, this report has been criticised for not taking into account the long-term effects of GM crops. For instance, the problems related to co-existence among GM crops, conventional crops and organic crops indicate that economic issues are strongly linked to matters of environmental protection. Causes of contamination include cross-pollination, spillage of seed or mixing after harvest. The extent to which co-existence is feasible has been intensively discussed (Binimelis, 2008). Co-existence may be difficult to implement since it puts a burden on farmers and will require very stringent measures to maintain volunteers at low levels and restrict gene flow. It may mean that all farmers, both GM and non-GM, will have to comply with mitigation measures aimed at controlling the spread of herbicide resistance, and this may involve extra costs for non-GM farmers. Another economic issue concerns liability measures and economic compensation related to co-existence. This illustrates that there may be potential inequitable distribution of economic benefits and risks among industry, GM-growing farmers and non-GM- farmers, which is no less controversial for GMOs than for environmental contaminants.

Genetic modifications of crops have been motivated primarily from the production side, in order to increase

agricultural output, rather than from the perspectives of consumer demand or health. Batie and Ervin (2001) refer to this as 'technology push' rather than 'demand pull'. Manufacture of GM seeds takes place in an industrial structure characterised by close integration of seed and herbicide production. At present in the USA and worldwide, 71% of the GM crops grown commercially (James 2006), such as soybean, maize, oilseed rape and cotton, are herbicide-tolerant and have been developed and promoted by chemical companies. The adoption of herbicide-tolerant GM crops and new market opportunities for herbicides may create incentives to promote future herbicide-tolerant crops. Whether this can be considered as sustainable development needs closer examination.

5.5 Societal utility

The concept of societal utility is found in the Gene Technology Act §10. Societal utility is a complicated concept that may have multiple meanings. The NBAB has chosen to separate the assessment of societal utility with regard to a) product properties, and b) the development and use of the product, and has elaborated the following questions to be addressed:

Properties of the product:

- Is there a need for this product?
- May the product solve or contribute to solve a societal problem?
- Is the product better than equivalent products on the market?
- Are there any alternative products that may solve or contribute to solve the societal problem in questions?

The development and use of the product:

- Does it help to create new opportunities?
- Does it help to create new opportunities in urban areas?
- Does it help to create new opportunities in other countries?
- Does it entail problems for existing production that need to be conserved?
- Does it entail problems for existing production in other countries?

Judging the relevance and acceptability of a GMO varies in time and space, and depends on scientific understanding and other factors, such as social values within a religious, cultural or national context. Important aspects include the consideration of factors such as whether the technology is suited to small or large farming enterprises, the effects on employment, food security, landscape aesthetics, human and animal health and welfare and a consideration of who would benefit from the technology. Adverse effects may be acceptable in some circumstances, viewed in the light of broader societal goals, the benefits that accrue, and the distribution of harm and benefit. The key determinants with regard to risk perception are the distribution of risks and benefits, voluntarism and consent, 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). Governmental policy, regulations and public debate may also influence attitudes towards using GM crop varieties as an alternative to traditional or conventional as well as organic varieties among both large-scale and small-scale farmers.

6. Sustainable development and societal utility impact assessment

In order to identify the practical implications of the criteria of sustainable development and societal utility, we will apply the Norwegian checklist on two GM plants: Monsanto's soy 40-3-2 ('Roundup Ready' soy) and Pioneer Hi-Bred's 1507xNK603 maize.

6.1 Sustainable development and societal utility impact assessment of Monsanto's soy 40-3-2

Soy 40-3-2, developed by Monsanto Company, has been genetically modified to tolerate the herbicide Roundup Ready. The method for genetic modification was particle acceleration, used to introduce the cp4 epsps gene cassette into the soybean genome. The cp4 epsps gene, isolated from Agrobacterium sp. strain CP4, encodes for a version of EPSPS, which is an enzyme that degrades the herbicide glyphosate and therefore leads to increased tolerance to glyphosate-containing herbicides like Roundup Ready.

We access questions ***1 (global impacts)*** and ***2 (ecological limits***) according to the risk assessment performed by the applicant and on the basis of available scientific literature.

Persistence and invasiveness & selective advantage/ disadvantage

Soybean is a quantitative short-day plant. In Europe it is planted especially in Italy, France, Hungary and Romania, but the largest quantities are produced in the USA, Argentina and Brazil. In Norway soybean is not grown, so any potential spread to the environment of beans might occur only through spill during storage and transport. Due to Norwegian climatic conditions the soybean will not have the ability to persist and became invasive. In the literature there are no reports on that GM soy in field releases or in GM soy-growing countries is more invasive or more persistent that non-GM soy.

Potential for gene transfer

As mentioned, in Norway the soybean will not be grown, so there is no potential for gene transfer to crop plants. Soy is, however, extensively used in processed form in food and feed, involving a potential for spread of trangenes by horizontal gene transfer to micro-organisms in soil, intestines and aquatic environments. In countries where GM soy is grown, it may cross-pollinate with non-GM soy relatives as well as with wild annual species of the subgenus Soja and wild perennial species of the subgenus *Glycine*. These wild species are not found in Europe but in Asian countries. According to the applicant, the potential frequency of hybridisation with wild species is considered to be very low. Field releases have shown that cross-pollination with non-GM soy occurs with low frequency and only over short distances (Ray et al., 2003).

Interaction between GMP and target organisms

- not applicable since 40-3-2 does not express any insecticides. Implications by reduction of weeds are discussed under 'Changes in cultivation pattern'.

Interaction between GMO and non-target organism

The purpose with modification of the 40-3-2 is to increase tolerance to herbicides. As use of the GMP involves spraying with herbicides, potential adverse effects involved in the use of the herbicide may also need to be considered: all agricultural systems exist within an ecosystem, and also weed control may disrupt numerous interrelationships (This is further discussed under 'Changes in biogeochemical processes and cultivation pattern').

Changes in biogeochemical processes

According to Monsanto, 40-3-2 includes an agricultural practice that ensures conservation tillage. Conservation tillage includes several environmental benefits, among them improved soil quality, improved water infiltration, reductions in erosion and sedimentation of water resources, reduced runoff of nutrients and pesticides to surface water, improved wildlife habitat, increased carbon retention in the soil, reduced fuel use and encouragement of sustainable agriculture practices. However, a long-term consequence of using herbicide-tolerant plants together with the relevant herbicide is that the chemical will have a damaging effect on the fauna and soil aquatic microflora (Solomon & Thompson, 2003; Ono et al. 2002; Blackburn & Boutin, 2003). Findings from the USA on the use of glyphosate-resistant soybeans point in the direction of a change in soil microbial activity towards favouring fungi over bacteria. For example, Kremer et al.

(2005) found that in soils grown with glyphosate-tolerant soy and repeatedly treated with glyphosate, soybeans fell victim to the Fusarium fungus, causing 'damaging off'. In Brazil, it has been found that the soybean crop is increasingly affected by stem canker and sudden death syndrome. Soybean rust is a new fungal disease of growing proportions in South America, where fungicide applications are on the rise (Benbrook, 2005). In addition, since 1992, more than 2 million hectares have been infected by cyst nematodes. Many of these pest problems are linked to the genetic uniformity and increased vulnerability of soybean monocultures, as well as to the direct effects of Roundup on soil ecology, through the depression of mycorrhizal fungal populations and the elimination of antagonists that otherwise keep many soil-borne pathogens under control (Altieri, 2004).

Soil systems react quite sensitively to chemical inputs, but because agricultural soils are already highly disturbed and generally poor in biodiversity, and require significant external inputs of agrochemicals to maintain productivity, changes are not easily detectable. More research is needed on how herbicides may affect soil and aquatic ecosystems.

Changes in cultivation pattern

Ease of management plays an important role in the adoption of a new agricultural crop or practice. The objective with the soybean 40-3-2 is to improve weed-management practices with soybean. 40-3-2 is tolerant to glyphosate, which is a broad spectrum herbicide. According to the applicants, 40-3-2 benefits the farmer by providing (1) an additional broad-spectrum weed control option in soybean, (2) a new herbicidal mode of action for in-season soybean weed control, (3) increased flexibility to treat weeds on an 'as needed' basis, (4) cost-effective weed control and (5) excellent fit with reduced-tillage systems. Hence, the introduction of the GM plant is held to provide easier management and maintenance with lower labour and inputs required.

Quantitative field studies, like the farm scale evaluation (FSE) (Squire et al., 2003), have shown that the environmental impact of changes in agricultural management can be at least as significant as those associated with GM crops. Examples include the change from spring to winter sowing in arable crops, the shift from hay cutting to silage production, and growing different crops. The FSEs showed that differences in the impact on wild flora and fauna can be greater between different crops (e.g. between maize and oilseed rape) than between a GM herbicide-tolerant crop and its non-GM herbicide-susceptible counterpart. However, the FSE showed also that the spraying regime involved in the use of herbicide-tolerant crops causes biodiversity effects (Watkinson, 2000). It was also found that herbicide-resistant crop management within and on the margins of beet and oilseed rape production led to reductions in beetle, butterfly and bee populations. Counts of predacious carabid beetles that feed on weed seeds were also lower in GM crop fields. The abundance of invertebrates that serve as food for mammals, birds, and other invertebrates was also found to be generally lower in herbicide-resistant beet and oilseed rape (Defra, 2005). The absence of flowering weeds in GM fields can have serious consequences for beneficial insects that require pollen and nectar for survival.

Glyphosate is one of the most widely used herbicides in the world. Hence it is difficult to predict how significantly the additional usage of herbicide-tolerant crops would speed up the evolution of tolerant weeds. Widespread use glyphosate-tolerant crops increase the likelihood of the development of other glyphosate-tolerant plants. In 2000 in the USA the first glyphosate tolerant horseweed was identified; its evolution was attributed to the planting of glyphosate-tolerant soybean and cotton cropping systems (Hartzler et al., 2004). From Argentina it has been reported that the weed Johnsongrass has become tolerant to glyphosate (Valverde & Gressel, 2006), while in Brazil it has been reported that four different weeds have developed resistance to glyphosate (Weedscience, 2007). Glyposate-resistant weeds will initially be an agricultural problem but could also become an environmental issue if the result is increased usage of the herbicide, a strategy used to kill glyphosate-tolerant weeds, or the change to herbicides with far worse environmental impacts. Hence, growing 20-3-2 requires a spraying regime that minimises the likelihood of selecting glyphosate-tolerant weeds and to adopt management practices to minimise gene flow to sexually compatible feral species.

Socio-ecological effects

Considerations of socio-ecological effects with 40-3-2 are related to the distribution of effects of production and use. Cultivation of 40-3-2 entails the use of herbicides (see above for potential environmental effects) and may have the greatest impacts on small-scale agriculture, since it involves a shift to monoculture and thereby reduction of agricultural biodiversity. In the literature there are almost no studies of the social-ecological effects of growing 40-3-2, except from Argentina. How 40-3-2 has affected agricultural practice in Argentina is further elaborated in this report under the point: Distribution between poor and rich countries. Another important issue with regard to socio-ecological effects is the possibility of reversibility

of effects that may develop over long time as well as potential cumulative effects. Also relevant is whether the widespread adoption of GM soy may cause a decline in the use of other varieties and/or decrease future choices of alternative soy varieties. As yet, no studies have been carried out to investigate these issues.

Basic human needs

Soybean is extensively used as a source of important oils in food and meal in feed around the world. It is widely used in vegetarian diets. In Norway huge amounts of soya are imported every year and used both in human food (especially processed food) and animal feed. Many producers in Norway have expressed concern that it is becoming increasingly difficult to ensure that the feed sources they receive are GM-free.

Distribution between generations

Herbicide-tolerant crops like 40-3-2 hold promise for environmental solutions and environmental problems. Important questions concern if how the change in cultivation practice may have adverse environmental effects, and whether this will cause an unequal distribution of the benefits and risks for future generation. However, as yet no studies of these issues have been carried out.

Distribution between rich and poor countries

At present most of GM soy is cultivated in rich countries, and there has been little research into how growing GM soy affects small farmers. South America, and especially Brazil, Paraguay and Argentina, have adopted GM soy in large areas, at the expense of forests and other habitats. In Argentina, 5.6 million hectares of non-agricultural land has been converted to soy production the last ten years, causing forest conversion rates that are three to six times the global average. In Paraguay, much of the Atlantic forest has been cut (Donald, 2004), while in Brazil, the *cerrado* (woodland savanna) and grasslands have been converted to agricultural land. In South America around 70% of the soy harvested is converted into oil, most of which is exported. The expansion of soybean production is driven by prices, government and agro-industrial support, and demand from importing countries, especially China, which is the world's largest importer of soybean and soybean products (James, 2006). Argentina is the source of 81% of the world's exported soy oil, and 36% of the soybean meal. Altieri and Pengue (2006) claim that this GM soybean expansion has led to extreme concentration of land and income, with high displacement of agricultural workers and small farmers. Furthermore, GM soy has caused farmers to abandon dairy, maize, wheat and fruit production: the consequences have been more imports of basic foods at the expense of food self-sufficiency, and, for poor small farmers and consumers, increased food prices and more hunger (Jordan, 2001; Pengue, 2005). However, most of these consequences are due to a change to industrial agriculture and hence it is difficult to draw any conclusion concerning whether these effects are due to GM soy and if the consequences might have been different with the introduction of non-GM soy.

Altieri and Pengue (2006) argue that Roundup Ready soy requires more, not less, herbicide than conventional soy. In 2001, 9.1 million more kilograms of herbicide were used for GM soy in comparison with non-GM. Moreover, according to Altieri and Pengue, weeds resistant to Roundup Ready soy have already been identified in Argentina. This weed resistance has led to the use of highly toxic herbicides on Roundup Ready soy; farmers have also started using several herbicides that are banned in other countries (including 2,4-D, 2,4-DB, Atrazine, Paraquat and Metsulphuron Methyl).

Key issues for assessment of societal utility by the NBAB

The following questions have been identified as important for assessment of societal utility by the NBAB.

Properties of product:

- Is there a need for this product?
- May the product solve or contribute to solve a societal problem?
- Is the product better than equivalent products on the market?
- Are there any alternative products that may solve or contribute to solve the societal problem in questions?

The development and use of the product:

- Does it help to create new opportunities?
- Does it help to create new opportunities in urban areas?
- Does it help to create new opportunities in other countries?
- Does it entail problems for existing production that need to be conserved?
- Does it entail problems for existing production in other countries?

Most of these questions have been discussed under the section of sustainable development. For instance, the product's properties are related to *basic human needs*, where we argued that soy is important in Norway in food, especially processed food, and indirectly as feed in aquaculture and agriculture. Today it is becoming more and more difficult for Norwegian importers to get GM-free soy, and in the future GM soy may be important for food

and feed producers. The aquaculture industry provides employment opportunities along the cost and contributes revenues to the national income as an export industry. Ensuring ingredients for feed, whether of non-GM or GM origin, is therefore important, and the choice of non-GM and the GM version will be dependent on market price and consumer acceptance. However, whether GM soy is a better product than non-GM soy in terms of consumer health remains an unresolved question (Domingo, 2007).

With regard to the societal utility accruing from developing and applying the product there are several uncertainties. See for instance discussion under *socio-ecological effects, changes in cultivation pattern and distribution among rich and poor countries*. Highly relevant here are also any differences between countries from the developed world and the developing world with regard to whether the agricultural areas used for planting GM soy could have been used for other purposes. In the USA, for example, the same land would most probably be used for planting non-GM soy, whereas in Argentina it is an open question whether the forest and the grasslands would have been converted to agriculture areas if GM soy had not been introduced.

6.2 Sustainable development and societal utility impact assessment of Pioneer Hi-Bred's 1507xNK603 maize

The genetically modified 1507xNK603 maize is resistant to certain *Lepidopteran insects*, such as the European corn borer (*Ostrinia nubilalis*) and can tolerate the use of glufosinate-ammonium and glyphosate herbicides. This maize was derived through traditional breeding methods between progeny of the genetically modified 1507 maize, which is resistant to certain lepidopteran insects and tolerant to glufosinate herbicide, and NK603 maize (from Monsanto), which is tolerant to glyphosate herbicide.

1507xNK603 maize contains the following genetic elements:

- the cry1F gene from *Bacillus thuringiensis var. aizawai* that confers resistance to certain *Lepidopteran insects*, such as *Ostrinia nubilalis*;
- the pat gene from *Streptomyces viridochromogenes* that confers tolerance of glufosinate-ammonium herbicide;
- the cp4epsps genes from *Agrobacterium sp.* strain CP4 that confers tolerance of glyphosate herbicide.

We will assess questions ***1 (global impacts)*** and ***2 (ecological limits)*** according to the risk assessment performed by the applicant and on the basis of available scientific literature.

Persistence and invasiveness & selective advantage or disadvantage

There are no reports to indicate that GM maize is more invasive or more persistent than non-GM maize. In Norway, the climate is too cold for maize volunteers to survive. The 1507xNK603 maize is tolerant of two broad-spectrum herbicides, so it could become a problematic volunteer in countries where climatic conditions permit the seeds to survive.

Potential for gene transfer

Cross-pollination of non-GM maize with wild relatives will not occur in Europe since there are no known wild relatives. However, this is a major concern in Latin America, since these countries are the centres of origin of biodiversity of maize and there are wild relatives (teosints) that are considered to be weeds. Gene transfer to neighbouring fields growing non-GM maize is also conceivable, leading to seed contamination.

Interaction between GMP and target organisms

The 1507xNK603 expresses Bt toxins continuously, and if Bt crops are planted over vast areas one important concern is that this high selection pressure may lead to rapid selection of Bt-resistant pests. A substance designed to kill insects will also act as selection pressure for resistance to the same substance. To prevent resistance from developing, the implementation of resistance-management strategies requiring refuges of host plants without Bt toxins near Bt crops to promote survival of susceptible insects has been initiated. The development of resistance among pest insects may have environmental and health consequences, since Bt proteins are used as a non-toxic biocontrol agent in organic agriculture. Accordingly, the development of resistance among pests may lead to the use of more toxic sprays, which in turn will have such implications as increased occupational exposure to insecticides as well as increased adverse effects on soil and water through run-off. Recently, Tabashnik et al. (2008) have reported that the development of resistance has been observed in pest insects in laboratory bioassays.

Interaction between GMO and non-target organism

Non-target effects by Bt plants include effects on beneficial organisms (e.g. insects and soil microfauna). For instance, the toxicity of the pollen of Bt plants on

Monarch butterflies has received considerable attention (see Losey et al., 1999; Shelton & Sears, 2001; Stanley-Horn et al., 2001). At present it is uncertain whether Bt toxins can accumulate in the food chain and cause complex negative effects, as for instance in Bt resistant-herbivores (e.g. caterpillars which are able to ingest the Bt toxin and thus accumulate it and/or its metabolites without dying), and so pass the Bt toxins and/or its metabolites to organisms higher up the food web (e.g. to predators and parasitoids which feed on Bt-resistant herbivores (Hilbeck & Schmidt, 2006). Although applicants have proven no toxicity in their studies, there have been very few studies involving Cry 1F. Hence, toxicity and environmental impact data on other species (such as regionally appropriate non-target insects, including other non-domesticated herbivores) and regional environments (local-growing, regional) would be needed to accurately determine any toxicity and environmental impacts to local fauna from Bt maize Cry 1F and its degradation products resulting from ingestion by herbivores and decomposition in the soil of plant material root exudates.

Many laboratory studies have been performed to measure the effects of Bt on target and non-target insects. Some studies show no effect, while other indicates that there may be a adverse effect. This has caused a debate about the quality of the different models (relevance and sample size), and with regard to the statistical methods used (Marvier, 2002). For instance, there is scientific debate over the most appropriate testing methods and scales (spatially and temporally) for determining realistic ecological effects of Bt crops (see e.g. Hilbeck & Schmidt, 2006; Sanvido et al., 2007 and references therein). Many experts do now consider simplified bi-trophic testing systems based on eco-toxicological models to be ecologically realistic for assessing multitrophic interactions of Bt crops over several insect generations and spanning at least three trophic levels. Sub-lethal effects detected in small-scale or short-term studies (such as lab or contained glasshouses) might possibly be exacerbated by longer-term exposure (as over a growing season encompassing multiple generations of non-target insect species) and by toxic interactions between expressed Bt toxins and other components of the normal diet of the non-target organism.

According to Lövei & Arpaia (2005), power analysis has rarely been considered in laboratory tests of the impact of GM plants on arthropod natural enemies. They argue that, in future, studies of non-target effects, power analysis should be employed, since this may help research planning (giving indications of sample size and duration of project) and contribute to clarifying the interpretation of the results. Of relevance here is also the dearth of studies on the effects on wild birds, reptiles and mammalian species that may also be exposed to Bt toxins.

Changes in biogeochemical processes

Unlike biocontrol with parasitoids, Bt toxin enters soils with decaying plant material (from plants left behind after harvesting), through post-harvest incorporation of Bt maize crop residues and through root exudates, and it can persist. Cry toxins can adsorb and bind to clays and humic substances in soil, and have been detected in some soils years after incorporation of plant biomass (Saxena & Stotzky, 2005; Zwahlen et al., 2003). Indications have also been found that the earthworm (*Lumbricus terrestris*) can be affected when fed Bt maize litter in experiments. It has therefore been proposed that extensive pre- and post-commercial marketing is necessary to assess the long-term impacts of Bt toxin in transgenetic plant residues in soil (Zwahlen et al., 2003) and in water surrounding fields (Rosi-Marshall et al., 2007).

The evolution of C into CO_2 during decomposition has been reported to be reduced during decomposition of Bt cotton compared to non-Bt cotton. Whether this is also true of Bt maize is as yet unknown. However, this finding raises an interesting question, relevant to the problem of trade-off benefits to one criterion with risk to another (e.g. benefit to climate change versus risk to biodiversity). The problem of incommensurability is also relevant, as 1507xNK603 not only expresses Bt toxins but also carries tolerance to glyphosate and glufosinate. These herbicides are considered to be less toxic than many others, but it would be making a normative judgement to infer that less toxicity would justify their more intensive use. The question of trade-off between incommensurable issues needs further elaboration. For instance, in general the cultivation of Bt maize is held to result in less synthetic insecticide entering soil; however, this benefit may be lost with 1507xNK603 maize, since it is tolerant to glyphosate and glufosinate, both of which are broad-spectrum herbicides. For more information on potential changes in biochemical processes by use of the herbicide glyphosate, (see page 31-32). Currently, there is concern in Europe with regard to the toxicity of glufosinate. Its use has been restricted to apple production, and there are indications that it is more toxic to health and the environment than previously assumed (Matsumura et al., 2001; Heard et al., 2005).

Changes in cultivation pattern

Conventional control of European pest insects involves deep ploughing and pesticides. This practice is necessarily based on monitoring of the pest, as timing is crucial to efficacy of control method: it is essential to catch the larvae before they tunnel into the stem. Shifting to Bt maize may prove more effective in controlling European pest insects than biocontrol or synthetic insecticides. Bt crops are modified to include genes from the bacteria *Bacillus thuringiensis*, thereby causing the crops themselves to produce Bt toxin. Hence, changing from biocontrols or pesticides to Bt maize entails lower workloads for farmers. For instance, practice dependent on biocontrol requires mass releases of parasitoids, whereas with Bt maize farmers only have to buy the appropriate seeds. On the other hand, farmers using control agents do not have to comply with any co-existence or resistance-management requirements.

Bt farmers need to plant areas with non-Bt maize as a refugee; indeed, this is required in several countries as a resistance-management strategy. Co-existence regimes in Europe are likely to require Bt maize farmers to co-ordinate their plantings with neighbouring farmers. By contrast, in many developing countries co-existence regimes have not been implemented, so the planting of Bt maize may provide net benefits for farmers in terms of lighter workload and less exposure to toxic insecticides. However, it is not known whether these benefits may prove short-term especially if resistance develops among pests. (See 40-3-2, page 32 for analysis of changes in cultivation patterns due to herbicide use.)

Socio-ecological effects

Considerations of socio-ecological effects of Bt maize are related to the distribution of effects of production and use. Bt maize gives farmers the opportunity to develop integrated management systems to keep other pests below financially damaging levels (Huang et al., 2007). Further, some studies indicate that the use of Bt maize has provided farmers with more security and higher yields (Gouse et al., 2006).

Bt maize is easier to manage for farmers, as few or no insecticide sprays are required and workers are less likely to be exposed to toxic insecticides. However, as noted, Bt farmers need to plant areas with non-Bt maize as a refuge. This could prove problematic for small-scale farmers, since the external costs by refugees may outweigh the benefits of using Bt crops. On the other hand, planting Bt maize without refuges may hasten the development of resistance among target insects, making it difficult for organic farmers who depend on biocontrols. Agriculture practice without refuges will also hamper co-existence between the GM field and conventional and organic fields in case of cross-pollination happen. This is especially relevant in Latin America, which is considered to be the centre of origin of maize.

Basic human needs

In Norway maize is not an important food ingredient, but is used extensively in animal feed, (especially for salmon, chickens and pigs), as an inexpensive input. Given the soaring costs of animal feed, Bt maize may become a central issue for local livestock producers.

With regard to food security, we should note that Bt maize has been reported to have lower levels of mould and mycotoxin contamination (Wu, 2007). Mycotoxins are secondary metabolites of fungi that colonise crops. Thus Bt maize may help to reduce the consumer risk of fungal contamination; however, this benefit will need to be weighed against the still-debated issue of the potential adverse effects of consuming Bt maize.

Distribution between generations

Bt maize holds promise for environmental solutions and environmental problems. Important questions concern how the change in cultivation practice may have adverse environmental effects and whether this will lead to unequal distribution of the benefits and risks for future generation. As yet, no studies have looked into these issues. It is especially relevant to investigate the long-term effects of the build-up of toxins and Bt genes in soil and aquatic environments, since this may adversely affect biodiversity.

Distribution between rich and poor countries

As noted, Bt maize is easier to manage for farmers: few or no insecticides sprays are required, and farm workers are less likely to be exposed to toxic insecticides. However, some insecticides may still be required in areas where other pests cause economic damage.

Most Bt maize has been developed and tested in the USA. It is difficult to translate and extrapolate risk assessment results on the toxicity of Bt maize to human and non-target organisms to other countries, given the great differences between regional growing environments, scales of farm fields, crop management practices, local/ regional target and non-target species considered most important in the agro-ecosystem, interactions between cultivated crops, and the surrounding biodiversity. Toxicity and environmental impact data on other species (e.g. regionally appro-

priate non-target insects, including other non-domesticated herbivores) and regional environments (local growing regions) would be needed to accurately determine the toxicity and environmental impacts to local fauna of Bt maize Cry1F and its degradation products resulting from ingestion by herbivores and decomposition in the soil of plant material and root exudates. Even for target pest species from different countries or regions, sensitivities to expressed Bt toxins may vary widely. It is reasonable to expect that the same species-specific and even population-specific variability in sensitivity to Bt toxins will apply to local non-target species that could be affected by this Bt toxin – like local butterflies of conservation concern and heritage value.

Key issues for assessment of societal utility by the NBAB
The following questions have been identified as important for assessment of societal utility by the NBAB.

Properties of the product:
- Is there a need for this product?
- May the product solve or contribute to solve a societal problem?
- Is the product better than equivalent products on the market?
- Are there any alternative products that may solve or contribute to solve the societal problem in questions?

Development and use of the product:
- Does it help to create new opportunities?
- Does it help to create new opportunities in urban areas?
- Does it help to create new opportunities in other countries?
- Does it entail problems for existing production that need to be conserved?
- Does it entail problems for existing production in other countries?

Most of these questions have been discussed under the section of sustainable development. For instance, the product's properties are related to *basic human needs*, where we argued that maize is not very important in Norway in human food, but is highly relevant in the animal feed industry. Although it currently is not as difficult for Norwegian importers to get GM-free maize, as is the case with soy, this may change. The 1507xNK603 applicant argues that consumption is safe; this is supported in general with Bt maize. The majority of feeding studies support the claims that the GM maize is as safe as its non-GM counterpart. However, whether the 1507xNK603 is a better product than non-GM maize in terms of consumer health remains an unresolved question. Also relevant is that the pests for which the 1507xNK603 is toxic are not a problem in Norway; this means the GM plant would not be solving an existing problem for Norwegian agriculture. In other parts of the world where these pests are a major problem, however, the use of 1507xNK603 may provide environmental benefits to agriculture by increasing yields on the same amount on land with fewer inputs, thereby also reducing exposure for farmers to toxic pesticides. However, this is a highly complex issue, due to the employment of resistance management, potential resistance development among pests and with regard to the usefulness of Bt toxins against major pests (see Change in cultivation pattern page 37 and Target effects page 35).

With regard to the question of societal utility from the development and use of the product, various uncertainties remain. See for instance the discussion under *socio-ecological effects, changes in cultivation pattern and distribution among rich and poor countries* (page 37-38). It is also important to acknowledge that cultural concerns may be more significant than the functional utility, as highlighted with the debate concerning effects of Bt maize in Mexico on Monarch butterflies and land-race corn.

7. Summing up and looking ahead

An overall finding in this report is the wide range of practices and advice that characterises GMO policy at the regional and member-state level within the EU. Some of these practices and advice are more and others less in harmony with Norwegian developments in this issue area. Scientific uncertainty is common for the GMO issue in general, but would seem even more pronounced in Norway, where the assessment procedures increasingly involve demands for additional and different types of information. The public at large tends to see the GMO issue in a broader perspective, as part of the trends toward globalisation, with less local control over choices in food and medicine. A narrower focus on risk assessments tends to exclude this type of concerns. This type of scenario could indicate that GMOs are still regarded as solely a technological issue, and this raises the question of whether it is legitimate to exclude the more comprehensive, societal arguments. Because of the specific clauses in the Gene Technology Act, this particular situation is less likely to occur in Norway. Rather, Norway's Gene Technology Act has made possible comprehensive evaluation, including consideration of conditions in the GM-producing country. This means that Norway is able to pursue its international role as a 'green' bridge-builder between North and South to a greater extent than would have been likely without the Gene Technology Act.

Several sources have maintained that the industry, with its one-sided claims to knowledge, should not be the sole producer of arguments in this decision-making process (see Myhr & Traavik, 2002). Norway is not alone in this view, but is supported by part of the EU Commission along with the hard-core states in the EU. Documentation attached to GMO applications represents a problem that would hardly be resolved by accepting the principle of a reversal of the burden of proof, leaving the responsibility for documentation of public utility and sustainable development up to Norwegian authorities. In this view Norway is supported by EU Commissioner Stavros Dimas and by the report of the Swedish Riksrevision.

A main reason why Norway can continue to reject GMO applications may be that they are not (yet) financially interesting to Norwegian farmers. In addition come the small size of the Norwegian biotechnology sector. However, this situation may change; indeed, some GM products may already be interesting for the animal fodder industry. The GMO issue provides a prime example of the dilemma of regulators, in seeking to skirt the dangers of being co-opted by technocrats with little democratic control, or on the other hand, leaving the agenda to be shaped in populist terms. Norwegian regulators will be hard pressed in the final round when forced to choose between disappointing a unified public opinion that includes a wide range of Norwegian interest groups, and going against certain trends and expectations in the European Union and parts of the biotechnology sector.

This points up how the Norwegian Gene Technology Act does not represent an 'easy option' out of a difficult situation, where scientific truth is not likely to resolve the dilemma. Decisions on GMO policy are inherently political in nature – much like the concept of sustainable development itself. This gives rise to a number of unresolved problems:

First, there is a need to identify how ethical issues, as well as the choice of perspectives and value commitments, affect risk assessment and management of genetic engineering applications and GMOs.

Second, there is a need to elaborate more holistic approaches to genetic engineering applications and GMO risk issues, to remedy the current lack of scientific understanding.

Third, assessing utility against risk is an important element with regard to implementing the criteria of the Norwegian Gene Technology Act, and as such, this warrants much broader analysis.

A fourth element, still incompletely understood, is the relationship between short-term concerns for human health and longer-term concerns for environmental consequences. There is insufficient scientific understanding of both the economic and long-term impacts of the use and release of GMOs. Very little research has been carried out to identify the environmental and health effects of GMOs, although such knowledge is necessary to inform decisions on sustainable development. The concern for human health has its legal counterpart in evolving regulations for labelling GMO products, which enables informed consumer choice. There is, however, no legal counterpart with regard to environmental concerns, as 'the environment'

cannot be expected to read labels and make rational choices. On a similar note, the EFSA 'divisions of risk', which was to some extent accepted by the VKM, raises highly relevant issues with regard to implementation of the criterion of sustainable development in the Gene Technology Act. This would imply the need for an environmental assessment of GMOs, for instance in the form of an official White or Green Paper.

Fifth, in the impact assessment, the word 'will' is used in the beginning of every aspect that is to be considered. 'Will' is a strong word that places considerable demands to the information to be used to inform the NBAB. We are concerned about how the word 'will' may affect the relevance of the use of the precautionary principle when there is insufficient scientific understanding, and since assessments related to sustainability involve dealing with technical facts and social issues that almost always are incommensurable. The word 'will' may also reduce the flexibility of the concept of sustainable development with regard to changing conditions and developments in scientific understanding.

Sixth, we have noted the lack of scientific discussions and public deliberation concerning such reflections as: How to act when the long-term consequences are unknown? How sure is 'sure enough'? 'Who are the affected parties?' Answers to these questions can be used to inform safety requirements for health and the environment, how to take long-term perspectives, elaboration of the considerations for present and future members of society as well as concerning the distribution between rich and poor countries.

Lastly, we have pointed out the need for legal analysis of the scope and type of responsibilities that the Gene Technology Act places on Norwegian authorities for finding and making available documentation and information about societal utility and sustainable development in GMO applications. This question is related to the imperative of transparency in the decision-making processes on GMOs.

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Utredninger oversikt

2007

2007-1:	Den norske våtmarksarven. Styrket forvaltning og utvidelse av nettverket av Ramsarområder og andre vernede våtmarker i Norge. Tiltaksplan 2007-2010	50,-
2007-2:	Bestandsstatus for laks 2007. Rapport fra arbeidsgruppe	50,-
2007-3:	Reetablering av laks på Sørlandet. Årsrapport fra reetableringsprosjektet 2006	50,-
2007-4:	Supplerende kartlegging av biologisk mangfold i jordbrukets kulturlandskap, inn- og utmark, i Rogaland med en vurdering av kunnskapsstatus - Nasjonalt program for kartlegging og overvåking av biologisk mangfold	50,-

2008

2008-1:	Supplerende kartlegging av biologisk mangfold i jordbrukets kulturlandskap, inn- og utmark, i Midt-Norge; Møre og Romsdal og Oppdal, med en vurdering av kunnskapsstatus. Nasjonalt program for kartlegging og overvåking av biologisk mangfold	50,-
2008-2:	Nasjonal overvåking av marint biologisk mangfold i havområder og Arktis – Forslag til overvåkingselementer, lokalisering og kostnadsoverslag	50,-
2008-3	Supplerende kartlegging av biologisk mangfold i jordbrukets kulturlandskap, inn- og utmark, i Buskerud med en vurdering av kunnskapsstatus Nasjonalt program for kartlegging og overvåking av biologisk mangfold	50,-
2008-4:	Supplerende kartlegging av biologisk mangfold i jordbrukets kulturlandskap, inn- og utmark, i Agder, med en vurdering av kunnskapsstatus	50,-
2008-5:	Bestandsstatus for laks i Norge. Prognoser for 2008. Rapport fra arbeidsgruppe	Internett
2008-6:	Supplerande kartlegging av biologisk mangfald i jordbrukets kulturlandskap, inn- og utmark, i Sogn og Fjordane. Nasjonalt program for kartlegging og overvaking av biologisk mangfald	50,-
2008-7:	Evaluering av bekjempelsesmetoder for *Gyrodactylus salaris*. – Rapport fra ekspertgruppe	50,-
2008-8:	Reetablering av laks på Sørlandet. Årsrapport fra reetableringsprosjektet 2007	50,-
2008-9:	Nå eller aldri for Vossolaksen - anbefalte tiltak med bakgrunn i bestandsutvikling og trusselfaktorer	50,-
2008-10:	Klima og effekter på økosystemer og biologisk mangfold – scenarioer stølslandskapet i Valdres	Internett

2009

2009-1:	Supplerande kartlegging av biologisk mangfald i jordbrukets kulturlandskap, inn- og utmark, i Hordaland med en vurdering av kunnskapsstatus Nasjonalt program for kartlegging og overvaking av biologisk mangfald	100.-
2009-2:	GMO Assessment in Norway as Compared to EU Procedures: Societal Utility and Sustainable Development	100,-

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Rapport er utarbeidet av DN, og gir uttrykk for direktoratets forslag eller standpunkter.

Notat er enklere oversikter, sammenstillinger, referater og lignende.

Håndbok gir veiledning og konkrete råd om forvaltning av naturen, som regel til bruk for lokale forvaltningsorganer

Temahefte gir en popularisert framstilling av et tema.

Mer info:
www.dirnat.no/publikasjoner

Direktoratet for naturforvaltning (DN) er det sentrale, utøvende og rådgivende forvaltningsorganet innenfor bevaring av biologisk mangfold, friluftsliv og bruk av naturressurser. DNs visjon, **For liv i naturen og natur i livet,** er et uttrykk for dette. DN er administrativt underlagt Miljøverndepartementet.

Myndigheten til å forvalte naturressurser er gitt gjennom ulike lover og forskrifter. Ut over lovbestemte oppgaver har direktoratet også ansvar for å identifisere, forebygge og løse miljøproblemer ved samarbeid, rådgivning og informasjon overfor andre myndigheter og grupper i befolkningen.

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Direktoratet for
naturforvaltning

7485 Trondheim Telefon: 73 58 05 00
Telefaks: 73 58 05 01 www.dirnat.no