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Assessing Socio-Economic Impacts of GMOs

Issues to Consider for Policy Development

Final Report

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Table of Contents

List of Acronyms

BCH	Biosafety Clearing House
BMG	Austrian Federal Ministry for Health
BMLFUW	Austrian Federal Ministry for Agriculture, Forestry, Environment, and Water Management
CAC	Codex Alimentarius Commission
CAP	Common Agricultural Policy
CA	Competent Authority
CBD	Convention on Biological Diversity
CEES	Economic, Ethical and Social Committee (French High Council on Biotechnology)
CFI	European Court of First Instance
CGRFA	Commission on Genetic Resources for Food and Agriculture
COGEM	Netherlands Commission on Genetic Modification
COP-MOP	Meeting of the Conference of the Members of the Protocol
CSO	Civil Society Organisations
DG SANCO	Directorate General for Health and Consumer Affairs
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
EGE	European Groups on Ethics in Science and New Technologies
ERA	Environmental Risk Assessment
FOE	Friends of the Earth
GATT	General Agreement on Tariffs and Trade
GIC	Global Industry Coalition
GM	Genetically Modified
GMO	Genetically Modified Organism
GTG	Austrian Gene Technology Act
ILSI	International Life Science Institute
IRGC	International Risk Governance Council
LMO	Living Modified Organism
NSDS	National Sustainability Development Plan
OC	Organic Center
RDP	Rural Development Plan
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
SCFCAH	Standing Committee on the Food Chain and Animal Health
SIA	Social Impact Analysis
SOEIA	Socioeconomic Impact Assessment
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UNEP	United Nations Environment Programme
WTO	World Trade Organisation

Executive Summary

This Report

This report is motivated by the conclusions of EU Council of Environment Ministers of December 4, 2008, asking the European Commission to explore the possibility to consider other factors beyond health and environmental risks, i.e. "socio-economic benefits and risks and agronomic sustainability" (all covered by the term socioeconomic in this report) in GMO market authorisation. While socioeconomic issues have played a major role in the long standing EU debate on GMOs, there is, however, very little experience in explicitly and systematically assessing socioeconomic impacts of GMOs. Against this backdrop, this report aims to identify and explore the issues relevant to the topic and provide recommendations for policy development and further research. Research was structured along the following main questions: (i) what are socioeconomic effects of GMOs and what are the relevant issues and controversies? (ii) Whether and how can socioeconomic effects be differentiated or clustered e.g. according to the specific GMO, the intended application or the type of release? (iii) How could socioeconomic effects be assessed in the course of GMO market authorisations? Furthermore (iv), the study should explore the awareness and views of Austrian stakeholders on this topic. The study draws on a review of published literature and policy documents as well as phone interviews with stakeholders in Austria.

Socioeconomic considerations in the literature

There is a substantial body of literature on anticipated and documented impacts of GM crops beyond the health and environmental dimension. These impacts are referred to as economic, agronomic, agro-environmental, societal, social, socioeconomic etc. The term 'socioeconomic' seems to be used very broadly as involving a combination of social and economic factors. With the possible exception of ethical issues, the term appears to cover almost everything which does not fit into the health and environmental risk box. As the scope of "other factors" in GMO authorisation is not yet clear it is considered pertinent to keep the vagueness of the term in this report.

The majority of the publicly available literature investigates economic effects. Studies on developing countries have a strong bias towards farm level effects and cotton. Many reports can be traced to either industry and close-to-industry sources or to environmental NGO sources. Comprehensive studies from public authorities or independent organisations are scarce. Two examples are briefly described: a study compiled by the UK Cabinet Office in the course of the GM Nation exercise, and a large-scale assessment conducted in the context of the United Nations: the International Assessment on Agricultural Knowledge, Science and Technology for Development (IAASTD) aiming to investigate the impacts of agricultural knowledge, science and technology (AKST) on hunger, poverty, nutrition, human health, and environmental and social sustainability in relation to both the past and the future.

The UK study concluded that for the UK context economic benefits might be outweighed by additional costs though expecting the balance to change with future generations of GM crops. The IAASTD exercise was sceptical about the relative contribution of biotechnology for solving the main societal problems described above.

Many studies, the authors of which are related to industry showed clear benefits, especially on the farm level, while NGO studies often came to different conclusions.

Socioeconomic considerations in EU and national regulatory regimes

Socioeconomic impacts of GMO market approvals are considered in a broad range of countries including Armenia, Bangladesh, Bhutan, Cambodia, China, Honduras, India, Lebanon, Mauritius, Nigeria, Philippines, South Korea, and the Syrian Arab Republic. Scope and nature of requirements seem to vary considerably between these countries as does the way they are being established: part of national legislation, draft legislation, policies or regulatory practice. Australia, Brazil, Canada, Japan, and Thailand are examples for countries not taking into account socioeconomics. Among EU/EEA Member States, only France and Norway are known to explicitly assess socioeconomic impacts; the Austrian national law on GMOs includes a provision on socioeconomics which has not yet been implemented though.

Norway established a mandatory requirement to consider socioeconomic impacts back in 1993, focusing on ethical and social aspects as well as sustainability assessment. Requirements were subsequently detailed in regulations on impact assessment and opinions of the NBAB. Sustainability assessment includes all three pillars of sustainable development and explicitly recognises the global scale. It thereby extends environmental risk assessment when considering effects on biodiversity in third countries. Social utility aspects include for instance demand, problem solving capacities, and alternative products. Ethical assessment considers for instance the moral views of the general population, impacts on traditional cultures and weaker groups, and the integrity of species. Socioeconomic information is being weighted against health and environmental risks and associated uncertainties and irreversibility. The unfavourable opinions of the NBAB frequently included lack of benefit to the society and a positive contribution to sustainable development, though, health and environmental risks seem to be still the most important reason. The lack of socioeconomic information in the dossiers is perceived by Norway to be a particular problem. It is neither possible to force applicants to provide such information nor to comment on such aspects in the EU authorisation procedure because they are considered by EFSA to be out of scope.

In France, the High Council on Biotechnology (HBC) was established following a recent change in GMO policy. One of the two HCB Committees (CEES) provides advice to the government on economic, ethical, and social aspects of GMOs including in the course of routine evaluations of Directive 2001/18/EC and Regulation 1829/2003 dossiers. Based on the limited experience gained so far, CEES perceives its main challenges to be the lack of relevant information in the dossiers and the lack of guidance for criteria, methods, data, and assessments. CEES practice apparently includes providing quite prescriptive advice instead of options to the formal decision makers based on a weighing-up of health and environmental risks on the one hand, and socioeconomic concerns and benefits on the other hand. This practice is potentially changing lines of accountability and needs a more careful analysis in the context of the EU governance framework established for the food chain.

The Austrian GMO law includes a provision allowing decision makers to ban the marketing of products which are considered ‘socially unsustainable’ (‘sozial unverträglich’) - referring to social, economic, and ethical aspects. The meaning of this provision has never been clarified; it has been discussed to be potentially in conflict with EU legislation. In no case, explicit reference was made to this provision – which could therefore be considered as void. In case of an EU policy change, e.g. allowing for national assessments of socioeconomic impacts of GMOs, this provision could become an interesting reference. A more detailed legal analysis might be required to identify possible constraints.

Challenges from international regulations

Article 26 of the Cartagena Protocol on Biosafety establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms in reaching a decision on whether to import these organisms, especially with regard to the value of biological diversity to indigenous and local communities. The scope of this Article is contentious with the USA and industry favouring a more narrow interpretation, and others including socioeconomic effects beyond the role of biological diversity to indigenous and local communities. The Article also includes a provision to make sure that Parties' considerations of socioeconomic aspects meet their other international requirements thereby possibly limiting the scope of interpretations. Clearly, the WTO agreement has to be considered in the next steps of discussion. Moreover, non-Parties, such as the USA, are and will not be bound to the requirements of the Protocol. Therefore the possible role of the Article as a reference point for EU or national policy remains unclear.

WTO legislation does not a priori exclude socioeconomic aspects as long as they are verifiable, transparent, and non-discriminating. In developing their line of argumentation, countries need to define socioeconomic aspects as risk-, health- or trade-related to make them subject to any of the three WTO Agreements. Since the WTO dispute, GMOs have been considered almost exclusively in the context of the SPS Agreement as if no other possibilities exist. In fact, both the TBT- and the GATT Agreement provide more scope for addressing socioeconomic factors compared to the SPS Agreement. The recent WTO dispute on GMOs concluded that it is possible to base measures on more than one agreement. Overall, it seems to be possible to meet the key requirements, i.e. a legitimate objective, based on scientific or other evidence, not more trade-restrictive than necessary, and non-discrimination when making a case for socioeconomic consideration.

The FAO Draft International Code of Conduct on Plant Biotechnology prepared by the FAO Commission on Plant Genetic Resources in 1993 also holds relevant provisions on the consideration of socioeconomic factors. If finalized and adopted, the Draft Code of Conduct could facilitate the broadening GMO assessment and decision making.

Challenges from EU institutional arrangements

A key issue in implementing socioeconomic assessment for GMOs would be the institutional location at the EU level. Socioeconomic factors have so far been perceived to belong to the realm of risk management, i.e. the EC and the Member States. If risk management frequently asked for and evaluated socioeconomic data, the establishment of a dedicated body might be envisaged. From a governance perspective, providing advice on socioeconomic aspects can be considered as just another scientific advice to risk management and not as part of its core tasks, weighting of evidence on impacts and decision options, and mitigating negative effects. Applying the rationale which was underlying the establishment of EFSA to separate expert advice from decision making would require a functional and/or institutional separation to the EC. There is, however, no obvious entity at the EU level which could deal with socioeconomic assessments. EFSA has been proposed to cover some aspects (health and environmental benefits). EFSA's scope might even be broadened to include a social science unit for more broadly assessing societal concerns. The latter proposal is, however, objected by industry and stakeholders. Moreover, commentators diverge on the need for changing the legal basis of EFSA, the EU General Food Law.

Industry suggested making use of the European Group on Ethics which could be complemented by another committee looking into economic and social issues. Though the remit of such a committee/body remained to be determined, it can reasonable be expected that it would comprise the evaluation of socioeconomic data provided in dossiers and coordination to Member States. Given the context specifity of socioeconomic impacts, Member States will have to play an important role in

providing data and evaluations more specifically for national and regional context. It appears to be unlikely that a Committee of independent expert advisors could play such a role.

In principle, the mandate of EFSA could be modified along the lines of REACH legislation, which allowed establishing two committees: a scientific and a socio-economic committee linked to the European Environment Agency. This would, however, require amending EU legislation in particular, the EU General Food Law.

Challenges to a socioeconomic assessment framework

The analysis in this chapter is based on essential similarities between risk assessment and socioeconomic assessment (subsequently referred to as socioeconomic impact analysis, SOEIA). First, SOEIA is conceptualised as scientific advice on policy making, though largely based on social science. Second, this scientific advice can be expected to meet EU standards established for good governance and expert advice in policy contexts. Third, a SOEIA framework could be designed in symmetry to risk assessment. Fourth, the need for an elaborate framework which allows for both public participation and public scrutiny also comes from the inherent similarities of the conflicts. Both the assessment of health and environmental risks and the socioeconomic considerations led to contradicting results and conclusions and stir fierce debates among stakeholder groups as well as in the scientific literature. Given this similarities of both types of scientific advice, the concepts on inclusive and integrative risk governance can also be employed.

Setting an assessment means to clarify normative baselines, key concepts, criteria, impact dimensions, 'endpoints', and methods. Taking the example proposed by the Netherlands Commission on Genetic Modification (COGEM) report it is shown that conventional agriculture and sustainable development might have different meanings in Austria and the Netherlands. Such context specifity is likely to translate into divergence in scope, impact dimensions and criteria. Issues of scope could also be limited by international legislation, e.g. if considering not only impacts on Member States or EU territory but also on third countries. Different proposals have been made for criteria, impact dimensions and endpoints though, quite a few specifically covering a broader range of socioeconomic issues. Recent examples come from COGEM and Norwegian Biotechnology Advisory Board (NBAB) and from a German report. It remains unclear how and to what extent these proposals have been checked against empirical evidence on socioeconomic impacts described in scientific literature and public reports. This is, however, important as there is considerable evidence which needs to be systematically collected and scrutinised in order to verify and possibly develop the criteria proposed. Existing reviews do not seem to be comprehensive enough or seem to be biased in one or another direction. Putting together impact dimensions, endpoints, criteria and methods is a valid endeavour, however, it is still highly questionable if anything like a definitive checklist can be obtained. Researchers of social impact analyses widely disagree on what constitutes social impacts and which variables should be included in assessment criteria.

Austrian stakeholders highlighted impact dimensions relevant for Austria given its specific agroeconomic and sociocultural context: small-scale agriculture with a very high proportion of farmland located in disadvantaged (mainly mountainous) regions, very high proportion of organic farms; strong resistance from consumers and the general public to adopt GM crops and derived food/feed. Hence, serious short-term and long-term impacts can be envisaged on conventional and organic producers and the entire food chain including consumers and seed producers, thereby affecting costs and gains for farmers, food producers and retailers, market shares and position, as well as competitiveness. It is also perceived to conflict with Austrian agriculture policy goals.

Setting up a framework and approaches for socioeconomic assessment of GMOs is breaking new ground, though this does not necessarily mean to start from scratch. Existing impact assessment approaches could be explored, e.g. social impact analysis and environmental impact assessment.

Given the need to clarify and agree on normative baselines, key concepts, criteria, impact dimensions, 'endpoints' and methods it is proposed to establish a distinct framing step which would provide for framing deliberations between expert advisors (here: mainly social scientists) and policy makers (here: risk management, i.e. the European Commission and the Member States). The importance of such a framing step has been acknowledged for risk assessment not only in the scientific literature but also in policy contexts, e.g. recently by the Codex Alimentarius Commission. This framing step could be designated as 'impact assessment policy' in analogy to the term 'risk assessment policy' used by the Codex. Generally agreed procedural and substantive aspects of impact assessment policy can and should be included in guidance documents. Trait/crop/application-specific guidance in analogy to the crop-specific OECD Consensus or Biology documents could also be considered. This framing stage could also have a clearing house function to allocate issues to either the scientific or the socioeconomic assessment. Over time the scientific risk assessment has been widened to include environmental impacts such as resistance management which are particularly important from an agronomic point of view. Such information might (also) be considered in the course of a socioeconomic assessment.

Public participation is considered important, in particular in the framing and evaluation step (when the expert advice is being considered and weighted by decision makers). The degree of public participation might be flexible depending on the issues at stake.

It is also important to consider the characteristics of socioeconomic data and the differences compared to data from scientific risk assessment. Socioeconomic data are crop/trait/application-specific but not necessarily event-specific. Thus there is no need to produce extensive socioeconomic data for each particular event. Supplementary event-specific information might only be relevant if important characteristics of the crop/trait/application combination are being affected. On the other hand, socioeconomic data can be specific for a particular geographical, climate, agroeconomic and socio-political context and such data cannot be directly applied to other contexts. This is complicating the establishment of trait/crop/application-specific guidance documents and putting the value of socioeconomic data from other contexts into perspective.

Wider policy challenges

This chapter briefly discusses other aspects still relevant for policy development.

The most important aspect is the need to set the stage for a broader debate on the EU level. A scoping document should be composed which clarifies some cornerstones of a socioeconomic assessment of GMOs. These clarifications should include the relationship to the parallel debate on allowing Member States to ban cultivation on their own territory (opt-out); whether socioeconomic impacts should only be considered in case of cultivation and restricted to the EU only or all GMOs and extended to impacts on third countries; whether socioeconomics would be routinely assessed in each case and – if not – what would trigger such an assessment; whether it would be possible to object to an application based on socioeconomic grounds; to whom the responsibilities would fall to provide socioeconomic data.

Another important question is how stakeholders will respond if this is becoming a broader debate. There is preliminary evidence from literature that a majority of stakeholders would positively receive the consideration of socioeconomic aspects with the biotechnology industry possibly opposing such a move. Almost all Austrian stakeholders interviewed in the course of this study also expressed a positive view. At this early stage, Austrian stakeholders have not yet taken any official position or view as there is still a lack of clarity whether at all and how socioeconomic considerations might become relevant. The majority highlighted prior occupancy with the issue of socioeconomics given the specifics of the Austrian context: lack of tolerance of consumers for trace amounts of GMOs; the threshold for GMOs in seeds, and organic food products being as low as 0.1%.

Other aspects not directly related to a socioeconomic assessment framework are

- Changing lines of accountability – in particularly if linked to opting-out: blame avoidance strategies ('no' votes or abstaining while predictably receiving a positive decision by the EC) might no longer be sustained.

- Administrative burden for Member States with strict coexistence laws is likely to increase in any case: if there is cultivation of GM crops in these countries, efforts will increase for implementing national legislation and control. In case of an opt-out clause based on socioeconomic reasons, Member States might be required to provide extensive socioeconomic data for their specific geographic and socio-cultural contexts.

- The appropriateness of regulation might again be subject to criticism if GM crops were rejected on socioeconomic grounds, while conventional varieties with a similar socioeconomic 'profile' would not be assessed at all and continue to be marketed.

- Applicants might not provide extensive and context specific data for less important markets – this is one explanation why Norway has so far not received additional socioeconomic information along with the risk assessment dossiers.

Characteristics of the Austrian context

Austria has a very distinct agricultural structure compared to other EU Member States. It has one of the highest proportions of farms in mountainous regions (more than 70%) - dominated by small-holders - and by-far the highest proportion of organic farms (15.2% corresponding to a share of 18.5% of total arable land). Since the late 1980ies, Austrian agricultural policy has highlighted sustainable and multifunctional agriculture (landscape management, tourism, biodiversity, rural development, socio-cultural aspects etc.) and strongly promoted ecological measures, organic farming and organic food, regional food supply, local and regional farmer-business initiatives etc. This is also mirrored in Austria's National Sustainable Development Plan. Austria has the highest percentage of participation in EU agri-environment programmes (some 17%). National policies foresee to continue with this policy and to expand organic farming to 20% of total arable land by 2010.

Present generations of GM crops are not perceived to provide relevant benefits, a fact that is partly linked to the low infestation rates with pests such as the corn borer. Yield increase over the last few decades in case of maize compares and even exceeds the numbers from the USA.

Coexistence of GM and conventional/organic crops is being considered very difficult for two main reasons. First, the small-scale agriculture with an average plot size of some 1.7 hectares and plots typically scattered over an area. Policies in place support small-holder structures and less intensive farming as important in mountainous regions for the maintenance and management of cultural landscapes, tourism and rural development in general. Second, there is strong pressure to avoid any GM content in food exceeding 0.1%. This threshold is embedded in standards of the organic farmers association and in legal requirements for food labelled as GM-free. Beyond that many food processors and retailers are striving to avoid any GM content because of public demand. In fact, the acceptance of GM crops and food in Austria has been continuously ranking very low and lowest compared to other EU Member States.

As a consequence, coexistence measures would have to be much stricter and more comprehensive compared to other geographical contexts. For instance, according to simulation experiments with

rape and maize considerable loss of conventional/organic crop land of 36 to 100% could be anticipated in order to allow for sufficient isolation distances.

The organic farming movement has also triggered ecological modernisation in Austrian agriculture with many farmers adopting ecological measures even if not farming organically. Organic farmers are frequently key actors in bottom-up initiatives of rural development which have become more and more important, especially in disadvantaged regions. These initiatives are typically comprising of several rural communes and could also cover larger regions. They are frequently linking regional actors along the food chain and other business sectors such as gastronomy, tourism and energy production. High quality food and specialities from sustainable production are being linked to regional characteristics. Many of these initiatives – even if not subscribed to organic farming – have adopted sustainability standards for farming, food-production and supply with GM-freeness as one of the key criteria. Members of such rural development initiatives, therefore, perceive cultivation of GM crops as a threat to their economic basis and sociocultural regional identity.

Overall, these characteristics have led to strict coexistence legislation by all Federal Provinces and the establishment of numerous initiatives promoting GM-free regions and GM-free food supply.

Overall this context has led to strict coexistence legislation by all Federal Provinces and the establishment of numerous initiatives promoting GM-free regions and GM-free food supply.

Austrian stakeholders consulted in the course of this study highlight these agro-economic and sociocultural specifics. Hence, serious short-term and long-term impacts can be envisaged on conventional and organic producers and the entire food chain including consumers and seed producers, thereby affecting costs and gains for farmers, food producers and retailers, market shares and position, as well as competitiveness. It is also perceived to conflict with Austrian agriculture policy goals.

Recommendations

Based on the analysis in this report, recommendations for policy development and research are provided:

General recommendations

- Clarification and agreement on the EU level is needed
    - On the cornerstones for socioeconomic assessment in order to set the stage for developing an assessment framework
    - On the legal leeway to widen the scope of EFSA to also consider socioeconomic impacts
    - On a base-set of socioeconomic indicators

More research is required on

- Recent WTO case law to explore the legal leeway in the international context for considering socioeconomic factors
- Assessment criteria, and methods which can be employed

- How the various concepts of impact analysis and integrated risk governance can provide guidance

- How to envisage a centralised multilevel assessment framework which allows for gathering and evaluating 'contextualised' socioeconomic information from individual Member States

- On stakeholders and public perception

Recommendations for policy development in Austria

Given the active role of Austria in shaping and improving EU GMO regulation over the last two decades and given the important role of socioeconomic factors for Austria's GMO policy, it is both pertinent and in-line with its policy goals to play an active role in the upcoming debate on socioeconomic assessment.

Assuming the next steps taken by the European Commission reveal that socioeconomics will be an important issue, it is proposed that Austria should

- Launch a process for policy development which allows for inputs of a broad range of stakeholders

- Indentify and conduct research on impact dimensions and possible impacts of GM cultivation *specifically relevant for Austria*

- Based on the research described above conduct transdisciplinary research on best practice models, approaches, and methods appropriate for measuring and assessing the impacts as well as the normative baselines and criteria *identified as relevant for Austria*.

Even if socioeconomic consideration turned out not to play a key role in routine EU GMO authorisation, they might be very relevant for assessing technological innovations already in the pipeline, e.g. GM crops with altered composition claiming health benefits, GM crops for industrial uses or energy production, and novel breeding methods. It might therefore be pertinent to proceed in any case with exploring socioeconomics and socioeconomic assessment of GMOs.

Zusammenfassung

Einleitung

Anlass für diese Studie ist ein Ratsbeschluss der EU-Umweltminister vom 4. Dezember 2008, der die Europäische Kommission auffordert, neben Gesundheits- und Umweltrisiken die Berücksichtigung von anderen Faktoren, „sozioökonomische Vor- und Nachteile sowie nachhaltige Landwirtschaft“ (dies wird im Rahmen dieses Berichts alles unter dem Begriff „sozioökonomische Auswirkungen“ subsumiert) zu prüfen. Sozioökonomische Aspekte spielen in der EU-Gentechnikdebatte eine wesentliche Rolle, allerdings gibt es kaum Erfahrung mit einer expliziten und systematischen Abschätzung und Bewertung. Vor diesem Hintergrund zielt der vorliegende Bericht darauf ab, die relevanten Themenfelder im Zusammenhang mit der Abschätzung sozioökonomischer Auswirkungen von GVOs zu identifizieren und zu charakterisieren und weiterführende Politik- und Forschungsempfehlungen auszuarbeiten. Der Forschungsprozess wurde entlang folgender Leitfragen strukturiert: (i) was sind soziökonomische Effekte von GVOs und was sind die relevanten Themenfelder und Kontroversen? (ii) Können sozioökonomische Auswirkungen differenziert werden, z.B. nach dem spezifischen GVO, der Anwendungs- oder Freisetzungsform? (iii) Wie könnten sozioökonomische Auswirkungen im Rahmen der GVO Marktzulassungsverfahren abgeschätzt und bewertet werden? Zusätzlich (iv) sollte die Studie Anhaltspunkte zu Kenntnisstand und Sichtweisen von österreichischen Stakeholdern auf dieses Thema ermitteln. Die Arbeit basiert im Wesentlichen auf Literatur- und Dokumentrecherchen sowie auf Telefoninterviews mit österreichischen Stakeholdern.

Sozioökonomische Aspekte von GVOs in der Literatur

Es gibt eine beachtliche Menge an wissenschaftlichen Aufsätzen und Berichten über antizipierte oder dokumentierte Auswirkungen von GV-Pflanzen jenseits von Gesundheits- und Umweltrisiken. Diese werden häufig als ökonomische, agronomische, agrar-umwelt-bezogene, soziale und sozioökonomische Dimensionen beschrieben. Der Begriff ‚sozioökonomisch’ scheint dabei sehr breit verwendet zu werden und bezieht sich ganz allgemein auf eine Kombination von sozialen und ökonomischen Auswirkungen. Ausgenommen ev. ethische Auswirkungen scheint unter diesem Begriff alles versammelt zu sein, was eben nicht die Box der Risikoabschätzung passt. Nachdem auch der Interpretationsspielraum für die „anderen legitimen Faktoren““ in der GVO-Bewertung und bei Marktentscheidungen nicht genau definiert ist, erscheint es für die vorliegende Studie zweckmäßig diese Vagheit beizubehalten.

Die meiste Literatur bezieht sich auf ökonomische Auswirkungen. Bei Entwicklungsländern fokussiert ein bei weitem überwiegender Teil auf Auswirkungen auf die Anwender und bei den Nutzpflanzen auf Baumwolle.

Viele Berichte können industrienahen oder Umwelt-NGO-nahen Kreisen zugeordnet werden. Umfassende Studien von öffentlichen Einrichtungen oder unabhängigen Organisationen sind selten zu finden. Zwei Beispiele werden kurz beschrieben: eine Studie, die vom britischen Cabinet Office im Rahmen der GM Nation durchgeführt wurde und ein sehr umfassendes Verfahren im Rahmen der United Nations: das International Assessment on Agricultural Knowledge, Science and Technology for Development (IAASTD). Letzteres zielte darauf ab, die Rolle von landwirtschaftlichen Wissen, Wissenschaft und Technologie für die Bekämpfung von Hunger und Armut, für die menschliche Gesundheit und umweltbezogene und soziale Nachhaltigkeit zu untersuchen.

Die britische Studie kam zum Schluss, dass bei der ersten Generation von GV-Pflanzen im britischen Kontext die entstehenden Kosten die Vorteile überwiegen würden, wobei erwartet wird, dass sich

diese Einschätzung bei den nachfolgenden Generationen von GV-Pflanzen zugunsten der GV-Pflanzen wendet. Die IAASTD Studie war in ihren Schlussfolgerungen zur Rolle der Biotechnologie in ihren Beiträgen zu den oben erwähnten Problemen noch zurückhaltender. Viele industrienahe AutorInnen zeigten in anderen Studien klare Vorteile, speziell für Anwender, während NGO-Studien teilweise zu gegenteiligen Schlussfolgerungen gelangten.

Sozioökonomische Aspekte in EU- und nationalen Gentechnikregelungen

Armenien, Bangladesch, Bhutan, China, Honduras, Indien, Kambodscha, Libanon, Mauritius, Nigeria, die Philippinen, Südkorea und Syrien berücksichtigen bei GVO Marktzulassungen nach eigenen Angaben auch sozioökonomische Aspekte. Umfang und konkrete Anforderungen scheinen dabei sehr unterschiedlich zu sein, ebenso die Form der Verankerung, sei es in nationalen Gesetzen, in Gesetzesentwürfen, in politischen Leitlinien oder in der regulatorischen Praxis. Australien, Brasilien, Japan, Kanada und Thailand geben an, sozioökonomische Aspekte nicht zu berücksichtigen. Unter den EU/EEA Mitgliedstaaten ist nur von Frankreich und Norwegen bekannt, dass sie sozioökonomische Aspekte explizit berücksichtigen. Das österreichische Gentechnikgesetzt enthält zwar eine Bestimmung zu sozioökonomischen Aspekten, bislang wurde diese jedoch noch nicht umgesetzt.

Norwegen hat sich bereits im Gentechnikgesetz von 1993 verpflichtet, ethische, soziale und Nachhaltigkeitsbezogene Auswirkungen von GVOs zu bewerten. Die Anforderungen dazu wurden in nachfolgenden Gesetzen und Stellungnahmen des Norwegian Biotechnology Advisory Boards (NBAB) konkretisiert. Die Nachhaltigkeitsbewertung bezieht sich dabei auf alle drei Säulen nachhaltiger Entwicklung und bezieht explizit die globale Dimension mit ein. Durch die Berücksichtigung von Auswirkungen auf die Biodiversität in Drittländern erweitert sich demnach auch die Umweltrisikoabschätzung. Die Erfordernis von Nutzen für die Allgemeinheit bezieht sich z.B. auf Nachfrage, Problemlösungskapazitäten und berücksichtigt auch alternative Produkte. Die ethische Bewertung berücksichtigt u.a. die moralischen Standpunkte der Bevölkerung, Auswirkungen auf tradierte Kultur und schwächere soziale Gruppen sowie auf die Integrität von Arten. Die sozioökonomischen Bewertungen werden gegen Gesundheits- und Umweltrisiken abgewogen - unter Berücksichtigung von Unsicherheiten und allfälliger Irreversibilitäten. Die ablehnenden Stellungnahmen der NBAB identifizierten zumeist einen Mangel an Nutzen für die Allgemeinheit und sahen auch keinen positiven Beitrag i.S. der Nachhaltigkeit. Allerdings scheinen die Gesundheits- und Umweltrisiken, nach wie vor die bedeutsamsten Gründe für Ablehnungen zu sein. Das Fehlen von relevanten sozioökonomischen Daten in den Dossiers wird aus norwegischer Perspektive als zentrales Problem gesehen. Weder können Antragsteller zum Vorlegen solcher Informationen gezwungen werden, noch ist es möglich, sozioökonomische Aspekte im Rahmen der EU-Risikoabschätzung zu kommentieren, da EFSA diese als außerhalb ihres gesetzlichen Zuständigkeitsbereiches ansieht und nicht berücksichtigt.

In Frankreich wurde das High Council on Biotechnology (HBC) in Folge einer Änderung der Gentechnikpolitik etabliert. Eines der beiden HCB Komitees (CEES) berät die Regierung zu ökonomischen, ethischen und sozialen Aspekten von GMOs u.a. im Rahmen von Zulassungsverfahren nach EU-Richtlinie 2001/18/EG und EU-Verordnung 1829/2003. Allerdings gibt es diesbezüglich erst eine kurze Zeitspanne mit Praxiserfahrungen. Aus der Perspektive von CEES bestehen die Hauptprobleme im Fehlen von entsprechenden Informationen in den Dossiers, dem Fehlen von Leitlinien für Kriterien, Methoden, Daten und Bewertungen. CEES bezieht in seine Beratungen die Ergebnisse der wissenschaftlichen Abschätzung von gesundheitlichen und Umweltrisiken mit ein und nimmt bereits teilweise Abwägungen vor. Diese Praxis hat das Potential die politische Verantwortung für Entscheidungsprozesse teilweise zu verschieben und bedarf daher einer eingehenden Untersuchung im Kontext der Governance bei Lebensmittelsicherheit.

Das österreichische Gentechnikgesetz beinhaltet eine Bestimmung, die es erlaubt „sozial unverträgliche“ Produkte zu verbieten. Hierbei wird Bezug auf soziale, ökonomische und ethische Aspekte genommen. Diese Bestimmung ist im Bezug auf eventuelle Widersprüche mit EU-Recht diskutiert, inhaltlich aber nicht präzisiert worden. Bislang wurde noch in keinem Fall explizit Bezug auf diese Bestimmung genommen. Aus diesen Gründen könnte diese Bestimmung als totes Recht betrachtet werden. Falls infolge einer Änderung der EU-Gentechnikpolitik die Bewertung von soziökonomischen Auswirkungen möglich oder notwendig würde, könnte diese Bestimmung allerdings eine Rolle spielen. Dies würde jedoch eine genauere rechtliche Analyse erfordern.

Völkerrechtliche Einschränkungen

Paragraph 26 des Cartagena Protokolls zur Biologischen Sicherheit gestattet den Signatarstaaten sozioökonomische Aspekte im Rahmen von Importentscheidungen bei GVOs zu berücksichtigen. Der Wortlaut der Bestimmung hebt dabei die Rolle von Biodiversität für indigene oder lokale Gemeinschaften hervor. Der Anwendungsbereich dieser Bestimmung wird nun unterschiedlich interpretiert: die USA und die Industrie bevorzugen eine enger gefasste Interpretation, während andere auch sozioökonomische Faktoren, die weit über Rolle von Biodiversität für indigene oder lokale Gemeinschaften hinausgehen als mit aufgehoben sehen. Der Text betont auch, dass bei der Umsetzung dieser Bestimmung andere völkerrechtliche Vereinbarungen eingehalten werden müssen, was insbesondere als auf die WTO-Vereinbarungen zutreffend interpretiert werden kann. Länder wie z.B. die USA, die das Protokoll nicht unterzeichnet/ratifiziert haben, sind nicht an dessen Bestimmungen gebunden, insofern bleibt die Rolle des Paragraph 26 als möglicher Referenzpunkt für EU oder nationale Politik im Unklaren.

Die WTO-Regelungen schließen die Berücksichtigung von sozioökonomischen Aspekten nicht *a priori* aus, sofern diese nachvollziehbar, transparent und nicht-diskriminierend sind. Bei der Entwicklung einer Argumentationslinie ist es erforderlich, entsprechend der Rahmen der relevanten WTO Abkommen, sozioökonomische Aspekte entweder als Risiko-, Gesundheits- oder Handelsmaßnahme zu definieren. GVOs wurden im Zuge des WTO-Konflikts zwischen der USA und den EU bislang fast ausschließlich im Kontext der SPS-Vereinbarung berücksichtigt, was die Rolle der anderen relevanten Abkommen in den Hintergrund gedrängt hat. Allerdings sind es gerade das TBT- und das GATT-Abkommen, die beide für die Berücksichtigung von sozioökonomischen Aspekten mehr Spielraum bieten. Der WTO-Entscheid zum GVO-Konflikt beinhaltete u.a., dass Maßnahmen auf mehreren Abkommen gleichzeitig basieren können. Insofern scheint es durchaus möglich, sozioökonomische Aspekte in einer Form zu berücksichtigen, die den wichtigsten WTO-rechtlichen Erfordernissen entsprechen: ein legitimes Ziel auf der Basis von wissenschaftlichen oder anderen Fakten zu verfolgen; nicht mehr Handelsbeschränkungen zu etablieren, als unbedingt notwendig; und nicht-diskriminierend zu sein.

Der FAO Draft International Code of Conduct on Plant Biotechnology der FAO Commission on Plant Genetic Resources aus dem Jahr 1993 enthält ebenfalls Bestimmungen zur Berücksichtigung sozioökonomischer Faktoren. Falls dieser fertig gestellt und angenommen wird, würde dies dazu beitragen, GVO-Bewertungen und Entscheidungsfindungen über den Rahmen von Gesundheits- u. Umweltrisiken zu verbreitern.

EU-regulatorische und institutionelle Probleme

Ein wichtiger Aspekt betrifft die institutionelle Verortung einer sozioökonomischen Bewertung von GVOs auf der EU-Ebene. Die Berücksichtigung von sozioökonomischen Faktoren ist bislang dem Risikomanagement zugerechnet worden, d.h. der Europäischen Kommission und den Mitgliedstaaten. Falls sozioökonomische Aspekte häufig/routinemäßig berücksichtigt würden, wäre die Einrichtung einer eigenen spezialisierten organisatorischen Einheit zweckmäßig. Aus der Governance-Perspektive kann die Aufbereitung und Evaluierung von sozioökonomischen Informationen/Bewertungen analog zur Evaluierung der Risikoabschätzung gesehen werden, wobei sich erstere von letzterer lediglich als eine andere Art von wissenschaftlicher Beratung des Risikomanagements unterscheidet. Die Kernkompetenzen des Risikomanagements, z.B. die Abwägung von Vor- und Nachteilen und zwischen Entscheidungsoptionen sowie Kompensationsmaßnahmen blieben davon unberührt.

Entsprechend des Prinzips, das auch der Einrichtung der EFSA zugrunde liegt, nämlich wissenschaftliche Abschätzung und Bewertung von politischer (policy) Entscheidungsfindung zu trennen, wäre auch in diesem Fall eine institutionelle oder funktionelle Trennung zwischen einer solchen Einheit und der Europäischen Kommission angezeigt. Es ist allerdings nicht offensichtlich, welche Institution eine solche Einheit aufnehmen könnte. Es wurde bereits vorgeschlagen, dass das Mandat der EFSA neben Risiken auch gesundheitliche und umweltbezogene Vorteile mit einschließen sollte. Auch die Einrichtung einer eigenen sozialwissenschaftlichen Abteilung zur Bewertung von gesellschaftlichen Bedenken wurde angeregt. Letzterer Vorschlag wird jedoch von der Industrie und von anderen Stakeholdern abgelehnt. Analysten sind sich zudem nicht einig, ob zu einer solchen Ausweitung, eine Änderung der Allgemeinen Lebensmittelrechts der EU erforderlich wäre. Falls eine Änderung des Allgemeinen Lebensmittelrechts tatsächlich notwendig und denkbar ist, könnte man das Mandat von EFSA analog zu REACH ändern, das die Einrichtung von zwei Komitees im Rahmen der ECHA vorsieht: ein wissenschaftliches und eine sozioökonomisches Komitee.

Nach einem Alternativvorschlag von Seiten der Industrie könnte auch die European Group on Ethics durch ein analoges Komitee zu sozioökonomischen Aspekten ergänzt werden.

Zu den Aufgaben einer solchen Einrichtung würde jedenfalls gehören, sozioökonomische Informationen/Bewertungen in den Dossiers zu evaluieren. Infolge der Kontextabhängigkeit von sozioökonomischen Informationen und Bewertungen würde den Mitgliedstaaten eine wichtige Rolle zukommen, da sie Informationen und Bewertungen für ihre(n) spezifische(n) nationalen und regionalen Kontexte zur Verfügung stellen müssten. Von daher müsste eine derartige Einrichtung wohl auch die Kommunikation mit den Mitgliedstaaten koordinieren. Ein solches Aufgabenportfolio würde allerdings ein Komitee aus unabhängigen Experten klar überfordern.

Anforderungen an und Probleme für ein geeignetes Bewertungssystem

Die Analysen in diesem Kapitel beruhen auf Ähnlichkeiten zwischen der Abschätzung von Gesundheits- und Umweltrisiken und der Abschätzung sozioökonomischer Auswirkungen (im weiteren Verlauf als SOEIA bezeichnet): Erstens stellt SOEIA eine Form von wissenschaftlicher Politikberatung dar (hauptsächlich basierend auf sozialwissenschaftlicher Expertise). Zweitens kann man als wissenschaftliche Politikberatung davon ausgehen, dass diese den EU-Leitlinien für ‘Good Governance’ und wissenschaftliche Politikberatung entsprechen sollte. Drittens könnte daher ein Rahmen für SOEIA in Analogie zur Risikoabschätzung konzipiert werden. Viertens resultiert das Erfordernis für ein gut strukturiertes Bewertungssystem auch aus den Ähnlichkeiten der Konflikte in beiden Feldern. In beiden Feldern gibt es widersprüchliche Resultate und Schlussfolgerungen, die auch in heftige Kontroversen zwischen Stakeholdergruppen und in der wissenschaftlichen Literatur

münden. Infolge dieser Ähnlichkeiten kann man in Analogie zur Risikoabschätzung auch die Konzepte von 'inclusive' und 'integrative risk governance' heranziehen.

Um ein Abschätzungsverfahren zu etablieren, muss geklärt werden, auf welchen normativen Referenzrahmen man sich bezieht und welche Konzepte, Kriterien, Auswirkungsdimensionen, 'Endpunkte' und Methoden herangezogen werden sollen. An zwei Beispielen für normative Bezugspunkte, konventionelle Landwirtschaft und nachhaltige Entwicklung, wird gezeigt, dass diese in verschiedenen Ländern unterschiedlich interpretiert werden – je nach landwirtschaftlichem und politischem Kontext. Es ist davon auszugehen, dass diese Unterschiede, diese Kontextabhängigkeiten, sich auch im Umfang, bei Auswirkungsdimensionen und Kriterien niederschlagen würden. Im Zusammenhang mit der Berücksichtigung möglicher Auswirkungen von GVO auf Drittländer würde der Bewertungsumfang auch durch den völkerrechtlichen Rahmen beeinflusst.

Vorschläge für Kriterien, Auswirkungsdimensionen und Endpunkte sind bereits vorgelegt worden, allerdings umfassen nur sehr wenige dieser Arbeiten breitere Bereiche sozioökonomischer Auswirkungen, z.B. die Berichte der Netherlands Commission on Genetic Modification (COGEM) und die Empfehlungen des NBAB. Es erschließt sich nicht und konnte im begrenzten Rahmen der vorliegenden Studie auch nicht geprüft werden, in welchem Verhältnis diese Vorschläge mit den empirischen Studien zu tatsächlich beschriebenen sozioökonomischen Auswirkungen stehen – also welche Aspekte auf Annahmen oder normativen Vorgaben alleine beruhen und welche Auswirkungsdimensionen bereits empirisch belegt sind. Vorhandene Überblicksarbeiten erscheinen in ihren Beurteilungen teilweise voreingenommen. Die Ausarbeitung und internationale Abstimmung von Auswirkungsdimensionen, Endpunkten, Kriterien und Methoden für SOEIA wird zusätzlich dadurch kompliziert, dass Wissenschaftler sehr unterschiedliche Ansichten haben, z.B. was unter sozialen Auswirkungen zu verstehen ist und welche Variablen wichtig für die Abschätzung und Bewertung sind.

Die Kontextabhängigkeit von Auswirkungsdimensionen wird am Beispiel Österreich sichtbar. Österreichische Stakeholder weisen in Interviews auf den spezifischen agrar-ökonomischen und soziokulturellen Kontext hin: kleinräumige Landwirtschaft, hoher Anteil von Bergbauern bzw. Ungunstlagen, sehr hoher Anteil von Biolandbau, starker Widerstand gegen GV Pflanzen und -Lebens-/Futtermittel, Nachhaltigkeitsziele der österreichischen Agrarpolitik.

Obwohl man beim Aufbau eines Rahmens für SOEIA Neuland betritt, lassen sich Anregungen bei ähnlichen Konzepten holen, z.B. von Konzepten zu 'social impact analysis' und 'environmental impact assessment'.

Da der Klärung und Abstimmung des normativen Referenzrahmens sowie von Konzepten, Kriterien, Auswirkungsdimensionen, ‚Endpunkten' und Methoden eine hohe Bedeutung zukommt, wird vorgeschlagen, eine eigene Stufe im Abschätzungsprozess für diese Rahmensetzungen ('framing') vorzusehen. Diese müsste in diskursiver Form zwischen wissenschaftlichen BeraterInnen und EntscheiderInnen (hier: Europäische Kommission, Mitgliedstaaten) erfolgen. Die Notwendigkeit und Bedeutung von Framing-Stufen ist bereits in der Risikoabschätzung anerkannt und sowohl in der wissenschaftlichen Literatur als auch in Policy-Dokumenten gut dokumentiert, z.B. kürzlich durch die Internationale Codex Alimentarius Commission. Eine derartige Stufe könnte in Analogie zum Codex Begriff 'risk assessment policy' als 'impact assessment policy' eingeführt werden. Abgestimmte verfahrensbezogene oder materielle Aspekte der 'impact assessment policy' sollten in Leitlinien aufgenommen werden werden. Merkmal/Pflanzenart/Anwendungsspezifische Leitlinien könnten in Analogie zu den pflanzenspezifischen OECD-Consensus oder -Biology-Dokumenten erstellt werden. Die Framing-Stufe könnte auch eine zusätzliche Clearinghouse-Funktion haben, durch die Fragen/Teilbereiche zur Evaluierung entweder der naturwissenschaftlichen oder der

sozioökonomischen Bewertung zugeteilt werden. Manche Themen könnten auch von beiden Seiten beleuchtet werden. Im Laufe der Zeit wurde beispielsweise die Abschätzung von GVO-Umweltrisiken auf Bereiche wie Resistenzmanagement ausgeweitet, welche speziell bedeutsam für agronomische Betrachtungen sind und daher auch dem SOEIA zugehen sollten.

Auf Öffentlichkeitsbeteiligung sollte ebenfalls besonderer Wert gelegt werden, speziell in der Framing- und Evaluierungsstufe (Interpretation der SOEIA durch Entscheidungsträger), wobei die Form der Beteiligung dem Thema entsprechend unterschiedlich gehandhabt werden könnte.

Sozioökonomische Daten und Bewertungen haben - verglichen mit den Informationen für die wissenschaftliche Risikoabschätzung - zudem besondere Eigenschaften. Sozioökonomische Informationen sind nicht event-spezifisch, sondern eher Pflanzenart/Merkmals/Anwendungs-spezifisch. Aus diesen Gründen müssen derartige Daten nicht für jeden Event produziert werden. Ergänzende Eventspezifische Informationen sind nur erforderlich, wenn wichtige Pflanzenart/Merkmals/Anwendungs-spezifische Eigenschaften verändert wurden. Anderseits können sozioökonomische Daten spezifisch für einen bestimmten geographischen, klimatischen, agronomischen und soziokulturellen Kontext sein, der wiederum nicht direkt mit Daten aus einem anderen Kontext verglichen werden kann. Letztere Eigenschaft von sozioökonomischen Informationen kompliziert die Ausarbeitung von Merkmals/Anwendungsspezifischen Leitlinien und schränkt die Aussagekraft von Studien aus anderen sozioökonomischen Kontexten ein.

Andere relevante Aspekte

In diesem Kapitel werden weitere Aspekte diskutiert, die für die Politikentwicklung potentiell relevant sind.

In einem ersten Schritt wäre es wichtig, überhaupt die Voraussetzungen für eine breitere Diskussion auf EU-Ebene herzustellen. Ein Scoping-Dokument sollte dafür erstellt werden, das die Eckpfeiler für eine sozioökonomische Bewertung von GVOs skizziert. Dieses Dokument sollte eine Reihe von Punkten klären: u.a. den Zusammenhang zur Paralleldiskussion über mehr Subsidiaritätsrechte von Mitgliedsstaaten beim Anbau von GVO (opt-out Diskussion); ob sozioökonomische Aspekte nur bei Anbau und nur bezogen auf das Gebiet der EU oder ausgedehnt auf alle GVO und Drittländer relevant sein sollen; ob eine Routinebewertung für jeden Antrag oder – falls nur in bestimmten Fällen – in welchen Fällen eine solche Bewertung erforderlich wäre; ob es möglich wäre, einen Antrag alleine aus sozioökonomischen Gründen zurückzuweisen; wem die Verantwortung zufällt, sozioökonomische Informationen zur Verfügung zu stellen.

Eine andere Frage ist, wie die Ausweitung der Bewertung von GVOs im Rahmen der Marktzulassung von Stakeholderseite aufgenommen würde. Es gibt Hinweise, dass eine Mehrheit der Stakeholder dies positiv aufnehmen könnte, wobei es eine klare Ausnahme gibt: die Biotechnologieindustrie. Fast alle interviewten österreichischen Stakeholder äußerten sich ebenfalls positiv. Die Interviewpartner gaben auch mehrheitlich an, sich aufgrund der Spezifika des österreichischen Kontextes bereits mit dem Thema beschäftigt zu haben: Ablehnung der KonsumentInnen sogar von geringen Anteilen von GVOs in Lebensmitteln und den niedrigen Schwellenwerten für GVO bei Saatgut, Bio- und Gentechnik-frei Produkte.

Weitere Aspekte, die eine Rolle spielen könnten:

- Veränderte Verantwortungszuschreibungen: die Divergenz zwischen innenpolitischer und außenpolitischer Rationalität mancher Mitgliedstaaten (‘blame avoidance’ durch Ablehnung oder Enthaltung im EU-Rat bei berechenbarem Scheitern und positiver default-Entscheidung der Europäischen Kommission) wäre viel schwerer durchhaltbar.

- Der administrative Aufwand für Mitgliedstaaten mit strikten Koexistenzregelungen würde deutlich zunehmen: Im Fall des Anbaus von GVOs in diesen Ländern wäre dies durch Implementierung und Kontrolle der Koexistenzregelungen gegeben. Im Fall von opt-out Verbotsmöglichkeiten, könnte es sein, dass zur Begründung solcher Maßnahmen umfassende Daten und Begründungen für beispielsweise den jeweiligen spezifischen geographischen und soziokulturellen Kontext vorgelegt werden müssten.

- Die Möglichkeit eine Neuauflage der Diskussion über Angemessenheit der spezifischen Regelung von GVOs, falls GV-Pflanzen auf Basis sozioökonomischer Bedenken zurückgewiesen würden, obwohl konventionelle Pflanzen mit einem ähnlichen sozioökonomischen ‚Profil' überhaupt keiner Bewertung unterzogen und weiter angebaut würden.

- Antragsteller könnten den Aufwand zur Bereitstellung von kontextspezifischen sozioökonomischen Informationen für weniger bedeutsame Märkte scheuen – was ev. auch das bisherige Fehlen von derartigen Informationen in den Dossiers für die norwegischen Behörden erklärt.

Spezifika des österreichischen Kontextes

Österreichs landwirtschaftliche Struktur hat einige Besonderheiten verglichen mit anderen EU-Mitgliedsländern: einen der höchsten Anteile an Bergbauern (mehr als 70%) – vor allem Kleinbauern – und mit Abstand den höchsten Anteil an biologisch wirtschaftenden Betrieben (15,2% der Betriebe, 18,5% der landwirtschaftlichen Fläche). Seit den späten 1980er Jahren hat sich die Landwirtschaftspolitik zunehmend auf nachhaltige und multifunktionelle Landwirtschaft (Landschaftspflege, Tourismus, Biodiversität, ländliche Entwicklung, soziokulturelle Aspekte etc.) hin orientiert und Ökologisierungsmaßnahmen, Biolandbau und Bioproduktion, regionale Lebensmittelversorgungen sowie lokale und regionale Landwirtschaft-Gewerbe-Kooperationen etc. stark gefördert. Dies spiegelt sich auch im österreichischen nationalen Nachhaltigkeitsplan wider. Österreich hat zudem den höchsten Anteil aller EU-Staaten an EU-Agrarumweltprogrammen (ca. 17%). Eine Fortführung dieses Weges ist vorgesehen – ebenso ein weiter Ausbau der Biolandwirtschaft, mit der Zielperspektive, bis 2010 20% der gesamten landwirtschaftlichen Nutzfläche biologisch zu bewirtschaften.

Bei der derzeitigen Generation von GV-Pflanzen werden keine relevanten Vorteile gesehen, was beispielsweise mit dem geringen Befallsdruck durch Schädlinge wie z.B. dem Maiszünsler und die Verfügbarkeit alternativer Maßnahmen in Zusammenhang steht. Die mit konventionellen Sorten in Österreich erreichten akkumulierten Ertragssteigerungen liegen in einem ähnlichen Bereich wie in den USA bzw. übertreffen diese sogar.

Eine Koexistenz von GV- und konventionellen Sorten wird aus zwei Hauptgründen problematisch gesehen: Erstens wegen der kleinstrukturierten Landwirtschaft mit Feldstückgrößen von ca. 1,7 Hektar. Die kleinbäuerliche Struktur und extensive Bewirtschaftung wird dabei als wichtig für Erhalt und Pflege von Kulturlandschaften, für Tourismus und für die ländliche Entwicklung im Allgemeinen angesehen. Zweitens haben konventionelles Saatgut, Bioprodukte und gentechnikfreie Lebensmittelprodukte mit 0,1% einen sehr niedrigen Schwellenwert für GVO-Anteile. Aber auch bei konventionellen Lebensmittelprodukten versuchen Lebensmittelhersteller und -handel infolge der weitgehenden Ablehnung durch KonsumentInnen, GV-Inhaltsstoffe möglichst weitgehend zu vermeiden. Österreich gehört zu den EU-Ländern mit sehr niedriger bzw. geringster Akzeptanz von GV-Pflanzen und -Lebensmittel.

Daraus resultieren – im Vergleich zu anderen geografischen Kontexten – sehr hohe Anforderungen an Koexistenzmaßnahmen, die sich auch auf die Agrarstruktur auswirken würden. Dies lässt sich am Beispiel der Isolationsabstände illustrieren. Für Raps und Mais wurde simuliert, dass – unter typisch-österreichischen Bedingen bei Einhaltung entsprechender Isolationsabstände zwischen GV- und konventionellen bzw. biologisch angebauten Pflanzen – mit Verlusten von 36-100% an konventionellen/biologischen Anbauflächen zu rechnen ist. Bei Raps wird Koexistenz überhaupt als unmöglich angesehen.

Die erfolgreiche Entwicklung der biologische Landwirtschaft hat zu einer generellen Ökologisierung der konventionellen Landwirtschaft in Österreich geführt, die sich auch in der Regionalentwicklung niederschlägt. Biolandwirte bilden vielfach die Kerngruppen in Regionalentwicklungsinitiativen, die typischerweise mehrere Gemeinden aber auch größere Regionen umfassen können. Solche Initiativen sind häufig in benachteiligten Regionen entstanden und haben sich auf regionale Qualitätsprodukte aus nachhaltiger Landwirtschaft und Lebensmittelproduktion konzentriert. Dies geht zumeist mit einer regionalen Vernetzungen entlang der Lebensmittelkette aber auch mit anderen Sektoren (Gastronomie, Tourismus, Energieproduktion) einher. Gentechnikfreiheit wird häufig als Schlüsselkriterium etabliert, auch dann, wenn biologische Landwirtschaft und Bioprodukte keine dominante Rolle in der Initiative spielen. Der Anbau von GV-Pflanzen im Bereich solcher Regionen wird von den Akteuren als Bedrohung der ökonomischen Basis und soziokulturellen Identität angesehen.

Diese Rahmenbedingungen führten schließlich zur Etablierung von strengen Koexistenzregeln in allen Bundesländern sowie zu zahlreichen Initiativen für gentechnikfreie Regionen und eine gentechnikfreie Lebensmittelversorgung.

Österreichische Stakeholder betonen diese agro-ökonomischen und soziokulturellen Besonderheiten und befürchten schwerwiegende Kurz- und Langzeitschäden für die konventionelle und die biologische Landwirtschaft, die auch die gesamte Lebensmittelkette, inkl. KonsumentInnen und Saatgutproduzenten mit betreffen würde. Dies würde die Kosten von Landwirten, Lebensmittelverarbeitern und dem Lebensmittelhandel steigern sowie deren Gewinne verringern und könnte sich nachteilig auf Marktanteile, Marktposition und Wettbewerbsfähigkeit auswirken. Zudem stünde dies in Widerspruch mit den Zielen österreichischer Landwirtschaftspolitik.

Empfehlungen

Auf der Basis der Analysen und Schlussfolgerungen dieser Studie werden folgende Empfehlungen für die Politikentwicklung und weiterführende Forschungen gegeben:

Allgemeine Empfehlungen

- Klärung und Übereinkunft auf EU-Ebene
    - zu den Eckpfeilern für eine sozioökonomische Bewertung von GVO, als Referenz und Rahmen für eine breite Diskussion;
    - über die rechtlichen Möglichkeiten, das Mandat der EFSA auf sozioökonomische Auswirkungen auszudehnen;
    - zu einem Basisset sozioökonomischer Indikatoren

Weiterführende Forschungen sind erforderlich zu

- Fallstudien zu WTO-Konflikten im Zusammenhang mit sozioökonomischen Faktoren, um die rechtlichen Spielräume besser ausleuchten zu können;

- möglichen Bewertungskriterien und -methoden;

- wie man die verschiedenen Konzepte von 'impact analysis' und 'integrated risk governance' für die Konzeption einer SOEIA fruchtbar machen kann;

- wie ein zentralisiertes Bewertungsverfahren im EU-Mehrebenengefüge aussehen könnte, das es ermöglicht, kontextualisierte sozioökonomische Informationen und Bewertungen von Mitgliedstaaten zu verarbeiten;

- Wahrnehmungen und Sichtweisen von Stakeholdergruppen und Öffentlichkeit.

Empfehlungen für die Politikentwicklung in Österreich

Österreich hat über zwei Jahrzehnte hinweg wesentlich zur Entwicklung und Verbesserung der Gentechnikregulierung in der EU beigetragen. Sozioökonomische Erwägungen waren und sind für Österreichs Gentechnikpolitik bedeutsam. Aus diesen beiden Gründen erscheint es sowohl angezeigt als auch im Einklang mit den Politikzielen, auch beim Aufbau einer sozioökonomischen Bewertung eine maßgebliche Rolle zu spielen.

Unter der Voraussetzung, dass die Bewertung von sozioökonomischen Auswirkungen für die weiteren Entwicklungs- und Veränderungsschritte auf EU-Ebene eine wichtige Rolle spielen werde, wird empfohlen, dass Österreich

- Einen partizipativen Politikentwicklungsprozess zum Thema startet;

- Auswirkungsdimensionen und mögliche Auswirkungen identifiziert und beforscht, die *spezielle und spezifische Relevanz für Österreich* haben;

- transdisziplinäre Forschungen zu normativen Referenzrahmen und Kriterien sowie best-practice Modellen, Zugängen, und Methoden, die *insbesondere relevant für Österreich* sind durchführt.

Selbst für den Fall, dass sozioökonomischen Bewertungen doch keine Schlüsselrolle bei den GVO-Zulassungen zukommen würde, werden sie dennoch zunehmend wichtig durch die zahlreichen technologischen Innovationen, die sich in der Pipeline befinden, z. B. GV-Pflanzen mit veränderter Inhaltsstoffzusammensetzung, GV-Pflanzen für industrielle Zwecke und Energieproduktion oder Pflanzen, die mit neuen Züchtungsmethoden hergestellt wurden. Es ist daher in jedem Fall angezeigt, die sozioökonomischen Auswirkungen von GVOs und ihre Bewertung weiter zu explorieren.

This Report

Context

This report is motivated by developments at the EU level which raised the possibility to broaden the assessment of genetically modified organisms (GMOs) to also include other factors beyond health and environmental risks. On 4 December 2008, the EU Council of Environment Ministers met to discuss how to deal with the deadlock in GMO authorisation in the EU. Member States had (and still have) different views on GMOs, with some supporting the decision making process considered as a sound science based system and others favouring significant improvements of the current system while a third group is strongly favouring GM-free policies (Strauss 2009). The Council also discussed a French initiative to consider socio-economic benefits and risks in GMO authorisation procedures (CEU 2008) and concluded that

"… under Regulation 1829/2003 it is possible, under certain conditions and as part of a case by case examination, for legitimate factors specific to the GMO assessed to be taken into account in the risk management process which follows the risk assessment."

"… under Directive 2001/18/EC, the [European] Commission is to submit a specific report on the implementation of the Directive, including an assessment, inter alia, of socio-economic implications of deliberate releases and placing on the market of GMO." (ibid: 3).

The Council requested that information on socio-economic implications of the placing on the market of GMO's including socio-economic benefits and risks and agronomic sustainability should be collected, and asked the European Commission (EC) to prepare a report based on information provided by the Member States by June 2010 for due consideration and further discussions by the European Parliament and by the Council.[1] In mid 2009, the EC circulated a questionnaire to Member States Competent Authorities (CAs) aiming to collect information relevant to the topic by Jan 2010. These responses are presently being processed by the EC. Visible activities on the level of the Member States have so far been limited. Germany and The Netherlands held stakeholder consultations and published reports.

The possibility of considering socio-economic factors in GMO authorisation is new and has not been seriously considered before in the scientific literature or policy documents though there have been attempts to broaden the environmental risk assessment to also include some aspects which are considered by some as socio-economic (e.g. developments of Bt resistant insects or herbicide tolerant weeds). Norway is the only relevant exception – with a requirement for a socio-economic assessment explicitly included in their GMO legislation. Given the novelty of the problem there is no clarity and awareness about the issues and dimensions of the topic. For this reason, the Austrian Federal Ministry of Health and the Federal Ministry of Agriculture, Forestry, Environment, and Water Management jointly commissioned this report to describe and explore the issues linked to a possible consideration of socio-economic factors in order to inform policy development.

[1] The Council conclusions also covered other issues relevant to GMOs: strengthening of environmental assessment and monitoring arrangements, better use of expertise, European labelling thresholds for seeds, and sensitive and/or protected areas (CEU 2008).

Approach, scope, and limitations

Research work was structured along the following questions: (i) what are socio-economic effects of GMOs and what are the relevant issues and controversies? (ii) Whether and how can socio-economic effects be differentiated or clustered e.g. according to the specific GMO, the intended application or the type of release? (iii) How could socio-economic effects be assessed in the course of GMO market authorisations? Furthermore, the study should provide exploratory information on the awareness and views of Austrian stakeholders on this topic.

The consideration of socio-economic impacts in GMO authorisation procedures touches new ground. While a number of studies exist that describe particular types of potential agro-economic benefits and disadvantages of GM crops, studies aiming to reveal social impacts or taking a broader view on socio-economic impacts are scarce. Furthermore, the possible scope of socio-economic consideration is very broad as to the type of GMOs considered (crops, animals, microorganisms, to the type of application (e.g. cultivation, food processing, feed processing, industrial use), and as to the level of impact analysis (e.g. on a particular Member State, the EU as a whole, non-EU countries) and the type of impacts being considered.

The objective of this study, therefore, was to identify and explore the issues relevant to the topic and provide recommendations for policy development and further research. The focus is set on governance issues linked to the topic, in particular procedural and regulatory issues. The study, thereby, employs and extends on concepts developed and discussed in the academic literature on risk governance and draws on insights from the difficult debate on GMO risk assessment and management. The scope is limited to GM crops and cultivation, food and feed use and possible impacts and from a Member State perspective. A number of the observations made and issues raised, however, are of a more general nature and will be relevant to non-food/non-feed crops and GM animals as well. The study was designed to provide preliminary answers to the questions specified above to the extent of what could be achieved within the set timeframe and with the resources available. In particular, it does not attempt to systematically identify and investigate possible specific socio-economic impacts of GMO cultivation in Austria.

The study draws on a review of published literature and policy documents. A series of ten phone interviews was conducted with stakeholders in Austria in order to explore awareness and potentially specific views on the topic. A clear limitation here is that most stakeholders have not yet developed more elaborate views and positions. Given the early stage of the process the majority of stakeholders take a wait and see approach. The author of this study also participated in two conferences relevant to the topic: ‘Regional Aspects in Precautionary GMO Decision Making’, which was hosted by the Austrian Federal Ministry of Health, the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management, the Environment Agency Austria, and the Austrian Agency for Health and Food Safety and took place from 26 - 27 March 2009 in Vienna, Austria and the ‘International conference on GMOs in European Agriculture and Food Production’, which was organised by the Dutch Ministry of Housing, Spatial Planning and the Environment and took place from 25-26 November 2009 in The Hague, The Netherlands.

Socioeconomic considerations in the literature

This chapter briefly describes some general characteristics of the literature on socioeconomic impacts of GMOs. It does not aim at providing a review or inventory of anticipated or observed socioeconomic effects.

There is a substantial body of literature available on GMO impacts other than health and environmental. These impacts are referred to as economic, agronomic, agro-environmental, societal, social, socioeconomic etc. The term 'socioeconomic' seems to be used very broadly as involving a combination of social and economic factors. With the possible exception of ethical issues the term appears to cover almost everything which does not fit into the health and environmental risk box. As the scope of "other factors" in GMO authorisation is not yet clear it is considered pertinent to keep the vagueness of the term in this report.

Socioeconomic impacts of GM crops are mainly described in reports and peer-reviewed papers. The majority of the literature investigates economic effects. Several authors have compiled reviews and conducted assessments mainly based on literature, public databases and company data.

Industry or somehow affiliated to industry: extensive annual reviews are provided by PG Economics (Brookes and Barfoot 2010a, b) focusing on quantifiable economic farm level impacts of GM crops, environmental impacts from changes in herbicide or pesticide usage with herbicide tolerant or insect resistant crops resp. (including carbon sequestration). Brookes et al. (2010) reviewed effects on production and prices. EuropaBio has recently provided a review paper on socioeconomic effects with a focus similar to the PG economics studies (EuropaBio 2009). Www.croplife.org provides a comprehensive collection of material from many sources. The Council for Agricultural Science and Technology has analysed the sustainability of US soybean production comparing organic, conventional and GM soybeans (Heatherly et al. 2009).

Environmental NGOs and Small/Organic Farmer's Associations: comprehensive reports are also compiled by environmental NGOs and organic associations (FOE 2006, 2008). Some are focussing on selected aspects only, e.g. yield Gurian-Sherman 2009), effects on organic and conventional farmers and food producers (Greenpeace 2009, BÖLW 2009, Benbrook 2009b), and effects on pesticide use (Benbrooks 2009a).

Industry and NGO studies frequently differ in their results and conclusions which occasionally triggered controversies about appropriate methods, data, and interpretations (see also section "Arguments supporting the underlying assumptions").

Comprehensive studies from public authorities or independent organisations are scarce. Two examples are given in the following.

An extensive study was compiled by the UK Cabinet Office in the course of the GM Nation exercise[2] (Cabinet Office 2003a, b). This study provides an analysis of overall costs and benefits (beyond what is being expressed in monetary terms) of commercial cultivation of GM crops in the UK including the option of not-cultivating. The study focuses on crops available at that time and over a time period of 10-15 years. Research applied a participative design and used scenarios to develop possible futures.

[2] The GM nation was an extensive public dialog on GM crops sponsored by the UK government and conducted in 2002/2003 which included public consultations, a scientific review, and a study of the costs and benefits of GM crops.

The overall conclusion of this study is that - in the short-term - the possible economic benefits to farmers of first generation GM crops might be outweighed by additional costs for the seeds, coexistence measures and a lack of consumer demand. Given the differences in the regulatory environment and in consumer perception, the study highlights that care should be taken when considering impact studies from countries with large scale cultivation of GM crops. Profitability of UK farmers is perceived to depend more on the Common Agricultural Policy given that EU farmers do not operate in a fully competitive market. The balance could, however, vary considerable depending on the particular crop, farming practices and type of farm. Similarly, the studies identified scope for negative and positive environmental impacts from changes to farming. The study also concluded that benefits could be much higher with future generations of GM crops more likely to be accepted by consumers.

Another large-scale assessment was conducted in the context of the United Nations: the International Assessment on Agricultural Knowledge, Science and Technology for Development (IAASTD) is composed of one Global Assessment and five Sub-global Assessments, which use the same basic framework as the Global Assessment, i.e. the impacts of agricultural knowledge, science and technology (AKST) on hunger, poverty, nutrition, human health, and environmental and social sustainability in relation to both the past and the future (IASSTD 2008a). The assessment was designed as a problem-induced task, i.e. rather than appraising the various impacts of particular technologies or one technology, it analysed the contribution of a diversity of AKST to the combined social, environmental, and production goals. It thereby largely focused on evidence from commercial cultivation.

The report points out the pivotal contribution of biotechnology in solving major challenges including plant breeding, but it takes a cautious view on the productivity and sustainability of GM crops. It highlights that the assessment of biotechnology is lagging behind technical progress and that evidence on impacts is frequently contradictory and inconclusive especially for developing countries:

"An analysis of the global impact of biotech crops from 1996 to 2006 showed substantial net economic benefits at the farm level; reduced pesticide spraying, decreased environmental impact associated with pesticide use and reduced release of greenhouse gas emission (Brookes and Barfoot, 2006). A different study of the economic impact of transgenic crops in developing countries found positive, but highly variable economic returns to adoption (Raney, 2006). In this case, institutional factors such as the national agriculture research capacity, environmental and food safety regulations, IPRs and agriculture input markets determined the level of benefits, as much as the technology itself (Raney, 2006)" (IASSTD 2008a:196).

Benefits of GM crops are considered to be very variable depending on the year and crop and other factors with evidence indicating both positive and negative impacts. No conclusive evidence was found that GM crops have so far offered solutions to the broader socioeconomic dilemmas faced by developing countries. The potential of GM crops to serve the needs of the subsistence farmer is recognized, but – so far – this potential remains unfulfilled. The report also highlighted the problematic role of intellectual property rights (IPR) and new liabilities for farmers of GM crops. IPR instruments "eventually exhibiting seed-saving, exchange, sale and access to proprietary materials necessary for the independent research community to conduct analysis and long term experimentation on impacts […]. GM farmers may become liable for adventitious presence if it causes loss of market certification and income to neighbouring organic farmers, and conventional farmers may become liable to GM seed producers if transgenes are detected in their crops" (IAASTD 2008b).

The conclusions of this report led to a fierce debate in the biotechnology literature with industry and some analyses heavily criticising both process and outcome and calling to rewrite the biotechnology section of their report.

There are also reviews available in the peer reviewed scientific literature, e.g. Qaim (2009), Smale et al. (2006, 2008). Smale at al. (2008) reviewed applied economics literature on developing countries published between 1996 and 2006 and identified some 100 peer reviewed papers out of a total of about 300 papers and reports. Literature on farm level effects is usually specific to crop/trait combinations. Table 1 shows the uneven distribution of these studies: about half of these papers are investigating farm level effects with almost all focusing on cotton.

Table 1: Count of articles assessing the economic impact of genetically engineered crops in developing economies, by research question and crop (and trait).

Crop-trait	Farm	Farm/Industry	Industry	Trade	Total
Cotton – insect resistant	44	3	5	4	56
Maize – insect resistant	4	1	3	6	14
Rice – herbicide tolerant/ insect resistant	2	1	1	5	9
Soybeans – herbicide tolerant	3	1	1	6	11
All other crops[a]	1	1	4	2	8
GM – general			1	3	4
Total	54	7	15	26	102

a Other crops include bananas, potatoes, sweet potatoes, cassava, wheat, oilseeds, eggplant, mustard and coarse grains.

Source: Smale et al. (2008).

Summary

There is a substantial body of literature available on possible and documented impacts of GM crops beyond the health and environmental dimension. These impacts are referred to as economic, agronomic, agro-environmental, societal, social, socioeconomic etc. The term 'socioeconomic' seems to be used very broadly as involving a combination of social and economic factors. With the possible exception of ethical issues the term appears to cover almost everything which does not fit into the health and environmental risk box. As the scope of "other factors" in GMO authorisation is not yet clear it is considered pertinent to keep the vagueness of the term in this report.

The majority of the available literature investigates economic effects. The evidence base has a strong bias towards farm level effects and cotton. Literature reports can frequently be clearly traced to either industry and close-to-industry sources or environmental NGO sources. Comprehensive studies from public authorities or independent organisations are scarce. Two examples are briefly described: a study compiled by the UK Cabinet Office in the course of the GM Nation exercise, and a large-scale assessment conducted in the context of the United Nations: the International Assessment on Agricultural Knowledge, Science and Technology for Development (IAASTD) aiming to investigate the impacts of agricultural knowledge, science and technology (AKST) on hunger, poverty, nutrition, human health, and environmental and social sustainability in relation to both the past and the future.

The UK study concluded that for the UK context economic benefits might be outweighted by additional costs though expecting the balance to change with future generation of GM crops. The IAASTD exercise was sceptical about the relative contribution of biotechnology for solving the main societal problems described above.

Many studies the authors of which are related to industry showed clear benefits, especially on the farm level, while NGO studies often came to different conclusions.

Socioeconomic considerations in EU and national regulatory regimes

This chapter explores which countries are explicitly considering socioeconomic impacts of GMOs in decision making. The first part of the chapter provides an overview of socioeconomic considerations in national regulatory regimes. The main sources of information are the EC reviews on implementing Directive 2001/18/EC and Regulation (EC) 1829/2003 and documents provided by Parties in the course of the Cartagena Biosafety Protocol (CPBS). The chapter distinguishes EU and non-EU countries. A more detailed analysis focuses on Norway, France, and Austria .

EU level and EU Member States

For EU Member States there is little information whether socioeconomic impacts are explicitly considered when implementing Directive 2001/18/EC on the deliberate release and placing onto the market of GMOs. Member States responding in the context of the CPBS reviews that they are taking into account socioeconomic factors (Italy, Netherlands, Spain, and Germany) are referring to coexistence measures. Some EU Member States (Belgium, France, Hungary, Ireland, Portugal, Romania, and United Kingdom) and the European Commission responded not to have taken into account socioeconomic aspects. According to UNEP-GEF (2006), also the Czech Republic, Estonia, Latvia, Lithuania, Malta, Slovakia, and Slovenia are not considering socioeconomic aspects.

Austria, France (recently), and Norway are known to consider socioeconomic aspects in GMO decision making and/or having socioeconomic considerations included in their national legislation.

How is this reflected in EU legislation?

In the EU, GM crops can be authorised for cultivation either under Directive 2001/18/EC or – according to the one-door-one-key principle – under Regulation 1829/2003. Both differ in their scope for considering factors beyond human health and environmental risks.

The overall objective of Directive 2001/18/EC is to protect human health and the environment (Art. 1). Authorisation procedures for Part B and Part C releases allow for consultations with a broader range of stakeholders but do not extend the scope beyond human health and environmental effects. As the only exemption, Art. 29 acknowledges the particular importance of respect for ethical principles in Member States and accepts that ethical considerations may be taken into consideration when GMOs are placed on the market. It authorises the European Commission to take advice on general ethical issues from European Groups on Ethics in Science and New Technologies, and the Commission is obliged to submit an annual report to the European Parliament on ethical issues it has considered, accompanied if appropriate by a proposal to amend the Directive.

The Directive also requires the Commission to send the European Parliament and the Council, every three years, a report on the experience of Member States with GMOs placed on the market under this Directive. This report shall explicitly consider “socioeconomic implications of deliberate releases and placing on the market of GMOs.” (Art. 31 (7d)). Two reports have been issued to date. The 2004 report mainly considers possible variations between Member States concerning coexistence measures, thresholds, cost allocation and liability as a possible impact on the common market (Schenkelaars Biotechnology Consultancy & Risk & Policy Analysts Ltd 2004). The 2007 report does not mention socioeconomic aspects as such but also includes some information on coexistence, thresholds, and liability (CEC 2007).

Coexistence measures, thresholds, and cost allocation are not explicitly regulated by Directive 2001/18/EC neither by any other harmonised EU legislation, though, they are closely linked to the cultivation and approval of GMOs. Article 26a of the Directive (concerning coexistence) provides leeway for a broad interpretation and the relevant thresholds for Article 21 (2) have not yet been agreed. Liability still remains a subject of debate as Directive 2004/35/EC on liability for environmental damage has a limited scope only. These issues remain partially unresolved which has been recognised by the EC (EC 2006).

Regulation 1829/2003 provides more scope for including socioeconomic factors: Art. 7 and 19[3] foresee the inclusion of 'other legitimate factors'. The preamble specifies that these other factors 'in some cases' 'may' be taken into account (Whereas 32). EU General Food Law (Regulation 178/2002) states even more clearly:

"It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls" (Preamble 19).

So far, the EC did not make explicit use of these provisions in decision making procedures on GMOs.

Non-EU countries

Falck-Zepeda (2009) reviewed regulatory and policy information in the national CPBS Biosafety Clearing House, and identified a number of countries considering socio-economic impacts (see also Table 2) though the scope seems to differ between these countries and regulatory experience seems to be limited.

Argentina, for instance, considers impacts on export. The Philippines provide more details on the type of impacts but do not specify when, how and how long before a decision is being made. In South Africa, the scope of socioeconomic assessment for experimental field trials is limited to those communities living closely to the planned introduction sites. A number of countries such as Honduras, Kenya, and Uganda have included socioeconomic considerations in their draft policies. It is, so far, unclear if these polices will be translated into mandatory requirements embedded in legislation.

[3] "Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences" (Text identical in Art. 7 (1) and Art. 19 (1)).

Table 2: Biosafety protocols and socioeconomic considerations in relevant regulatory laws and regulations.

Country	Party CBD/ CPB[a]	CFT/ CO[b]	Language of relevant text considering socio-economic considerations	Relevant law and regulations for socio-economic considerations
Argentina	Y/N	Y/Y	Decision on the convenience of the commercialization the genetically modified material over its impact on markets, in charge of the National Market Directorate, so as to avoid potential negative impacts on Argentinean exports.	Resolution nº 656/92 of SAGyP and Resolutions n°39/03 and n°57/03 SAGPyA
Brazil	Y/Y	Y/Y	Article 48, Paragraph 1. The National Biosafety Council-CNBS shall: II-analyze, upon request by CTNBio, in the context of convenience, socio-economic opportunity and national interest, requests to grant license on the commercial use of GMO and GMO derivatives.	Decree NO. 5,591, of November 23, 2005
Canada	Y/N	Y/Y	Voluntary/additional information	None
Caribbean			Consideration of socio-economic impact of trade in LMOs and derived products is catered for by all draft final NBFs as part of the decision making process. Assessment of socioeconomic impact is required as part of the risk assessment report prepared by each National Competent Authority. In Dominica, this assessment is specifically delegated to a competent regional authority to make up for the absence of the necessary skills in the country.	
EU	Y/Y	Y/Y	The European Commission requires preparing a report on the socio- economic impact of GM crops every three years. Definition of socio-economic considerations is unclear in current legislation and associated guidelines, no provision for a risk-benefit analysis.	None
Georgia			CA makes decision, based on recommendation of the Advisory Council, standpoints of the Scientific Commission and other ministries, and they have right to make a decision on granting of permit on GMOs use taking into account, inter alia, socio-economic considerations and circumstances.	
Honduras	Y/Y	Y/Y	Socio-economic considerations will be conducted through partial studies that should include different social and economic impacts.	Honduras draft policy
India	Y/Y	Y/Y	India's biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance.	Not included or mandated by the Environmental Act or Biosafety Guidelines
Indonesia	Y/Y	Y/Y	"The utilization of GEAP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms."	Regulation 21 of 2005
Kenya	Y/Y	Y/N	"in reaching a final decision, the Authority shall take into account ... (e) socio-economic consideration arising from the impact of the GMO on the environment."	Kenya draft policy
Nigeria	Y/Y	N/N	assessment, which involves scientific, socio-economic, cultural and ethical considerations.	Nigeria National Biosafety Framework, 2005
Philippines	Y/Y	Y/Y	"Socio-economic, cultural and ethical considerations. Impacts on small farmers, indigenous people, women, small and medium enterprises, and the domestic scientific community to be taken in to account."	Executive Order 514 (EO514)

Country	Party CBD/ CPB[a]	CFT/ CO[b]	Language of relevant text considering socio-economic considerations	Relevant law and regulations for socio-economic considerations
Samoa			The policy pays attention to socio-economic related issues including improved quality of life, sustained economic growth, and cultural values. In the decision-making, the NCA will take account of the particular impacts of GMOs on communities; ensure that "Cabinet, and all Ministries and agencies, are fully informed of […] any other matter associated with GMOs which may affect the well-being of the nation or the health of its people"; and will take into consideration customs and traditions.	
South Africa	Y/Y	Y/Y	"The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction."	GMO Act 1997 (Act No. 15 of 1997)
Swaziland			Socio economic aspects of the people of Swaziland and their ethical considerations shall be taken into consideration when biosafety decisions are made.	
Tanzania			In implementing the NBF, the social, economic and ethical considerations shall be taken into account in Biosafety decisions. The NCAs have the mandate to undertake assessment of socioeconomic impacts.	
Uganda	Y/Y	Y/N	"no approval shall be given unless the GMO will not have adverse socio-economic impacts."	Uganda draft regulations of 2005
USA	N/N	Y/Y	Voluntary/additional information	None
Yemen			The draft legal instrument in Yemen states that the decision-making process shall consider an evaluation of socioeconomic risks in parallel with scientific risk assessment, and that Biosafety decisions shall take into account issues of: - Poverty alleviation, food security, etc; - Livelihoods of small farmers, indigenous people, women, small and medium enterprises, etc; - Cultural integrity of the country and communities.	

Sources: Falck-Zepeda (2009), UNEP-GEF (2006), www.cbd.int/biosafety.

Countries shaded in grey either included the need for assessing socioeconomic impacts in national legislations or are considering to do so based on draft policies.

a CBD/CPB=Party to the Convention on Biological Diversity/Cartagena Protocol on Biosafety

b CFT=Conducted confined field trials, CO=Has made approval for commercialization

a, b Y=Yes, N=No

According to the 2007 national reports[4] on the implementation of the CPBS, also Armenia, Cambodia, China, Mauritius, Philippines, and the Syrian Arab Republic are considering socioeconomic considerations.[5] UNEP-GEF (2006) mentions Bhutan, Lebanon, and South Korea to have included socioeconomic considerations either in their national biosafety policy or as part of biosafety regulations.

Falck-Zepeda (2009) discusses more in-depth the specific requirements of Nigeria, Honduras, and Bangladesh. The biosafety policies of these countries have been developed in the course of UNEP-GEF programmes (see Table 3). Requirements seem to vary considerably between these three countries; moreover, there is tremendous scope how to implement these policies.

Countries which do not have legal requirements for considering socioeconomic factors might do so as shown by the example of insect resistant cotton and Bt-eggplant. In both cases, the Indian Genetic Engineering Approval Committee (GEAC) requested socio-economic studies (Sharma 2008 cf. Falck-Zepeda 2009).

Table 3: Three examples describing inclusion of socio-economic considerations included in drafts policies done at the UNEP-GEF country projects.

Nigeria	**Honduras**	**Bangladesh**
(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the GMO or product thereof; (b) Possible threats to biological diversity, traditional crops or other products, and, in particular, farmers' varieties and sustainable agriculture; (c) Impacts likely to be posed by the possibility of substituting traditional crops, products, and indigenous technologies through modern biotechnology outside of their agro-climatic zones; (d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities, and in general, means of livelihood of the communities likely to be affected by the introduction of the GMO or product thereof;	Article 41. Socio-economic considerations will be conducted through partial studies that should include: (a) Estimation of changes in social and economic patterns as a result from the introduction of GMO and their products; (b) All those impacts related to the potential substitution of traditional crops and indigenous technologies through modern biotechnology outside their agro-climatic zones; (c) Anticipate the social and economic costs resulting from losses resulting from labour reductions, market opportunities, and in general, the community livelihoods potential affected by the introduction of GM crops and its products;	(i) Factors such as the potential impact on trade, labour, food security, gender, small business development, sustainable development, and poverty alleviation would be taken into consideration in the evaluation process; (ii) The impact on food security, impact on livelihood of communities, and ethical issues and the right to choice would identified as key socio-economic factors that need to be considered; (iii) Ethical issues and the right to choice—The right to choice could be addressed by having an effective labelling system; (iv) Where genes of certain animals or human genes have been inserted to produce GM crops, livestock, or food, it is necessary to identify and

[4] Each Party is required to monitor the implementation of its obligations under the Protocol and to report to the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) on measures taken to implement the Protocol. National reports have to be compiled with a frequency of every four years. The deadline for the first national report was 2007. This report included a response to three questions on socioeconomic aspects (http://www.cbd.int/biosafety/parties/national-reports.shtml).

[5] These countries were responding with yes to the question "If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities?" (Article 26.1). These national reports, however, do not provide a comprehensive picture, as 46 of 82 countries responded that they are not a Party of import. 23 countries responded not to have taken into account socioeconomic factors: EU: Belgium, European Community, France (note: the survey was conducted before the French regulatory reform), Hungary, Ireland, Portugal, Romania, United Kingdom; non-EU: Australia, Brazil, Cameroon, Costa Rica, Dominican Republic, Egypt, Ghana, Indonesia, Japan, Kenya, Mexico, Palau, Papua New Guinea, Thailand, Venezuela.

Nigeria	Honduras	Bangladesh
(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare; (f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the GMO or product thereof.	(d) Identify potential communities affected in terms of disruptions to their economic and social welfare; (e) Identify potential effects that are contrary to communities' social, cultural, religious, ethical values; due to the introduction of GM crops and its products.	incorporate the relevant socio-economic factors in the protocol for risk assessment. Detailed environmental impact analysis including socio-economic impact analysis will be the responsibility of the applicant/notifier/ proponent and the competent authority concerned or NCB/MoEF would undertake a detailed review of this analysis with the technical support of BCC.

Source: Falck-Zepeda (2009).

Countries publicly considering to include socioeconomic considerations into their GMO regulatory regime are sometimes facing resistance from GMO promoters as indicated by correspondence of the US biotechnology industry organisation BIO with South Korea which is considering to include a requirement to take into account "socio-economic impact of the living organism on the value of domestic biodiversity" (Art. 8.5. Import Approval cf BIO 2009a).

Countries explicitly stating not to require socioeconomic aspects by law are: USA, Canada, Albania, Belarus, Iran, Jordan (UNEP-GEF 2006, Falck-Zepeda 2009). Australia, Brazil, Cameroon, Costa Rica, Dominican Republic, Egypt, Ghana, Indonesia, Japan, Kenya, Mexico, Palau, Papua New Guinea, Thailand, and Venezuela stated in their first national reports to the CPBS that they have not taken into account socioeconomic aspects.[6]

Case Studies

Norway

Legal framework

As a member of the European Economic Area (EEA), both the Directive 2001/18/EC and the Regulation 1829/2003 apply to Norway. However, as part of the EEA agreement the safeguard clause was replaced by a provision that entitled the Norwegian Parliament the right to develop a more comprehensive legislative framework and thereby to permanently restrict or prohibit a GMO that had been authorised EU-wide for other reasons than those laid down in the EU Directive (Kvakkestad and Vatn 2008).

The Norwegian Gene Technology Act (NGTA) established in 1993, in fact, goes beyond what is required by Directive 2001/18/EC and includes a mandatory consideration of socioeconomic factors in decision making on GMO market approvals. The NGTA stipulates that processing and use of GMOs must take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment (Art.1) and that "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

[6] See also section "Cartagena Protocol on Biosafety".

sustainable development" (Art.10).[7] The scope of the NGTA thereby encompasses both the application of the GMO and the production process.[8] Thus, the Norwegian Biotechnology Advisory Board (NBAB) distinguishes product characteristics, production, and use.

Regulations were established (and replaced in 2005) to govern the details of impact assessment (IA regulation) pursuant to the Gene Technology Act (Ministry of Environment 2005a). Article 17 specifies "other consequences" than those on human and animal health and the environment:

1. "positive or negative effects of the project in relation to sustainable development,
2. ethical considerations that may arise in connection with the use of the genetically modified organism(s), and
3. any favourable or unfavourable social consequences that may arise from the use of the genetically modified organism(s)."

Appendix 4 of the IA regulation is essentially composed of checklist questions for guiding notifiers what information to include in the dossiers to allow for an evaluation of the Article 17 criteria. All the elements listed in the appendix should as far as possible be considered. However, the appendix is considered not exhaustive and not all the elements will be relevant in every case (Appendix 4: Introduction). This appendix is based on a 1999 opinion of the NBAB which in turn is based on the NGTA and preparatory documents and official Norwegian policies regarding sustainable development as well as the precautionary principle.

The following sections briefly describe the scope and focus of the assessment under point 1 to 3. As the legal test does not include more detailed explanations and interpretations, frequent reference is made to the NBAB opinion underlying the legal text.

Sustainable development

Sustainable development is defined with reference to the 1987 World Commission as a "development that meets the needs of the present without compromising the ability of future generations to meet their own needs" (Vik 2009, Norwegian Biotechnology Advisory Board 2000/2003). The assessment should be structured along ideas underlying the concept[9] and based on guiding questions detailing these ideas (see Table 4).

[7] Exact wording: "§1. The purpose of this Act is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment. §10.[…] In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development."

[8] Interpreted as including the entire production line – from development and pilot production to processing in a production facility – and thereafter the marketing, sales and distribution of the finished product (NBAB 2004: 7).

[9] "The idea of the global effects of human activities; the idea of ecological limits and that these limits have been exceeded in several areas; the idea of meeting basic human needs; the idea of just distribution between generations; the idea of just distribution between wealthy and poor nations; the idea of a new form of economic growth." (Norwegian Biotechnology Advisory Board 2000/2003).

Table 4: Checklist questions for evaluating impacts on sustainable development*

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?

Source: Ministry of the Environment (2005b).

**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.*

When it comes to biodiversity, sustainability assessment is extending health and environmental impact assessment in both time and space. Whereas the latter is deemed to be more local, regional and national, the former assessment applies globally and across generations. Reduction biodiversity is considered as reducing humankind's opportunities of pursuing sustainable development (Norwegian Biotechnology Advisory Board 2000/2003: 13).

Examples of sustainable use of gene technology in the 1992-1993 preparatory document given by the Ministry of Environment (cf. Vik 2009):

- Improved techniques for waste and sewage treatment
- Lessen the need for chemical input into agriculture such as pesticides and synthetic fertilizers
- Increase yield and nutritional value of crops decreasing the pressure on natural resources

Ethical considerations

These criteria are only mentioned in the aim of the Act and not specified in the provisions describing the assessment criteria. Nevertheless, they are considered by the NBAB as independent from societal benefit and sustainable development (Norwegian Biotechnology Advisory Board 2000/2003). The NBAB is drawing references to ethical values underlying the Gene Technology Act (common good, other key ethical values to ensure broad acceptance in Norwegian society).The ethical assessment should identify the parties affected, their underlying interests and how they are affected, and compare this to alternative options. Clarification should be sought how to balance possible gains and losses among different groups.

Appendix 4 provides a number of questions to guide through such an ethical assessment (see Table 5).

Table 5: Checklist questions for evaluating ethical considerations

A. General considerations
1. Analysis of the situation
What alternatives are there?
Which parties are involved? How will they be disadvantaged by or benefit from the different alternatives?
2. Ethical reasoning
Which norms are applicable?
How can any conflict between these norms be resolved?
3. Implementation
How can the best alternative be implemented in practice?
B. Checklist
1. Ethical norms and values relating to people
Will approval or prohibition of the product and its production and use be in accordance with the moral views of the general population?
Will the product or its production and use come into conflict with the ideals of solidarity and equality between people, such as the need to show special consideration for weaker groups?
Decisions made by mainstream society can have a serious adverse impact on indigenous peoples, people who live in highly traditional cultures, and weaker groups. Special account should be taken of the need of these groups to be able to control their own processes of social change.
Will the marketing and sales, in particular, of the product come into conflict with ethical norms and values relating to people?

2. Eco-ethical considerations
Will the product and its production be in conflict with any intrinsic value assigned to animal species?
Will the production of the product cause unnecessary suffering to animals?
Will the production of the product involve crossing species barriers in ways that are materially different from those otherwise found in cultivation or in the wild, and that must be considered incompatible with the value assigned to the integrity of species?

Source: Ministry of the Environment (2005b).

**An evaluation of other ethical and social considerations must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.*

Favourable or unfavourable social consequences

Lacking legal guidance, the NBAB drew analogies from the assessment of new drugs which is focusing on both efficacy and side effects. Broadening this into a societal dimension leads to the following questions:

- Which problem does the new drug seek to solve?
- Which alternatives are available for solving the same problem?
- Which problems could arise if the use of the drug leads to increased resistance?

These questions inspired the further considerations. In contrast to the wording in the Act, the benefit assessment is interpreted more broadly to also include disadvantages to society. Community is primarily understood as Norway. It might also include the wider geographical context but not address a kind of world communities. Given the dynamic developments in society which are difficult if not impossible to predict, the societal benefit assessment must primarily refer to the present situation or the near future. Based on these considerations, a number of guiding questions have been adopted into Appendix 4 (see Table 6).

Table 6: Checklist questions for evaluating favourable or unfavourable social consequences (a)

1. Characteristics of the product
Is it reasonable to say that there is a demand or a need for the product?
Is it reasonable to say that the product will solve or help to solve a social problem? (b)
Is it reasonable to say that the product is significantly better than similar products that are already on the market?
Is it reasonable to say that there are alternatives that are more suitable than this product for solving or helping to solve the social problem in question?

2. Production and use of the product
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities?
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in rural areas in particular?
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in other countries?
Will the product tend to create problems for existing production that should be maintained?
Will the product tend to create problems for existing production in other countries?

Source: IA Regulation, Appendix 4, Section V Favourable or unfavourable social consequences. *http://www.regjeringen.no/nb/dep/md/dok/lover_regler/forskrifter/2005/regulations-relating-to-impact-assessmen.html?id=440455*

(a) An evaluation of whether a product is of benefit to society must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.

(b) Limited to Norway (Vik 2009).

Relation between physical risks and socioeconomic considerations

The NBAB interpreted the requirements as "prerequisites that alone could carry decisive weight against granting an application, but that should also be considered in relation to, and weighed against the risk of detrimental effects, when such risk is low" (Norwegian Biotechnology Advisory Board 2000/2003: 7). The NBAB outlined a three-step assessment procedure:

1. "Danger of detrimental effects on health and the environment:
   a) What are the possible negative consequences?
   b) What is the likelihood of such consequences?
2. The precautionary principle:
   a) Is the risk assessment associated with justified uncertainty?
   b) Is there a possibility of substantial or irreversible harm?
3. Is it:
   a) in compliance with the principle of "sustainable development"?
   b) of 'benefit to the community'?
   c) 'ethically and socially justifiable'?"

Step 3 assessments should be conducted in any case even though there might be risks for detrimental effects. Considerable gains and benefits in step 3 might still outweigh the risks identified in step 1. Step 2 assessment is conducted if the information does not allow for an adequate assessment of possible detrimental effects (in case of doubts or uncertainty). The IA Regulation essentially followed the NBAB advice.[10]

Where is the IA of socioeconomic aspects conducted?

Norway conducts national hearings for each GMO notification and invites statements from relevant national authorities (Vik 2009):

- NBAB: major contributor in the hearing process

  The members of the Board comprise a wide range of scientific disciplines but also of stakeholders. The Board's expertise was described as being based partly on 'sound science' and partly on a variety of values and knowledge from sectors in society (Rosendal 2008).

- Norwegian Directorate for Nature Management: co-ordinates the hearing process and provides evaluation reports to the Ministry of the Environment

- Ministry of the Environment: national decision, free to follow the advice from the advisory bodies (Kavakkestad and Vatn 2008).

Socioeconomic considerations in practice

Rosendal (2007, 2008) analysed the reasoning provided by the NBAB in 50 GMO applications between 1995 and 2005. The NBAB's advice changed over time showing increasing stringency and more comprehensive reasoning on societal concerns. A major issue in the early phase (1993-1998) was the question of reduced pesticide use. Social (and health) issues became more important from 2003 onwards. Socio-economic issues considered are listed in Table 7. As described above, the need to consider sustainable development and social utility sometimes extends the scope of health and environmental assessment. For instance, with antibiotic resistance genes the scope of the assessment also includes environmental effects in case where no cultivation is envisaged in Europe.[11] According to the NBAB, antibiotic-resistance marker genes could particularly affect Third World-countries where many of the antibiotics phased out in Europe are still being used (ibid.). Rosendal highlights the link between the application of a wider scope and the precautionary principle. The consideration of socioeconomic aspects has been further supported by the increasing recognition and application of the precautionary principle.

[10] "The comments on section 10, second paragraph, make it clear that when applications for deliberate release pursuant to the Act are considered, any benefits to society and contributions to sustainable development are to be used both as independent criteria for the evaluation of applications and as criteria that may make result in less strict application of the requirement that the release of genetically modified organisms must not have adverse effects on health or the environment. An evaluation of benefits to society and contribution to sustainable development should be based on the principles of cost-benefit analysis" (Norwegian Ministry of Environment 2005).

[11] This contrasts the scope of EFSA's assessment.

Table 7: Socioeconomic issues brought up in NBAB opinions.

Societal utility
Changes/growing social inequity
Reduced opportunity to reuse seeds for farmers (due to hybridisation)
Ethics and sustainable development (b)
Effects on herbicide use (has it been reduced or not?) (a)
Antibiotic resistance (a)
Liability (a)
Co-existence (a)

Source: Rosendal (2007).

a) Rosendal considered these issues under the heading of 'environmental concerns' (Rosendal 2007).

b) In the early phase (1993–1998) this indicated a lack of documentation of the effects on use of chemicals (see also concerns about effects on herbicide use) when cultivating GM plants. In later phases (2003–2005), these concepts are used in a wider sense, including effects on global agricultural structures and North–South issues of equity.

Given the broad acceptance of NBAB recommendations in the Norwegian society and the increasing stringency over time, Rosendal (2008) concluded that this indicates that societal knowledge is broadly acceptable as legitimate input in the policy-making process and that it is accepted as part of practicing the precautionary principle.

By the end of 2005, the NBAB gave a favourable opinion in four cases only including three carnation lines, and one tobacco line (import). In some of the rejections the overall conclusion was that the release would not contribute to the sustainable development or that it was unclear whether it would do so. It was emphasised that GMOs would not contribute to a fair distribution from a global perspective. Herbicide-tolerant GM crops may in the long run impede the evolution of non-herbicide weed management strategies (Ministry of the Environment 2001 cf. Kavakkestad and Vatn 2008). Another reason for Norway to turn down GMO applications is that as of yet applications mainly aimed at GM crops which are of limited interest for Norwegian farmers (Rosendal 2008). In many cases, the overall conclusion of the Norwegian Authorities was that the GMOs failed to represent a societal benefit. The problems that GMOs are designed to solve are not considered to exist in Norway or are not providing significant improvements. Even GM crops which were approved were considered to conflict with sustainable development, e.g. carnation and tobacco (Kavakkestad and Vatn 2008).

According to Kvakkestad and Vatn (2008), the existence of health and environmental risks was still the most important aspect underlying Norwegian decisions. In contrast to the EFSA point of view, Norway often considered the information provided in the dossiers as inadequate. Only in case of the carnation dossiers the information was accepted.[12] The reasoning given in the rejections was that in the absence of a benefit to society and a contribution to sustainable development, the identified health and environmental risks are considered to be unacceptable. However, the relative role of the explicit socioeconomic factors in decision making is not entirely clear. Drawing on interview

[12] For the favourable decision on tobacco, Kvakkestad and Vatn (2008) speculated that this was either accepted because the information was considered sufficient or because the crop is not likely to be cultivated in Norway.

information, Kavakkestad and Vatn (2008) speculated that the notifications probably would have been rejected also if only health and environment were considered.

Overall, Kavakkestad and Vatn concluded that Norway differed from the EU in terms of both legislation and implementation. The NGTA includes stricter requirements for uncertainty and ignorance compared to the Directive 2001/18/EC.

A particular problem for the NBAB has been that applicants rarely include the type of information necessary for a wider socioeconomic assessment (ibid.). From this, the dilemma for the Norwegian CAs arising is how to receive information from the notifiers. Such questions cannot be sent to the EFSAnet as EFSA only considers comments and questions relevant to the scope of the EU legislation – essentially to health and environmental aspects. Another option which is being increasingly used is to approach notifiers directly. Still the problem remains that notifiers apparently have little incentive so far to conduct additional studies if this is just for the Norwegian market. In the absence of this type of information, the only way out would be to let the Norwegian CAs conduct studies and collect information. This, however, could be considered as a reversal of the burden of proof (Vik 2009).

France[13]

In June 2008, France passed a new biotechnology bill (Law n°2008-595 from 25th June 2008) which resulted in a major change in GMO assessment and authorisation (for a more detailed description of the policy change see Box 1). The newly established Haut Conseil des Biotechnologies (High Council of Biotechnology; HCB) replaced the Commission du Génie Génétique (CGG) and the Commission du Génie Biomoléculaire (CGB). In April 2009, the HBC was formally established. While the Agence française de sécurité sanitaire des aliments (AFSSA) is still in charge of assessing health risks relating the consumption of GMO products, the HBC was given a broader mandate. It is required to provide advice to the government on any question regarding biotechnology. This mandate includes the routine reviews of dossiers for both field trials and placing on the market of GMOs submitted under Directive 2001/18/EC as well as of dossiers for GM food/feed products submitted under Regulation 1829/2003. The HCB is linked to five ministries but portrays itself to be independent from political power. Government, elected officials and industrial boards, and NGOs can file inquiries to the HBC and the HBC can also launch proceedings by itself. The HBC is endowed with a one million € budget allowing to contract out external studies.

Its two committees, the Scientific Committee and the Economic, Ethical and Social Committee (CEES), conduct different types of assessments. The Scientific Committee provides a scientific evaluation of the health and environmental risks, while the CEES is mandated to evaluate the economic, ethical and social aspects. The CEES consists of 27 members, three experts (lawyer, economist, and sociologist) and 24 stakeholders (elected officials, representatives from professional organisations, unions, as well as from consumer, environmental, and health protection organisations). The CEES becomes active after the Scientific Committee has issued its opinion. Its opinion is transferred to the government along with that of the Scientific Committee.

Given its very recent establishment, the CEES has so far issued a few opinions:[14]

[13] This section is largely based on Noiville C 2009. The Haut Conseil des biotechnologies: towards a new assessment of GMOs in France. Presentation held at the Conference GMOs in European Agriculture and Food Production, 25-26 November 2009, The Hague, The Netherlands.

[14] http://www.ogm.gouv.fr/.

- Renewal of the authorization of maize MON 810
- Sugar-beet H7-1 (EFSA/GMO/DE/2008/63)
- Maize NK603 (EFSA/GMO/NL/2005/22 -)
- Maize MON89034xNK603 (EFSA/GMO/NL/2009/72)
- GM vine (application for field trial)
- The definition of GMO-free production and supply chains

Practice of CEES assessments

Given the limited time of activity, little is known about the practice of CEES[15]. The Chair of CEES, Christine Noiville describes the challenges to the Committee (Noiville 2009):

- Convergence from the diversity of viewpoints present in the Committee
- Absence of guidance on what to assess: in contrast to health and environmental risk assessment there is no guidance for providing data
- Lack of data/access to data: there is no basis in the EU law to require notifiers to conduct their own socioeconomic assessments; HBC has apparently asked all EU CAs to ask notifiers to provide socio-economic data and a briefing document
- What criteria, what methods, what data? The CEES is aiming to develop a checklist of questions which will complement the case by case approach.

For instance, when reconsidering the French ban on maize MON810, the CEES identified a number of concerns:

- Risks of an increase of the area treated with insecticides
- High seed price is considered a problem if infestation frequency is low
- Uncertainties on possible negative impacts on bees and livestock breeding
- Possible economic impacts on certain branches of agricultural production

The remit of the HBC and CEES is not entirely clear. As can be derived from its opinions, CEES does not only deliver assessments of socioeconomic aspects but does also interpret the results and conclusions of the Scientific Committee against this backdrop – providing a kind of synopsis of health and environmental risks, environmental benefits as well as socioeconomic impacts. For the hybrid maize MON89034xNK603 for instance, CEES acknowledged “few advantages” in case of maize monoculture and of higher infestation rates. Eventually the CEES found too many disadvantages for

[15] Any review of CEES activities is complicated by the fact that most CEES documents are in French language only.

conventional and GM –free agriculture and – in light of the uncertainties associated with the scientific aspects – recommended not grow the crop (HCB 2010).

While the formal decision is still to be made by the administration (Inf'OGM 2008), the activities of CEES can be perceived as intruding into the domain of risk management. It seems the HBC is weighting risks and benefits and provide monolithic prescriptive advice (lacking any alternative options). This practice illustrates a particular difficulty of socioeconomic advice: its relative position in the present EU risk governance framework favouring a separation of advice (science) and management (decision). For instance, even if socioeconomic assessment was considered not to belong to the realm of risk assessment, the mere assessment task would need to be distinguished from the weighing of impacts, options, and decision making in order not to change the lines of accountability. More of such conceptual considerations can be found in chapter "Challenges to a socioeconomic assessment framework".

Box 1: Change of GMO policy in France.

The establishment of the HCB resulted from a considerable change in French agricultural biotechnology policy following the election of Nicolas Sarkozy as the new French President in May 2007. Prior to 2008, France was the second largest producer of biotech maize in the EU with some 22.000 hectares in 2007. In summer 2007, Sarkozy launched the Grenelle de l'environnement[16], a broad stakeholder debate that brought together representatives of national and local government and organizations (industry, labour, professional associations, non-governmental organizations) with the aim of defining the key points for public policy on ecological and sustainable development issues for the coming five years. This consultation reconsidered agricultural biotechnology and concluded that scientific risk assessment should be strengthened to also include long-term effects and should be complemented by an analysis of socioeconomic impacts. In January 2008, the government banned the commercial cultivation of maize MON810 and passed a new biotechnology bill taking up recommendations from the stakeholder consultation. The line of reasoning given for the establishment of a specific body dedicated to socioeconomic assessments are that in cases of inconclusive and controversial scientific risk assessments, management decisions should not be imposed. Rather, these decisions have to consider impacts on the wider socioeconomic contexts. Explicitly addressing such factors would avoid that "real arguments must not be hidden behind scientific arguments put forward in an artificial manner in order to back up decisions which in reality partially finds its justification elsewhere".

Source: Noiville (2009).

Austria

The Austrian Gene Technology Act (GTG 1994) entered into force in January 1995 and has been amended several times, most recently in 2005. It regulates all aspects of contained use, release and marketing of GMOs, as well as human applications such as genetic tests and gene therapy. The preamble lists several 'principles' that have to be taken into account when the law is applied. Apart from explicitly mentioning the precautionary principle, the preamble also refers to the 'future principle' (stressing that the application of biotechnology should be promoted), the 'step-by-step principle', the 'democratic principle' (stipulating participation and information), and the 'ethical principle' (mainly relevant for human applications).

As a result of a Parliamentary Commission's work informing the law-making process, the part on marketing permissions contains a provision to avoid any 'social non-sustainability' resulting from a GM product. In Article 63, the law in fact included a provision on products that were considered

[16] http://www.legrenelle-environnement.fr/spip.php?rubrique112.

'socially unsustainable' ('sozial unverträglich').[17] This provision allows banning products that have passed health and environmental risk assessment, i.e., it provided a means not to grant permission to products that may have posed an 'inappropriate burden to groups of the population'.

This notion represented a novel concept in Austrian legislation and has stirred a lot of discussion following the introduction of the GTG. Given the lack of precision in the wording of the provision, the concept provides large leeway for interpretation and use which leads to various problems (Seifert and Torgersen 1997). In a pluralistic society it is difficult to think of clear-cut criteria what is deemed socially unsustainable and what is not. According to Torgersen, the concept contradicts with an Austrian constitutional principle (Legalitätsprinzip Art 18 B-VG) (Torgersen et al. 1995), and it is doubtful to what extent it can be used as a regulatory category. Some scholars have, therefore, considered this provision to be void and/or in conflict with EU legal requirements. In practice, despite the intense debate on socio-economic impacts of GM crops in Austria, no explicit reference was made in public policy to Article 63. Thus, the concept remained practically insignificant, even when public protest showed that certain applications were indeed 'socially unsustainable' (Torgersen and Seifert 2000).

In case EU policies would allow or even favour national assessments of socioeconomic impacts of GMOs, this provision might well provide a reference that could than be detailed by a Ministerial ordinance. This would require a more in-depth legal analysis based on different scenarios of EU policy development; e.g. considering a scenario of where Member States can restrict/ban cultivation of GMOs on their own territory based on socioeconomics grounds: here, clarification would be required, if the prescriptive phrasing of the text, suggesting a dominance of social, economic or ethical aspects over health and environmental risks (and economic benefits) was in line with EU- and international legislation and Austrian GMO policy.

Summary

Socioeconomic impacts of GMO market approvals are considered in a broad range of countries including Armenia, Bangladesh, Bhutan, Cambodia, China, Honduras, India, Lebanon, Mauritius, Nigeria, Philippines, South Korea, and the Syrian Arab Republic. Scope and nature of requirements seem to vary considerably between these countries as does the way they are being established: part of national legislation, draft legislation, policies or regulatory practice. Australia, Brazil, Canada, Japan, and Thailand are examples for countries not taking into account socioeconomics. Among EU/EEA Member States, only France and Norway are known to explicitly assess socioeconomic impacts; the Austrian national law on GMOs includes a provision on socioeconomics which has not yet been implemented though.

Norway established a mandatory requirement to consider socioeconomic impacts back in 1993, focusing on ethical and social aspects as well as sustainability assessment. Requirements were subsequently detailed in regulations on impact assessment and opinions of the NBAB. Sustainability assessment includes all three pillars of sustainable development and explicitly recognises the global scale. It thereby extends environmental risk assessment when considering effects on biodiversity in third countries. Social utility aspects include for instance demand, problem solving capacities, and alternative products. Ethical assessment considers for instance the moral views of the general population, impacts on traditional cultures and weaker groups, and the integrity of species. Socioeconomic information is being weighted against health and environmental risks and associated

[17] „Soziale Unverträglichkeit von Erzeugnissen […] liegt vor, wenn auf Grund sachlicher Grundlagen anzunehmen ist, daß [sic!] solche Erzeugnisse zu einer nicht ausgleichbaren Belastung der Gesellschaft oder gesellschaftlicher Gruppen führen könnten, und wenn diese Belastung für die Gesellschaft aus volkswirtschaftlichen, sozialen oder sittlichen Gründen nicht annehmbar erscheint" (Article 63 GTG).

uncertainties and irreversibility. The unfavourable opinions of the NBAB frequently included lack of benefit to the society and a positive contribution to sustainable development, though, health and environmental risks seem to be still the most important reason. A particular problem is the lack of relevant information in the dossiers. It is also neither possible to force applicants to provide such information nor to comment on such aspects in the EU authorisation procedure because they are considered by EFSA to be out of scope.

In France, the High Council on Biotechnology (HBC) was established following a recent change in GMO policy. One of the two HCB Committees (CEES) provides advice to the government on economic, ethical, and social aspects of GMOs including in the course of routine evaluations of Directive 2001/18/EC and Regulation 1829/2003 dossiers. Based on the limited experience gained so far, CEES perceives its main challenges to be the lack of relevant information in the dossiers and the lack of guidance for criteria, methods, data, and assessments. CEES practice apparently includes providing quite prescriptive advice instead of options to the formal decision makers based on a weighing-up of health and environmental risks on the one hand, and socioeconomic concerns and benefits on the other hand. This practice is potentially changing lines of accountability and needs a more careful analysis in the context of the EU governance framework established for the food chain.

The Austrian GMO law includes a provision allowing decision makers to ban the marketing of products which are considered 'socially unsustainable' ('sozial unverträglich') - referring to social, economic, and ethical aspects. The meaning of this provision has never been clarified; it has been discussed to be potentially in conflict with EU legislation. In no case, explicit reference was made to this provision – which could therefore be considered as void. In case of an EU policy change, e.g. allowing for national assessments of socioeconomic impacts of GMOs, this provision could become an interesting reference. A more detailed legal analysis might be required to identify possible constraints.

Challenges from international regulations

Any measures taken by the EC to consider socioeconomic aspects in the course of market authorisations have to be checked for compatibility with international legislations in particular with the Cartagena Protocol on Biosafety and with the WTO. This chapter provides a brief analysis of how a possible socio-economic impact assessment (subsequently referred to as SOEIA) in GMO decision making is or might be perceived in these contexts.

Cartagena Protocol on Biosafety

Article 26 of the Cartagena Protocol on Biosafety establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms (LMOs) in reaching a decision on whether to import these organisms, especially with regard to the value of biological diversity to indigenous and local communities.[18] When Parties are taking such considerations into account, they are at the same time required to ensure that the decision is consistent with their other international obligations.

Status of debate

Paragraph 2 of Article 26 calls upon Parties to cooperate on research and information exchange on socio-economic impacts of LMOs especially on indigenous and local communities. In accordance with the medium term programme of work adopted by the first meeting of the conference of the members of the protocol (COP-MOP) (Decision BS-I/12), this provision was considered by the COP-MOP at its second meeting. COP-MOP 2 requested Parties and other governments, among other things, to provide their views and case studies concerning socio-economic impacts of LMOs (Decision BS-I/12). It also invited Parties and other governments to share information and experiences on socio-economic impacts of LMOs with the Biosafety Clearing House (BCH).

COP-MOP 4 considered views and case-studies concerning socio-economic impacts of LMOs on the basis of submissions from Parties, other governments and relevant international organizations. COP-MOP 4, in its Decision BS-IV/16, effectively postponed any decision with regard to socioeconomic consideration to get more technical guidance.[19]

18 "1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities" (Article 26. Socio-Economic Considerations, Cartagena Protocol on Biosafety).

19 Decision BS-IV/16: "the next coordination meeting on capacity-building activities to further consider possibilities for cooperation in identifying needs for capacity-building for research and information exchange on socio-economic impacts of LMOs. Any recommendations from the coordination meeting are to be submitted for the consideration of the Parties at their fifth meeting. Parties and other Governments were invited to continue to share information and experiences on socio-economic impacts of LMOs through the BCH. In addition, Parties agreed to review socio-economic issues at their six meeting based on information that may be provided through the second national reports" (UNEP n.y.i.).

Diverging interpretations on the scope of Article 26

Countries and analysts diverge on the interpretation of the scope of Article 26 (Falck-Zepeda 2009, UNEP 2008a). The USA and some analysts favour a more narrow interpretation of Article 26, limiting the scope to socioeconomic impacts related to biodiversity especially if indigenous communities are concerned.[20] According to these views, socioeconomic considerations are only relevant in very specific cases in which they may play a role for biosafety management, e.g. in deciding about insect-resistance management strategies. Socio-economic considerations are deemed helpful to understand potential applications and may be included in dossiers on a voluntary basis. Biosafety decision making bodies, though, should not deal with socio-economic considerations.

In a similar vain, the Global Industry Coalition (GIC) urged Parties to "limit any consideration of socio-economic impacts of LMOs to those impacts on the conservation and sustainable use of biological diversity. Broadening the scope and type of socio-economic considerations to those beyond this limitation would be inconsistent with the provisions of the Protocol, reduce the transparency of the regulatory process, and increase the overall cost and length of time required in regulatory decision-making" (UNEP 2008b:6).

Both the USA and the GIC also highlighted that the consistency of Article 26 with other international obligations. The WTO SPS agreement allows Members to take into account economics factors when assessing the risk to animal or plant life or health damage and determining appropriate measures. Economic factors include the potential damage in terms of loss of production or sales in the event of entry; establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.[21] WTO Members must then apply the least trade restrictive measure to achieve their appropriate level of protection. To be consistent with the WTO obligations, socio-economic considerations under the Protocol would, hence, have to be "limited to a clearly defined economic analysis that addresses the potential impact, either positive or negative, when applying sanitary and phytosanitary measures that affect trade of LMOs" (UNEP 2008a:14).

A main concern of countries holding such a view is that socioeconomic considerations would be used as a blanket justification to reject GMOs without providing clear reasons. Falck-Zepeda concluded in his analysis that a too "broad and undefined inclusion of socioeconomic considerations will, in the end, cause major disruptions and thus become a major limitation to technology development" (Falck-Zepeda 2009:95).

Other countries favour a broad interpretation of Article 26, maintaining that socioeconomic considerations are important to protect indigenous and local communities and users against any potential negative impact of GMOs.

Norway referred to a decision taken at COP 6 of the Convention on Biological Diversity (CBD), in which environmental impact assessment is considered "a process of evaluating the likely environmental impacts of a proposed project or development, taking into account inter-related

[20] "Parties must first analyze the impacts of LMOs on the conservation and sustainable use of biological diversity and only then may consider socio-economic issues arising from those impacts. Any broader interpretation of socio-economic considerations falls outside of, and is inconsistent with, the scope of the Protocol. When considering socio-economic issues as part of the decision-making process, Parties should take a balanced approach that considers socio-economic benefits that may accrue from the use of LMOs" (USA in UNEP (2008a).

[21] Referring to SPS Agreement, Article 5, para 5.

socio-economic, cultural and human health impacts, both beneficial and adverse."[22] Norway referred to the Norwegian Gene Technology Act which requires an assessment of social and ethical aspects and of sustainability on top of assessing environmental and health impacts (UNEP 2008a).

Friends of the Earth (FOE) highlighted the need to take socioeconomic impacts into account and that it should be possible to base any measures including restrictions and bans on such considerations. The Protocol covers transit, handling, and use of GMOs. All impacts in the territories on the livelihoods of the people occupying a territory would fall under Article 26, including socioeconomic considerations arising from human health impacts (referring to Art 1 and 4 of the Protocol). Not only direct but also indirect and long-term impacts should be considered (UNEP 2008a, b). In its broadest interpretation, socioeconomic impacts may even include hypothetical and uncertain impacts and also include any potential ethical, philosophical, and religious concern (Fransen et al. 2004).

These different views reflect the different regulatory cultures for GMOs described for the USA and the EU by many scholars (e.g. Isaac 2002, 2004 cf. Falck-Zepeda 2009:95) and which will not easily be reconciled. A clarification of the scope of Article 26 is still an awaiting decision in the course of another COP/MOP. Discussions on this issue are, however, unlikely to continue before 2012 (personal comm.). In any case, it is unclear if the provisions of the Protocol would be of any relevance for the USA which still has not signed the Protocol. Thus, the relationship of the Cartagena Protocol to the WTO legislation is of key importance.

WTO

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is the main legal instrument relevant for GMOs and general food safety. The SPS Agreement covers a wide range of health and environmental issues (see Table 8).

Table 8: Scope of SPS Agreement.

What to protect	Threat/damage
Human or animal life	Risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages, feedstuffs
Human life	Plant- or animal-carried diseases (zoonoses)
Animal or plant life	Pests, diseases, or disease-causing organisms
A country	Damage caused by the entry, establishment or spread of pests

Source: WTO (no publication date indicated). SPS Agreement Training Module.

The SPS Agreement makes reference to the Codex Alimentarius Commission (CAC) as the main standard setting body. In fact, the CAC (CAC 2007) specifies that risk management can consider "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade" (item 32). It lists a number of general principles to be considered when taking other factors into account:[23]

[22] Para 1(a), Annex to decision VI/7, COP6 CBD.

[23] Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle. Decision of the 24th Session of the Commission, 2001.

- " […] other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts; […]

- only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of the Codex Alimentarius;

- the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

- the integration of other legitimate factors in risk management should not create unjustified barriers to trade[…]; particular attention should be given to the impact on developing countries of the inclusion of such other factors."

While it is clear that this wording provides some scope for considering socioeconomic factors, the remit of CAC does not cover environmental risk assessment for GMOs. Furthermore, there is a lack of guidance what particular factors would be considered by Codex and would be acceptable under the SPS Agreement (König 2009). The SPS Agreement does have some scope for considering such factors in the territory of a Party but they have to be linked to health and safety. Furthermore, one important interpretation of the Appellate Body in the recent WTO dispute on GMOs was that measures taken by WTO Members do not need to be based on and interpreted in the light of one particular WTO agreement only (Pauwelyn, personal comm.). Therefore other WTO agreements might also apply[24]:

- The Agreement on Technical Barriers to Trade (TBT Agreement): the TBT Agreement allows governments to take measures if they have a legitimate objective, such as protecting health or the environment. TBT measures should not be more trade-restrictive than necessary. [25]

- The General Agreement on Tariffs and Trade (GATT): Article XX provides for exceptions from GATT rules in order to protect health or the environment. In addition, a country would have to show that it is necessary to violate the GATT to achieve the desired health or environmental protection.[26]

Both the TBT and the GATT agreement apply to all goods including seeds. Measures taken have to have a legitimate objective and must not be more trade-restrictive than necessary to achieve their

[24] http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm

[25] http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf.

[26] http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf.

protection goals. According to Pauwelyn (2009)[27], these two Agreements provide a broader scope for considering socioeconomic factors. The GATT agreement provides a list of issues which give leeway for interpretation and ample scope for considering socioeconomic impacts. More difficulties are envisaged if effects outside the own territory are concerned. From the Shrimp-Turtle case, however, in can be inferred that it is possible to link measures to global issues.[28]

A key issue with both Agreements is discrimination. Measures taken must equally apply to products from all countries including domestic products. Also important is that measures must not discriminate between 'like products'.[29] Here the key question is what counts as a 'like product'. In case of a trade dispute, a Panel would thus have to decide whether GMOs and their products were substantially the same as their non-modified counterparts. In assessing likeness, the controversial issue of whether the analysis should be limited to the physical characteristics of the products or should also take into account the process and production methods is still open. The relevant jurisprudence is not conclusive and juridical experts are deeply divided on the subject (Zarrilli 2005). Pauwelyn, for instance, argues that the fact that consumers very much favour GM free food over GM food would for instance be important evidence of non-discrimination (personal comm.).

Another important question is how to avoid that such measures would be interpreted in the light of the SPS Agreement only. In the WTO dispute on GMOs, the EC in fact argued that the TBT agreement permits the use of trade-restrictive technical regulations for objectives such as protection of human health or safety, animal or plant live or health, or the environment.[30] The EC argued that the SPS Agreement does not provide sufficient scope as it restricts the term environment to the life or health of specific animals or plants. The protection of the environment more broadly referred to the protection of living space or of biodiversity, and damage can occur without a negative effect on wild flora and fauna. The Appellate Body did not accept this argument. The Panel Report highlighted a close relationship between the references in the Directives 90/220/EEC and 2001/18/EC to environment or environmental risk assessment and references to human, plant or animal life or health – with the latter being covered under SPS. Furthermore, the panel felt that 'other damage' as specified in Annex A (1)(d) of the SPS Agreement could itself apply to environmental damage beyond that covered in references of human, animal and plant life or health (Winham 2009). Winham considers this Panel decision as the most far-reaching element of the Panel Report. It attracted considerable criticism as unjustified interpretation of the SPS agreement (Palmer 2006), but since there was no appeal this issue will have to be resolved elsewhere. According to Winham, the problem here is not just the interpretation of the Panel - it is the 'expansive manner' the Agreement itself is written in, thereby covering a lot of grounds.

Overall, there seems to be ample scope for considering socioeconomic aspects in GMO authorisations. Measures taken in the context of the WTO regime should be rationally motivated, that is, related to a legitimate objective and based on scientific or other evidence, should not be more trade-restrictive than necessary to achieve their protection goals and should be non-discriminatory. One WTO legal expert interviewed in the context of this study believed that it is

[27] The remainder of this section is based on Pauwelyn (2009) partly documented in Ministry of Agriculture, Nature and Food Quality; Ministry of Housing, Spatial Planning and the Environment (2009).

[28] http://www.wto.org/english/tratop_e/envir_e/edis08_e.htm.

[29] The term 'like products' is referring to similar products.

[30] With the main constraint that such regulations "shall not be more trade restrictive than necessary to fulfil a legitimate objective, talking account of the risks non-fulfilment would create" (TBT Agreement, Art.2.2).

possible to meet these legal requirements. However, given the different interpretations of legal experts this requires an in-depth analysis considering case-law.

United Nations Organisation

The FAO Draft International Code of Conduct on Plant Biotechnology prepared by the FAO Commission on Plant Genetic Resources in 1993 (CGRFA 2002) also holds relevant provisions on the consideration of socioeconomic factors (cf. Glowka 2003):

For example, one of the draft Code's eight objectives is "to help assess and minimize possibly adverse socio-economic effects of biotechnology in agriculture and the food industry on farming communities" and to develop the countries' economies (CGRFAO 2002: Art.1.6). From this flows one of the key provisions of the draft Code: promoting the transfer and development of "appropriate biotechnologies" applied to plant genetic recourses (ibid: Art. 5.1). "Appropriate biotechnologies" include those "which contribute to sustainable development" (ibid: Art.3). Criteria for identifying appropriate biotechnologies are provided and include those that are: (i) technically feasible; (ii) bring tangible benefits to users; (iii) are environmentally safe; and (iv) socioeconomically and culturally acceptable (ibid: Art.3).

Additionally, the draft Code emphasizes preventing and mitigating possible negative effects of agro- and food biotechnologies. To this end, the draft Code first emphasizes foreseeing and preventing possible negative socio-economic effects of agro- and food biotechnologies (ibid Art.8.1). Governments and international organizations should, as part of their technology assessment procedures, monitor and assess the socio-economic impacts of biotechnologies.

The Draft Code of Conduct

In 1991, the Commission on Genetic Resources for Food and Agriculture (CGRFA) requested the preparation of a draft Code of Conduct on Biotechnology, with the aim of maximizing the positive effects, and minimizing the possible negative effects of biotechnology. The Draft Code of Conduct contains five modules: biosafety and other environmental concerns; intellectual property rights and farmer's rights; appropriate biotechnology for developing countries; minimizing the possible negative effects of biotechnology; and monitoring. In 1993, noting that the Convention on Biological Diversity was considering the development of a Biosafety Protocol, the CGRFA postponed further work on the Draft Code of Conduct till the completion of the negotiations for the revision of the International Undertaking on Plant Genetic Resources, which concluded in 2001. Work on the Code was resumed with a report on policy issues, gaps and duplications to the 2004 Tenth Session of the CGRFA.[31]

No documents have been released since then, so the status and the future development of the Draft Code of Conduct are not entirely clear. If finalized and adopted, the Draft Code of Conduct could facilitate the broadening GMO assessment and decision making.

United Nations Environment Programme (UNEP)

The UNEP Technical Guidelines on Biosafety acknowledge the importance of assessing socio-economic and other impacts of new biotechnologies. Unfortunately, the Guidelines do not elaborate on these issues (UNEP 1995).

[31] http://www.fao.org/ag//CGRFA/biocode.htm.

Summary

Article 26 of the Cartagena Protocol on Biosafety establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms in reaching a decision on whether to import these organisms, especially with regard to the value of biological diversity to indigenous and local communities. The scope of this Article is contentious with the USA and industry favouring a more narrow interpretation, and others including socioeconomic effects beyond the role of biological diversity to indigenous and local communities. The Article also includes a provision to make sure that Parties' considerations of socioeconomic aspects meet their other international requirements thereby possibly limiting the scope of interpretations. Clearly, the WTO agreement has to be considered in the next steps of discussion. Moreover, non-Parties, such as the USA, are and will not be bound to the requirements of the Protocol. Therefore the possible role of the Article as a reference point for EU or national policy remains unclear.

WTO legislation does not a priori exclude socioeconomic aspects as long as they are verifiable, transparent, and non-discriminating. In developing their line of argumentation, countries need to define socioeconomic aspects as risk-, health- or trade-related to make them subject to any of the three WTO Agreements. Since the WTO dispute, GMOs have been considered almost exclusively in the context of the SPS Agreement as if no other possibilities exist. In fact, both the TBT- and the GATT Agreement provide more scope for addressing socioeconomic factors compared to the SPS Agreement. The recent WTO dispute on GMOs concluded that it is possible to base measures on more than one agreement. Overall, it seems to be possible to meet the key requirements, i.e. a legitimate objective, based on scientific or other evidence, not more trade-restrictive than necessary, and non-discrimination when making a case for socioeconomic consideration.

The FAO Draft International Code of Conduct on Plant Biotechnology prepared by the FAO Commission on Plant Genetic Resources in 1993 also holds relevant provisions on the consideration of socioeconomic factors. If finalized and adopted, the Draft Code of Conduct could facilitate the broadening GMO assessment and decision making.

Challenges for EU institutional arrangements

As discussed in the preceding chapter, Regulation 1829/2003 provides scope for an ex-ante assessment of socio-economic assessment. This Regulation covers GM food and feed. It is assumed, however, that this scope would also exist in case of combined applications for cultivation and food/feed submitted under the Regulation according to the one-door-one-key principle. The discussion in this chapter therefore considers the legal context of the Regulation rather than of the Directive.

A key issue in implementing socioeconomic assessment for GMOs would be the institutional location at the EU level. Though the remit of such an institution remains to be determined, it can reasonable be expected that it would comprise the evaluation of socioeconomic data provided in dossiers and coordination to Member States. There is no obvious entity at the EU level which could deal with socioeconomic assessments. Socioeconomic considerations of GMOs have so far been considered as belonging to the realm of risk management and EFSA has been in charge of risk assessment. Still, the scope of EFSA has been extended and has been proposed to be further extended. Section ”Role of the European Commission and the Member States”, therefore, discusses the possible role of EFSA. Another key issue is the role of Member States given the context specifity of socioeconomic data (discussed in chapter ”Challenges to a socioeconomic assessment framework”). The section ”Role of the European Commission and the Member States” in this chapter, therefore, briefly discusses the role of the EC and the Member States.

Role of EFSA

According to the Commission's White Paper, EFSA shall not be entrusted with risk management tasks because this would reduce democratic accountability within the EU (EC 2000 note 38, at 32). The European Commission policy document on EU agencies and expert advice emphasises that its experts “cannot be granted decision-making power in areas where they have to arbitrate between conflicting public interests, exercise political discretion, or carry out complex economic assessments” (EC 2002a). EFSA’s remit is, therefore, clearly limited to provide scientific advice (EU 2002)[32].

The scope of EFSA’s assessments has so far been limited to health and environmental risks though recently being broadened to include health benefits in the course of health claims assessment (EFSA 2009b). EFSA prepares itself to introduce risk-benefit assessment more broadly (EFSA 2009a). In the course of such benefit assessments, EFSA will not address social, economic and other considerations such as ‘cost-effectiveness’ considerations which are considered the realm of risk management (EFSA 2009a; see also Geslain-Lanéelle 2007 cf. König 2009) though the border line between risk assessment and risk management is considered to be somehow flexible (EFSA 2007a). Risk-benefit comparisons and trade-off analyses involving monetary, economic and social aspects would be beyond the remit of EFSA (König 2009). EFSA proposed that if requested by the risk-benefit manager in the scoping step their experts could conduct a “comparison of risks and benefits using a composite metric […] to express the outcome of the risk benefit assessment as a single net health impact value” (EFSA 2009a: 2). Commonly used measures for comparing health risks and benefits often quantify benefits in terms of social health utility or monitory units. By using other types of measures, EFSA considers that it may be able to avoid this problem.

[32] EFSA shall “provide scientific advice and scientific and technical support … “[Art. 22. 2]; “… provide scientific opinions … “[Art. 22.6]; “…collect and analyse data to allow the characterization and monitoring of risks … “[Art. 22.4]; “…promote and co-ordinate the development of uniform risk assessment methodologies ...”[Art. 23(b)]; “… commission scientific studies …” [Art. 23(d)].

A potential role for EFSA in a broader assessment of GMO impacts could therefore be seen in analogy to its proposed role for assessing health benefits, e.g. assessing health claims if applications of second generation GM food would include such claims.

Whether EFSA could also assess potential environmental benefits of GMOs claimed in the dossiers appears to be a more difficult question. In contrast to health benefit assessment it might be more difficult to avoid expressing benefits in monetary or economic terms. EFSA, in fact, considered extending the scope of GMO environmental risk assessment (ERA) to include also benefits (EFSA 2007b, c, d; EFSA 2008) – though the most recent draft guidance for ERA does not include risk-benefit considerations. EFSA apparently considers including such aspects in its upcoming guidance for GM animals (EFSA 2009c).

Vos and Wendler (2009) proposed to extent the scope of EFSA's assessment even further. The authors suggested the establishment of a social science unit and a scientific "Concern Assessment Panel" within EFSA. In the framework of integrated food, safety governance developed in the course of the FP7 project SAFEFOODS[33] concern assessment is dealing with all types of societal concerns encompassing socioeconomic impacts. The proposal is not specific for GMOs but covers the whole food chain and all areas of food safety (Ely and Stirling 2009). According to Vos and Wendler (2009) this would still be in-line with EU General Food Law as long as socioeconomic aspects would be approached in a scientific way ,"…gathering evidence about concerns through scientific methods (and hence not about expressing opinions on that evidence)" (ibid: 108). The creation of a new scientific unit and panel is not unusual, e.g. the Plant Health Panel was established only recently. The authors, therefore, concluded that there would not be a need to change the mandate of EFSA in the Regulation 178/2002. Such an initiative would only require action by the Management Board and a Commission Decision in the framework of the comitology procedure.

This proposal is, however, strongly objected by industry which also has a different interpretation of the legal aspects (Rawling 2009).[34] Societal concerns are considered different from physical sciences – including that societal concerns within EFSA would distract its scientific reputation and could "overshadow the science" (p 236) thereby damage its credibility and hamper international harmonisation. Such an assessment would stretch EFSA's resources and could delay risk assessments. It is considered to be beyond the mandate of EFSA by the General Food Law (food and feed safety) and these legal limitations would require changing the mandate only a few years following EFSA's inception. Moreover, concern assessment is also considered to be dealt with by risk management advised by the European Groups on Ethics in Science and New Technologies (EGE). Rawling (2009) concluded that therefore, concern assessment should be kept in the risk managers' toolbox while strengthening expert advice and stakeholder participation on these issues.

Interestingly, Rawling does not generally object to the underlying idea suggesting that parts of the industry might accept broadening the assessment to included societal concerns. The commentary, however, seems to be based on the assumption that societal concerns would rather be considered in the context of new legislation than market approvals with already existing EU law. The proposal to establish an additional unit and Panel within EFSA would allow societal concerns to be considered in the latter type of assessments too.

[33] http://www.safefoods.nl/.

[34] The commentary of Rawling (2009) seems to be a rather general food industry's perspective and does not preclude a different view from the agricultural biotechnology industry.

In principle, the mandate of EFSA could also be changed. Such a reform of EFSA could be inspired by the REACH legislation (EU 2006) which allowed establishing two committees: a scientific and a socio-economic committee linked to the European Chemical Agency (ECHA). This would, however, require amending EU legislation in particular, the EU General Food Law.

Objections and even outright opposition can also be expected from other stakeholders to extent the scope of EFSA's assessment too much beyond food and feed safety issues. Another issue here is the lack of trust in EFSA (see stakeholder interviews summarised further down this chapter).

Role of the European Commission and the Member States

Under the EU General Good Law, risk managers (DG SANCO and the Member States' authorities) have to take into account: a) the results of risk assessment, in particular the "opinions" of the EFSA; b) "other factors legitimate to the matter under consideration", and c) the "precautionary principle" within the limits laid down in Article 7 of the Regulation (Alemanno 2008).

Depending on the legal interpretation, this provision allows risk managers to take other factors into consideration when reaching a final decision[35] – at least in cases where the precautionary principle is invoked (König et al. 2010). This is because "it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based"[36]. The relevant factors for the health protection of consumers may consist, for instance, of societal, economic, traditional, ethical and environmental factors[37]. This approach is in line with the Communication on the precautionary principle, which indicates that in case of scientific uncertainty, "[…] judging what is an 'acceptable' risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers" (EC 2000: Summary).

The European Court of First Instance (CFI) made also clear that the EC and the Council have considerable scope when weighting all bits of information[38]. The EC may disregard conclusions drawn from expert opinion, as members of expert committees have "neither democratic legitimacy nor political responsibilities", whereas the EC's authority "is rendered legitimate and democratically accountable" pursuant to Article 211 of the European Community (EC) Treaty, and by the European Parliament's political control.

Risk management measures are decided in the regulatory committee – in case of Regulation 1829/2003 this is the Standing Committee on the Food Chain and Animal Health (SCFCAH). Members

[35] Several provisions of the Regulation provide that risk management decisions may consider not only risk assessment but also "other legitimate factors". See preamble (19), Article 3 (12) and Article 6 (3). See also Article 7(1) of Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L287.

[36] See Recital (19) of the Regulation.

[37] The list of examples provided by the Preamble of the Regulation seems slightly narrower than the one contained within the White Paper (see supra note 145, para 4), which mentions "environmental considerations, animal welfare, sustainable agriculture, consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods". However, both lists containing mere examples, their differences do not carry any particular value and should not be overemphasised.

[38] European Court of Justice, T-13/99, Pfizer ECR II-3305, at paras. 200-201. the European Commission asked advice from the Scientific Committee on Animal Nutrition (SCAN) on the use of antibiotics as growth promoters. Although SCAN did not consider the use of Virginiamycin for the stated purpose an immediate risk to public health, the Commission and the Council decided to revoke the authorisation on grounds of remaining uncertainties. The court upheld the Council's decision (cf. König 2010).

of the SCFCAH are usually representatives of national CAs. In analogy to risk of GMOs it could be expected that SCFCAH would also discuss aspects of socioeconomic assessments which have not been resolved elsewhere. Any explicit weighting of scientific and socioeconomic factors and any decision proposed as a trade-off would be discussed and voted on by SCFCAH. Only if there was no qualified majority, the decision would go to the Council. If the deadlock continued, the decision would fall to the EC.

At present, it is entirely opaque how such factors, if at all, are being considered by the EC and the Member States and how they are influencing their views and voting. There is also little formal guidance for EC and Member States officials what these factors are, how they are considered and whom to consult – this is effectively in the discretion of the EC and the Member States. According to König (2009), there are no legal restrictions to design more formal procedures for assessing socioeconomic impacts.

In practice, however, the EC is not prepared to conduct such assessments internally. If such assessments are envisaged to be supplementary information considered on a limited range of GMO issues, it might be possible to dedicate a unit of e.g. DG SANCO to this issue and to contract out more extensive studies. If socioeconomic assessment is envisaged on a routine basis – e.g. in each or for many applications –, a need for establishing a dedicated body will arise. The remit and size of such a body would depend on the relative role of EU authorities in socioeconomic assessment.

A perhaps even more important reason for establishing a separate body is that the technical evaluation of socioeconomic data and even the conduct of a fully fledged socioeconomic assessment might be considered as additional scientific advice into risk management and different to the core tasks of risk management, weighting of evidence on impacts and decision options, and mitigating negative effects. Applying the rationale of the present paradigm in EU food safety governance to separate expert advice from decision making would require a body outside with some independence of the EC. An indirect consequence of this line of thoughts is that standards for expert advice to governments might also be applied to the design and work of such a body.

Such an EU body will have to liaise with its counterparts in the Member States. As discussed in more detail in chapter “Challenges to a socioeconomic assessment framework”, socioeconomic assessments are very much context specific and will therefore have to rely on an in-depth knowledge of the national or even regional context and will require access to such data. A dedicated EU body will be able to evaluate aspects which are less specific and will heavily depend on the work of similar bodies in the Member States. What can sensibly be done on the EU level and what requires contribution from Member States will have to be thoroughly discussed and regulated.

Views from Austrian Stakeholders

Views relevant to the question of institutional location were collected from Austrian stakeholders in the course of ten semi-structured interviews.[39] All respondents argued that it would not be sufficient to assess socioeconomic impact at the EU level only. An EU institution could possibly issue guidance, coordinate communication with Member States, and be in charge of some topics. Any serious assessment would have to rely on inputs, data and/or expertise from the Member States or might even be conducted in the Member States. In-depth knowledge about agricultural and rural context would only be available in Member States – sometimes even on the regional level only, e.g. to express assessments in monetary terms. Interviewees diverged on the question of the appropriate

[39] For the interview guidance and the list of interviewees see Annex.

location and whether Länder (provinces) and regions would have to be involved. Almost all respondents were reluctant to consider a role for EFSA. Some were strongly refusing any role for EFSA in evaluating socioeconomic assessment for two different reasons – because there is a lack of trust that EFSA is doing a good job in the GMO area, and to keep scientific risk assessment separate from socioeconomic assessment. Some respondents considered the EC to be the proper place; others proposed a role for the EEA or setting up a new institution or committee and/or to contract studies to universities.

Summary

A key issue in implementing socioeconomic assessment for GMOs would be the institutional location at the EU level. Socioeconomic factors have so far been perceived to belong to the realm of risk management, i.e. the EC and the Member States. If risk management frequently asked for and evaluated socioeconomic data, the establishment of a dedicated body might be envisaged. From a governance perspective, providing advice on socioeconomic aspects can be considered as just another scientific advice to risk management and not as part of its core tasks, weighting of evidence on impacts and decision options, and mitigating negative effects. Applying the rationale which was underlying the establishment of EFSA to separate expert advice from decision making would require a functional and/or institutional separation to the EC. There is, however, no obvious entity at the EU level which could deal with socioeconomic assessments. EFSA has been proposed to cover some aspects (health and environmental benefits). EFSA's scope might even be broadened to include a social science unit for more broadly assessing societal concerns. The latter proposal is, however, objected by industry and stakeholders. Moreover, commentators diverge on the need for changing the legal basis of EFSA, the EU General Food Law.

Industry suggested making use of the European Group on Ethics which could be complemented by another committee looking into economic and social issues. Though the remit of such a committee/body remained to be determined, it can reasonable be expected that it would comprise the evaluation of socioeconomic data provided in dossiers and coordination to Member States. Given the context specifity of socioeconomic impacts, Member States will have to play an important role in providing data and evaluations more specifically for national and regional context. It appears to be unlikely that a Committee of independent expert advisors could play such a role.

In principle, the mandate of EFSA could be modified along the lines of REACH legislation, which allowed establishing two committees: a scientific and a socio-economic committee linked to the European Environment Agency. This would, however, require amending EU legislation in particular, the EU General Food Law.

Challenges to a socioeconomic assessment framework

This Analysis

Underlying assumptions

The analysis in this chapter is based on the assumptions that (i) a socioeconomic impact assessment (SOEIA) framework will be an integrated part of an overall governance framework regulating GMOs and (ii) that it will need to be developed in symmetry to risk assessment. SOEIA is thereby conceptualised as another form of providing scientific expert advice on policy making. As such it will be expected to consider and accommodate relevant procedural guidance. While there is no such guidance specifically for the SOEIA type of assessments, there is general guidance on governance, expert advice and impact assessment for the EU context. Another point of reference are recent risk governance frameworks (better: risk benefit governance frameworks), some of which have already accommodated the need to include broader societal concerns. Furthermore, insights from social science research on risk governance would also be relevant.

The first section of this chapter provides arguments underlying these assumptions. Based on the assumption outlined above, the following sections outline what are considered to be key elements for establishing a robust socioeconomic assessment framework. Section “Specifity of socioeconomic data” highlights the special characteristics of socioeconomic data and section “Guidance and standards” draws some conclusions for the previous sections for establishing assessment guidance and standards. The final section discusses the relationship of socioeconomic considerations and risk assessment.

Arguments supporting the underlying assumptions

Standards for good governance and expert advice

Issues of governance and expert advice on policy making have been gaining increasing attention over the last 15 years as documented by some key policy documents issued by the EC: on food safety (EC 2000), on governance (CEC 2001), on expert advice (CEC 2002) and on impact assessment (EC 2005). These documents address issues of openness, participation, accountability, effectiveness, coherence, and the relationship between scientific advice and policy making. It can reasonable be expected that these documents provide a reference for a design and implementation of any kind of SOEIA.

The consideration of ‘other factors’ besides health and environmental risk assessment in agro-food decisions has often been blackboxed. Dreyer et al. (2009) and Dreyer and Renn (2009) have opened up this blackbox and conceptualised the consideration of other factors as scientific advice, though mainly from social science. Thereby governance framework is designed to include two strands of advice which feed into policy making. Going even beyond that, they proposed a design similar to scientific risk assessment. This proposed design has several advantages: it establishes symmetry between the two types of assessment, and it provides a structure for scientific consideration which would be open to scrutiny by and input from decision makers, stakeholders and interested public. It also provides for a separation of socioeconomic assessment (=scientific advice) from decision making (policy) – another central paradigm in EU food safety policy.

Another important similarity is that both data and interpretations of both risk assessment and socioeconomic considerations are under close scrutiny by a broad range of stakeholders and are triggering fierce controversies. Consequently, there is a need to design SOEIA in a similar way as risk assessment allowing to generate robust advice from social science and allowing for public scrutiny.

Controversial nature of assessment procedures and interpretation

The question of what constitutes a proper GMO risk assessment has been discussed for more than two decades. EU Member State CAs, Committees and individual experts sometimes have different views on scope, approaches, methods, data requirements and data interpretation. Over time, guidance documents on GMO risk assessment have become more and more comprehensive and detailed, and hands-on experience in conducting and evaluating risk assessments has accumulated. Nevertheless, GMO risk assessment requirements still include much more leeway for interpretation compared to more formalised procedures, e.g. for chemicals. There are, however, still controversial issues remaining.

As the literature on socioeconomic impact analysis suggests, similar or even more difficult controversies could be expected in case SOIEA data would be routinely reviewed in GMO application procedures.

The majority of literature on socioeconomic impacts of GMOs is focusing on agro-economic aspects. These assessments frequently use methods from applied economics and refer to existing databases in order to quantify the impacts of GMOs. These studies, however, sometimes arrive at very different conclusions which sometimes triggered discussions well documented in the literature.

One example is the study “Failure to yield” issued by the US Union of Concerned Scientists (Gurian-Sherman 2009). The study focussed on the performance of two GM food crops, maize and soybean, more specifically on the role of the genetic modifications in enhancing yield. This is an important distinction when a comparative analysis should specifically identify GM effects without confusing with effects from altered agricultural management practices. The study triggered a controversy about the appropriate geographical perspective, the exclusion of non-food crops etc. What is interesting here is the controversy about appropriate reference data: Gurian-Sherman used mostly data from field trials where GM and conventional crops have been comparatively analysed (2009a, c), whereas others are referring to data from commercial cultivation (PG Economics 2009a) and from world regions without commercial GM planting (Parrot 2009). Another point in the debate was whether operational yield or intrinsic yield[40] (as in the UCS report) provides an appropriate performance indicator. Gurian-Sherman (2009a, c) argues that intrinsic yield is important to assess the real contribution for improving food supply. Parrot (2009) argues that herbicide-tolerant crops contribute to reduce tillage which prevents soil erosion, saves fuel and reduces pesticide and fertilizer runoff.

Other controversies unfold on two reports of the Organic Center (Benbrook 2009a, b), mainly on scope and methodology:

- Scope: Organic Center (OC) report not considering environmental benefits from use of HT technology from facilitating of no/reduced tillage production systems (PG Economics 2009b on Benbrook 2009a report)

[40] Operational yield also considers losses due to pests, weeds, unfavourable growing conditions etc. In that sense, intrinsic yield serves as a theoretical value which – according to Parrot (2009) is almost never achieved.

- Methodology and basic assumptions for calculating herbicide use (with both authors criticising the other's approach (ibid); on US seed price premiums for GM and organic seeds (PG Economics 2009c, Benbrook 2009b).

The examples above highlight different views on scope and methods. Smale et al. (2008, 2006) highlight how applied economic methods determine the type and extent of limitation. The authors analysed peer reviewed literature on GMO impacts. Several interesting observations were made. First, about halve of the peer-reviewed papers focusing on developing countries between 1996 and 2006 investigate farm-level effects of GM cotton – hence much fewer data are available on effects on industry and trade and on other GM crops (maize, rice, soybean). Second, they found that only a small number of different authors are conducting these analyses. Third, the time periods considered in the analyses are usually quite short. Fourth, they highlighted a number of limitations regarding the methods being used. One example is the absence of information on one of the basic assumptions for calculating net benefits for farmers: which variety the famers would have grown and which practices the farmers would have used if they had not opted for GM crops. Another example is that GM crops perform with considerable variation depending on location and time. The frequent use of averages in the economic analysis masks these variations. In certain contexts, costs, in fact, outweigh benefits. The authors also stated that in general "no single method is in and of itself sufficient to analyse the impacts" (Smale et al. 2008: 539). In order to obtain more robust conclusions, multiple methods will be needed. Furthermore, they highlight the lack of rigorous consideration of impacts on labour, health environment, equity and poverty (ibid.).

The examples given above focus on agro-economic impacts employing quantitative methods. Assessment of broader social impacts and/or complex dimensions such as multifunctionality of agriculture and/or using qualitative methods can be assumed to raise even more controversy.

Once it has been accepted that SOEIA will have some similarities to risk assessment and will be developed along similar procedural standards and concepts, we can go on with identifying key issues that need careful consideration when setting up such procedures:

- What would be the normative baseline?
- What would be the scope?
- What approaches, concepts, criteria and methods to be used?
- How should the questions above be settled?
- What role for public participation?
- Is there a particular characteristic of socioeconomic data?
- What type of guidance would be needed?
- What would be the relationship to risk assessment?

These questions are considered challenges as some of them need agreement on the EU level. Each question is briefly described and discussed in the following sections.

How any assessment starts: clarifying normative baselines and key reference concepts

Any risk assessment/risk-benefit assessment starts with clarifying questions (IRGC 2005b):

- What are the potential damages or adverse effects?

- What are the primary and secondary benefits, opportunities and potential adverse effects?

These are questions referring to preconceptions of 'damages', 'adverse effects' (which are both linked to protection goals), and 'benefits' (which are linked to e.g. aims of agricultural policy) - all of which needs clarification *prior* to an assessment being conducted. If uncertainties about baselines prevail, disputes can emerge in assessment processes which can slow down the process and make it less predictable for applicants as illustrated for the case of GM crops in Box 2.

Box 2: Disputes about normative baselines in assessing adverse environmental effects of GM crops

In particular in the context of GM crop cultivation, the question of what would constitute the normative baseline for adverse effects to the environment turned out to be controversial (Levidow et al. 2000): under Directive 90/220/EEC, present agricultural practice was accepted as a baseline for evaluating environmental effects of GMOs. Hence, it was deemed acceptable that a herbicide (e.g. due to extensive cultivation of GM herbicide tolerant rape) would become ineffective to control weedy herbicide tolerant rape or if Bt-toxin would become ineffective for controlling insect pests in conventional agriculture due to occurrence of resistance triggered by extensive cultivation of GM Bt crops. This was a view initially held by the UK CAs. Other Member States took a different approach. Denmark, for instance, argued that the risk assessment should encompass the implications for the overall herbicide usage and future weed-control options, especially given that oilseed rape can hybridize with weedy relatives. Sweden argued that broad-spectrum herbicides would damage wildlife habitats by eliminating all vegetation and thus demanded that such effects should be included in the evaluation of herbicide tolerant GM crops. France and Italy pointed to the possible occurrence of multiple-resistance weeds that might result from large-scale commercial use of various herbicide tolerant GM crops. In case of Bt crops, the EC considered that the generation of Bt resistant pest insects was not an adverse environmental effect under Directive 90/220/EEC because conventional means for managing resistant pest insects are still available. By contrast, an increasing number of Member States see the occurrence of Bt resistant insects as adverse effects. Therefore, Denmark demanded that resistance management measures be included in the Bt maize dossier. Sweden requested additional studies on whether a reduction of the target-organism population would affect insects which feed on them or would affect plants which they pollinate. France, while initially adopting the view that insect resistance would not cause an adverse effect under Directive 90/220/EEC, did not sign the authorization before resistance management measures had been negotiated between the notifier and its CA.

In the course of these and other authorization procedures of GM crops (Levidow and Carr 2000, Torgersen and Seifert 2000), the normative baseline was challenged. The UK and the EU Scientific Committee on Plants, for instance, considered conventional chemical intensive farming as the normative baseline for assessing the risks. Austria, in contrast, considered organic farming as a reference and included agronomic effects in the scope of its assessment; meaning that any increase of herbicide usage is unacceptable. The Netherlands evaluates whether persisting effects on the natural vegetation may arise from GMO-release, Belgium will not accept a release that could aggravate existing environmental problems. The Italian authorities attached a monitoring requirement to permission for transgenic maize, whereas Denmark included agronomic effects by using the criterion of "sustainable social development" which was even included in the national law.41

In analogy to risk/benefit assessment it can therefore be asked: what is to be protected and what constitutes adverse/beneficial effects or – to put it into other words: what are the relevant normative baselines for assessing socioeconomic impacts? The answer to these questions is obviously more difficult compared to the risk assessment. A SOEIA is envisaged to reveal

[41] In fact, the inclusion of agronomic and socio-economic criteria had been essential for achieving national consensus on GMO regulation (see von Schomberg 1998).

socioeconomic impacts which will either be risks or potential benefits based relevant to normative baselines. Ideally a systematic identification and characterisation of all socioeconomic effects followed by a subsequent assessment will be done – clearly this will not be achievable. The practitioner's approach is to analyse impact dimensions (scope) which are linked to normative baselines. Only then it is possible to consider proper endpoints, methods etc. One example for such a baseline is the agricultural system. If agro-environmental, economic and social impacts on the agricultural context have to be considered, the question is which agriculture.

Conventional agriculture as a baseline?

When discussing the socioeconomic effects in GMO authorisation, the nature of such a normative baseline remains unclear. The Council Conclusions seem to require information on both socio-economic benefits and risks and on agronomic sustainability (CEU 2008). This request was subsequently interpreted by the Dutch Government and COEGM as assessing the contribution of GM crops towards more sustainable agriculture (COGEM 2009). COGEM selected conventional agriculture as their normative baseline[42]. The rationale of their approach is that GM crops should be checked against a list of sustainability criteria and should be expected to rank similar or better than conventional crops. By taken conventional industrial agriculture as a baseline it is implicitly accepted.[43]

Such a baseline might well work for The Netherlands. Different views can be expected though, from countries with different agricultural structures and practices. As illustrated by the examples in Box 2, Austria considers organic farming as a reference in GMO environmental risk assessment. As argued in the following section, conventional agriculture is even more unlikely to be accepted if social and economic effects will be considered.

Context dependency

Agriculture differs considerably between Austria and the Netherlands. More than 40% of Austrian farms are located in mountainous areas[44] which are considered disadvantaged agricultural areas according to EU criteria. So disadvantaged regions cannot compete with industrialised and intensive agriculture and are therefore seeking alternative market options (e.g. high quality, sustainable/organic products). In 2007, more than 17% of the total arable land was dedicated to organic farming. These agricultural regions differ in their socio-economic characteristics from regions with large-scale farming. Consequently, the meaning of conventional agriculture as a baseline would be specific for Member States or even for regions.

Moreover, the COGEM report seems to favour a more narrow technocratic definition of agriculture as "the entirety of economic activities in which the natural environment is modified for the production of plants and animals intended for human use" (COGEM 2009: 6). This definition does not consider the multifunctionality of agriculture. Multifunctionality, however, is *the* central feature of the European Model of Agriculture (EMA), which became a cornerstone of the Common Agricultural Policy (CAP) in the European Council in Luxembourg in 1997. Apart from its production function, the

[42] Referred to by COGEM as 'reference'.

[43] The COGEM report, however, acknowledges that conventional agriculture cannot be unequivocally defined and may differ from country to country.

[44] http://www.landnet.at/article/articleview/60304/1/1455.

agricultural sector "must be capable of maintaining the countryside, conserving nature and making a key contribution to the vitality of rural life, and must be able to respond to consumer concerns and demands regarding food quality and safety, environmental protection and the safeguarding of animal welfare" (CEU 1997). Austria has a long tradition in considering multifunctionality – the concept has become firmly established in Austrian agricultural policy as early as the mid 1990ies. Several authors have described characteristics of Austrian agriculture well beyond the pure productivity function (cf. Schmid and Sinabell 2004):

- Production function, supply of services
    - food, feed, fibre, biomass, energy carriers
    - tourism, secondary activities, community services, waste management, recycling
    - food security, animal welfare
- Spatial function, viability of rural economies
    - rural infrastructure, street network, provision of land, open landscape
    - direct and indirect employment, rural value added, direct sales, buffer function on labour market, support system for rural dwelling
- Ecological and landscape esthetical functions, viability of rural environment
    - landscape stewardship, landscape management, provision of cultural landscapes
    - maintenance of natural resources, biodiversity, deer feeding, genetic resources
- Protection function and regeneration of natural resources
    - groundwater recharge, maintenance of surface water courses
    - protection of the environment, protection against natural hazards
- Socio-cultural function, cultural role of farmers
    - rural life style, maintenance of historical objects and local traditions

A baseline model of agriculture factoring in all these characteristics and roles of agriculture would broaden the scope of a socio-economic assessment and is therefore likely to lead to different results and conclusions compared with a more narrow view on agriculture.

Similar differences are to be expected when referring to sustainable development.

Sustainable development as a key reference

Sustainable development appears to be a central theme when considering socioeconomic aspects. It is referred to in the Norwegian Gene Technology Act (Norwegian Biotechnology Advisory Board 2000/2003; see also section on Norway) and in the COGEM discussion paper (COGEM 2009). Similarly, the Council Conclusions highlighted "agricultural sustainability" (CEU 2008).

Sustainable development is a very broad and general concept which has been defined in many different ways. COGEM and the Norwegian Biotechnology Advisory Board (NBAB) referred to the Brundtland definition that sustainable development needs to meet "the needs of the present without compromising the ability of future generations to meet their own needs".

COGEM acknowledges the vagueness of the concept and the definition and that it needs to be translated into a clear framework specifying criteria and methods – it also acknowledges that there are no criteria for sustainable agriculture which can readily be used. Biomass and soy were mentioned as examples where a sustainability assessment was being operationalized (COGEM 2009). The Committee avoided the difficulty of defining sustainability first and then to derive criteria based on the definition. Thereby it maintained the vagueness and proposed sustainability dimensions (dubbed 'themes') and criteria (a list is provided in Table 10). These dimensions and criteria are largely based on the results of two preceding research projects of COGEM, an analysis of the recurring topics in the GMO debate, and an analysis of the possible contribution of GM crops to sustainable agriculture in the Netherlands.

The Norwegian Biotechnology Advisory Board (NBAB) specified 'ideas', on which sustainable development is based. To them, these ideas provide a structure for deriving the checklist questions and conducting the assessment[45] (Norwegian Biotechnology Advisory Board 2000/2003).

COGEM acknowledges that sustainable development is "not a clear-cut, static concept but a dynamic one, and depends on the context (e.g. society, culture and religion) and the spirit of the age". The Committee even questioned "whether there is any clear-cut answer to be given" (COGEM 2009: 22). In fact, differences can be found in practice for instance if comparing National Sustainability Plans (NSDS). These differences translate into indicators which vary widely across countries. Some NSDS specify relatively few (mostly environmental) indicators. Others have adopted large indicator systems (OECD 2006). A survey of NSDS of EU Member States also revealed differences (EC 2004, see also Table 9) in the dimensions considered. Some Member States consider additional dimensions on top of the three pillars of sustainability. For instance, Slovakia, Poland, the Czech Republic, Estonia, Slovenia, and France added an explicitly cultural dimension to the strategy emphasising local traditions, value systems, arts and the preservation of historical and cultural heritage as an integral part of sustainable development.

[45] For a list of 'ideas' and checklist questions see section on Norway.

Table 9: Focus and scope of NSDS. Source: EC (2004).

	Environment	Three dimensions	Three + additional
Member States	Italy	Austria, Germany, Finland, Denmark, Greece, Ireland, Luxemburg, Portugal, Spain (draft), Sweden, UK	France (cultural, regional, governance), Belgium (governance), the Netherlands (governance)
Accession Countries*	Hungary	Cyprus (NDP), Estonia (Draft), Slovenia (NEDS)	Slovakia (cultural), Slovenia (cultural), Poland (cultural), Lithuania (regional), Czech Republic (cultural)

** The survey was commenced in 2004. Source: EC (2004).*

Austria laid down the corner stones for its sustainability strategy in 2002 (Federal Ministry of Agriculture, Forestry, Environment and Water Management 2002). It highlights specific dimensions which are considered important for Austria including support to regionality and subsidiarity and enhancing local identity.[46] It can reasonably be assumed that across countries these dimensions differ in both their nature and their relative importance.

These differences in the NSDS are expected to be mirrored by or translated into Member States concepts of sustainable agriculture. COGEM also acknowledged that the "form sustainable agriculture may take could also differ from one country or region to another because importance is attached to different cultural values" (COGEM 2009: 22).

In Austria, the Agriculture Act specified the agricultural policy goal to consider social and ecological aspects, as well as regional balance. The Act highlighted that structural improvements should especially be environmentally and socially sound and compatible to a peasant's agriculture. Natural resources, soil, water, and air should be protected in a sustainable way (Landwirtschaftsgesetz 1992). Elsewhere and more recently the policy goal was described as "socio-ecological, sustainable agriculture with a clear organic priority".[47] The Austrian NSDS also highlights the multifunctionality of agriculture (Federal Ministry of Agriculture, Forestry, Environment and Water Management 2002). GMOs are perceived to negatively affect these goals – in particular organic agriculture (Berlakovich 2009). The government is therefore determined to continue the Austrian GM-free policy.[48]

The concepts of sustainable development and sustainable agriculture appear to differ between countries – reflecting differences in societal and cultural preferences, as well as policies. Given the experience from GMO risk assessment, it can be assumed that these differences will translate into different results of or views on SOEIA.

The context specificity of normative baselines and key concepts, and therefore also of impact dimensions and derived criteria is likely to be a major hurdle for establishing cornerstones for a SOEIA shared by all 27 Member States. This is, however, not to say that striving for agreement would

[46] "Supporting regionality and subsidiarity: In order to exploit the diversified knowledge of the local people, it is necessary to strengthen the future competence at the regional and communal level, whereby the different regional conditions and opportunities must be taken into consideration; Enhancing local identity: In order to preserve culture, tradition and local customs, globalisation requires a stronger awareness of local identity so that diversity and uniqueness can still be maintained in a globalised world in the future" (Federal Ministry of Agriculture, Forestry, Environment and Water Management 2002: 11).

[47] http://www.bmlfuw.gv.at/article/articleview/71768/1/13752/.

[48] Government Program 2008 – 2013, http://www.bmlfuw.gv.at/article/articleview/71882/1/27210/.

make no sense at all. In contrast, it should be possible to identify baselines, concepts and subsequent impact dimensions on which agreement can be achieved.

Scope

Scope typically refers to the selection of impact dimensions and the breadth and profundity of analysis in each dimension. Socioeconomic impacts potentially cover a wide range of economic and social impacts as well as their various interrelationships. A broad range of dimensions and impacts are being discussed under this heading. Some of these impacts are linked to issues in biosafety, others to coexistence. Some would like to include ethical considerations as well as public attitudes (Jarvis 2009).

Questions regarding the scope include for instance

- Whether only direct impacts are being considered or also indirect. For the issue here this could mean, e.g. whether only direct impacts of GM crop (cultivation) would be considered or also possible impacts if GMO health or environmental risks would translate into hazards.

- Another question is if and how the scope of the impacts should be limited to certain geographical areas, e.g. whether only impacts on the own territory are to be considered? Assessment may also include impacts on the EU as a whole and/or impacts on third countries. COGEM and the NBAB are, in fact, proposing to include third countries in the scope of socioeconomic considerations (COGEM 2009, Norwegian Biotechnology Advisory Board 2000/2003). Given the large quantities of agricultural goods imported to EU Member States, COGEM sees an explicit responsibility for considering such impacts. A positive contribution to the agriculture of their export partners would therefore be seen as to reduce the environmental foot print of a Member State/the EU as a whole (ibid.). This extension of the scope to third countries might, however, be more difficult to bring in-line with obligation under WTO law (see also section “WTO“).

A broad discussion on how to adjust the scope can be conducted based on the analysis of the Member States’ responses to the EC questionnaire on socioeconomic considerations. A clear and agreed scope is essential in order to identify approaches which can be used, and to develop a workable set of criteria and methods. Again a qualifier has to be made if it was possible to achieve full agreement – differences in normative baselines and key concepts can well translate into the scope and could add for instance cultural dimensions to the scope of a SOEIA.

Approaches, methods, and endpoints

Achieving more clarity on baselines, key concepts and scope would also be helpful in identifying approaches which can inform SOEIA, as well as identifying relevant endpoints and the appropriate methods to deliver data. A more fundamental question is whether to opt for a definitive list of impact dimensions and endpoints or to favour case-by-case assessments.

Need for a checklist approach?

There is a long standing controversy in GMO risk assessment between those favouring flexible case-by-case approaches along more general guidance and others fond of a more rigid check-list approach. The ones highlight the importance of considering the specifics of a given GMO; the others argue that a checklist would enhance clarity, transparency and consistency of risk assessments and if comprehensive enough - would avoid conflicts about interpretations.

Similar thoughts can be found when considering broader impact assessments. Certain types of impacts that might be specific to a given case and a specific context could be neglected (Day 2007, EC 2005). Dreyer et al. (2009) argue that an assessment of societal concerns (dubbed 'concern assessment')[49] should be sufficiently open to be able to grasp – at least to some extent – the "context-dependency of social impacts (institutional, socio-cultural, political context), the close relationship of social impacts with social concerns, the structure and interplay of the different actors engaging in a given issue, and the social dynamics that result from these relationships". Instead of striving for sophisticated checklists, they favour a direct engagement with social groups which could provide information on the relevance and future direction of concerns related to socio-political and cultural factors, such as perceived equity and justice, visions about future developments, and effects on one's interests and values. It therefore does not surprise that researchers in social impact assessment widely disagree on what constitutes social impacts and which variables should be included in the assessment. Not surprisingly, they are strongly reluctant to provide lists of social impacts (Becker and Vanclay 2003).

Despite these limitations it makes sense to strive for harmonisation and agreement on approaches, endpoints, and methods.[50]

Criteria and impacts

Normative criteria have been developed by the NBAB (Norwegian Biotechnology Advisory Board 2000/2003) and more recently, in the context of the debate on socioeconomic assessment of GMOs by COGEM (2009) and Nischwitz et al. (2009).

A list of possible impact areas was developed in the course of a questionnaire circulated by the EC to gather information from individual Member States about views and possible impacts of GMOs (EC 2009). This questionnaire was intended to provide a structure for possible impacts on relevant actors structured along the food chain.

The NBAB criteria and impacts are provided in section "Norway" (Table 4, Table 5, Table 6), the impacts listed in the questionnaire can be found in Table 13 and Table 14 in the Annex. The criteria developed by COGEM are provided in Table 10.

[49] Essentially envisaged as an assessment of the broad range of societal concerns.

[50] The term 'endpoint' is borrowed from risk assessment and is used to highlight the similarities of the problems.

Table 10: Concepts and criteria suggested by COGEM. Source: COGEM (2009).*

Concept	**Hypothesis**	**Elements/criteria**
Benefit to society	The production of GM crops leads to an increase in yield, contributes to harvest security or offers some other form of general benefit to society.	Harvest security, food security, food quality, environmental benefit, cost saving, recreation.
Economics and prosperity	The production and use of GM crops contributes equally to local and general prosperity and the economy and, where possible, leads to an improvement.	Employment, efficiency of the production process, productivity and profit.
Health and welfare	The production and use of GM crops means that the health and welfare of workers, the local population and consumers remains at the same level and, where possible, improves	Human rights and conditions at work
Local and general food supply	The production and use of GM crops means that the local food supply remains at the same level and, where possible, improves	Food security and fair trade
Cultural heritage	The production of GM crops offers room, if so desired, for the country or region concerned to conserve and continue specific cultural heritage aspects or other local applications (such as building materials, medicines).	Local applications and traditions, autonomy of the local population
Freedom of choice	Consumers' and manufacturers' freedom of choice regarding GMO (or GMO-free) is safeguarded in the production and import of GM crops.	GMO (or GMO-free) labelling of products, product information, co-existence and innovation, and research freedom
Safety	The admittance and assessment of GM crops in terms of safety to humans and the environment takes place in the country concerned in accordance with the legislation on the basis of the international agreements in force concerning human and environmental safety	Food safety and environmental safety
Biodiversity	The production of GM crops does not lead to a) a reduction in the agrobiodiversity of the agricultural environment and where possible strengthens it, and b) damage to protected or vulnerable biodiversity	Agrobiodiversity, protected or vulnerable biodiversity, places of origin of agricultural crops
Environmental quality	The production and processing of GM crops means that a) the quality of the soil, surface and groundwater, and air, does not deteriorate and, where possible, improves and b) the emission of greenhouse gases along the entire chain (development, production, processing and transport) remains neutral or declines relative to conventional agriculture.	Emissions of hazardous substances to the soil, surface water and air, soil fertility and disease resistance.

**COEGEM suggests these concepts and criteria for assessing the contribution of GMOs to more sustainable agriculture.*

It is beyond the scope of this report to scrutinize the criteria and impacts proposed or to develop a new set of criteria. Nevertheless, two general observations will be made which may guide further research in this area.

Link to empirical evidence

There is broad range of studies available summarising empirical evidence of socioeconomic impacts of GMOs (see also chapter "Socioeconomic considerations in the literature"). It is unclear or not transparent to what extent these normative criteria are based on such empirical evidence and how they are being derived. The study of Nischwitz et al. for instance seems to draw on the NBAB criteria with specifying one review prepared by a stakeholder organisation and focusing on negative effects as the only empirical evidence (Then & Lorch 2009). The dimensions and criteria proposed by the COGEM report seem to be largely based on the results of two preceding research projects of COGEM, an analysis of the recurring topics in the GMO debate and an analysis of the possible contribution of GM crops to sustainable agriculture in the Netherlands.[51] Both studies, however, were published in Dutch only.

While it is perfectly fine and legitimate to establish criteria where there is little or no evidence of an impact (but there might be societal concerns), any such proposed list of criteria should be double checked against empirical evidence.

Another way of developing criteria would be to start from a comprehensive review of existing empirical evidence of socioeconomic impacts which will also serve as a basis for developing a set of criteria. Such an undertaking has to tackle a few problems, though.

Empirical evidence is fragmented. Most studies so far have focused on specific types of impacts in particular countries or regions or on particular communities only. Most studies on economic impacts, especially on farm level impacts, have been conducted or commissioned by biotechnology developers or other biotech promoters. A number of studies on the costs of contamination have been conducted on behalf of public interest groups campaigning against GMOs. All studies, including those which are published in peer reviewed papers differ considerably in their focus, scope, quality, approaches, and methods used. Any comprehensive critical review would therefore have to tackle problems such as vested interests, bias, differences in scientific rigour, incompatible methods, or contradicting results. Research mapping and evaluating the bits of empirical evidence in a systematic way would be a useful contribution to the discussion.

There exist a small number of studies which analyse a range of empirical evidence covering a broader range of impacts, though these studies also lack scientific rigour. One example is a study which prepared a synopsis of socioeconomic effects based on views on and experiences of Parties of the Cartagena Protocol on Biosafety (CPBS) (UNEP 2008b; see section "Cartagena Protocol on Biosafety" for a discussion of the Article 26 provision on socioeconomic impacts).

By drawing on a large number of submissions, the fourth meeting of the Parties of the CPBS distinguished the following categories of socioeconomic effects (UNEP 2008b):

[51] COGEM report (2007) Het gentech debat ontleed; een analyse van terugkerendekern thema sen argumenten [The gene tech debate laid bare: an analysis of recurring themes and arguments] (CGM/071004); COGEM (2008) Perspectieven van gg-gewassen voor een duurzame landbouw [Prospect for GM crops in a sustainable agriculture] (CGM/080201-01).

1) Impacts related to soil fertility and soil structure
2) Impacts of LMOs on non-target organisms and the prevalence of pests
3) Impacts related to land use
4) Gene flow and co-existence
5) Impacts related to yields, inputs and products/outputs
6) Impacts related to employment and labour
7) Impacts related to international markets and market access
8) Health-related impacts
9) Food security and food sovereignty related impacts
10) Impacts on land tenure, rural-urban migration and communities
11) Impacts from opportunity costs and from the balance of costs and benefits
12) Impacts of LMOs on competition and small versus large farmers

These submissions, however, are in fact combining interpretations of empirical evidence, existing norms, and dominant views of CAs /Parties.

Another study was conducted in the context of preparing a World Resource Institute White Paper (Fransen et al. 2005). This study has a stronger focus on developing countries. It identified concerns over distribution of benefits; public sector research; labour; global markets; competition; organic agriculture; intellectual property rights; public opinion; and ethics, culture and religion. This study draws mainly on other organisations' reviews and falls short to consider studies prepared by industry or biotechnology promoters.

Stakeholder views

Ten stakeholder interviews were conducted to explore the views of Austrian stakeholders on socioeconomic impacts which would require considerations. These views are summarised in Box 3 and encompass a broad spectrum of impact dimensions and impacts. The majority of the interviewees, however, highlighted a similar set of issues linked to specific characteristics of the Austrian agroeconomic and sociopolitical context.

Box 3: Views from Austrian Stakeholders.[a]

The **majority of interviewees** anticipated serious impacts on growers of conventional and organic crops and the entire food chain from GM crop cultivation especially due to avoidance strategies, contamination events and the loss of GM-free status:

- On domestic seed production which has itself established in the GM-free niche

- On GM-free farming (isolation distances, surface reduction)

- On rural development

- On agricultural practice - shift towards intensive farming

- On the market niche for high-quality and healthy food products by sustainable agriculture

- On the image of Austria linked to good quality of life, organic food, sustainable agriculture, healthy and GM-free food

Impact mentioned by a few or one interviewee only:

On agro-food sector

- Does not correspond to the Austrian goal in agricultural policy embedded in the national legislation

- Yield
- Employment effects, costs per workplace lost
- Effects on agricultural practice
- Possible driving out of business of certain types of farming (e.g. organic rape in Canada)
- Effects on EU policy goals for biodiversity
- Costs for administering coexistence
- Efforts for resistance management
- Insurance costs for farmers
- Effects on farm enterprises aiming at agrobiodiversity
- Social pressure on the first farmers intending to grow GM crops
- Effects on landscape, agriculture and leisure industry
- Liability issues, e.g. near borderlines between Member States
- Pesticide prices
- Effects on bee keepers

- On consumers
- Freedom to choose for consumers
- Consumer demands and benefits
- Food sovereignty
- Broader environmental effects
- Protected areas
- Effects on genetic biodiversity

Other

- (Fairness of) distribution of costs and benefits
- Costs for risk research and coexistence research

a) Austrian stakeholders were collected in the course of ten semi-structured interviews.

For a more detailed description of Austrian stakeholder views see Chapter 'Characteristics of the Austrian context'. The interview guidance and a list of interviewees is provided in the Annex.

Make use of existing concepts

A SOEIA of GMOs does not necessarily need to be developed from scratch. There are approaches described in literature which could inform the development of a SOEIA framework, e.g. social impact assessment (SIA) and integrated risk governance (see Box 4 and Box 5 for a brief description).

Box 4: Social Impact Assessment (SIA).

SIA emerged in the USA in the 1070ies as the socio-economic component of the legally prescribed environmental impact assessment (EIA). In contrast to EIA, however SIA has not received any broader acceptance and has therefore been described as "something of the poorer cousin of EIA" (Lockie 2001 cf. Dreyer et al. 2009).

The Interorganizational Committee on Principles & Guidelines for Social Impact Assessment (Vanclay 2003) outlines several key steps which describe the general impact assessment process: (1) the identification of the problem to be dealt with by policy action, (2) the definition of the objectives of policy intervention, (3) the development of main policy options, (4) the analysis of the impacts of these options, (5) the comparison of the policy options in the light of these impacts, and (6) the outlining of policy monitoring and evaluation.

SIA has occasionally been applied in contexts of rural development and agricultural change (Barrow 2000) and has not been applied to contexts of food safety and risk governance in the EU (Dreyer et al. 2009).

A SIA framework was recently introduced at the EC level thereby broadening the scope of previously conducted single-sector assessments to include also environmental, economic, and social dimensions (Loefsted 2004). SIA is considered to improving the way the EU institutions design policies and laws. The growing emphasis on impact assessment is predicated on the assumption that a detailed consideration of economic, environmental and social impacts can positively contribute to reaching more easily the goals of better regulation and its underlying Lisbon (Renda 2006) and sustainable development strategies.

Box 5: Integrated Risk Governance.

A framework on integrated risk governance framework was developed by the International Risk Governance Council (IRGC 2005)[52] with the aim of assisting policy makers, regulators and risk managers both in understanding the concept of risk governance and in applying it to their handling of risks. Besides the standard elements of risk handling – risk assessment, management, and communication –, the IRGC framework incorporates additional activities which reflect the need to deal with risk in a way that fully accounts for the societal context of both the risk and the decision that is reached:

- risk pre-assessment, early warning and "framing" the risk in order to provide a structured definition of the problem, of how it is framed by different stakeholders, and of how it may best be handled
- risk appraisal, combining a scientific risk assessment (of the hazard and its probability) with a systematic concern assessment (of public concerns and perceptions) to provide the knowledge base for subsequent decisions
- characterisation and evaluation in which the scientific data and a thorough understanding of societal values affected by the risk are used to evaluate the risk as acceptable, tolerable (requiring mitigation), or intolerable (unacceptable)
- risk management, the actions and remedies needed to avoid, reduce, transfer or retain the risk
- risk communication, how stakeholders and civil society understand the risk and participate in the risk governance process

The framework urges risk governance institutions to gather and base their decisions not only on knowledge about the physical impacts of technologies, natural events or human activities, but also on knowledge about the concerns that people associate with these and other causes of risks.

The framework has been applied to and adopted for a broad range of socio-technical areas including, nanotechnology, bioenergy, synthetic biology, geoengineering, energy security and recently food safety.

[52] The International Risk Governance Council (IRGC) is an independent organisation whose purpose is to help the understanding and management of emerging global risks that have impacts on human health and safety, the environment, the economy and society at large. IRGC's work includes developing concepts of risk governance, anticipating major risk issues and providing risk governance policy recommendations for key decision makers (http://www.irgc.org/-About-IRGC-.html).

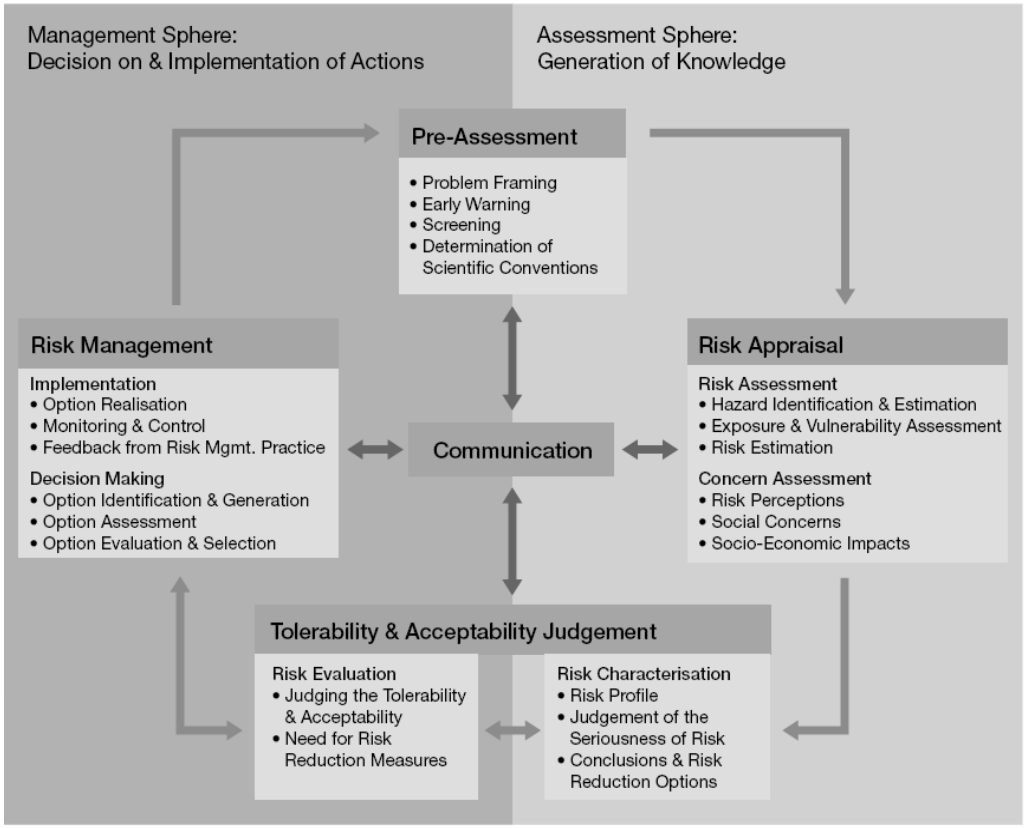


Figure 1: IRGC framework. Source: IRGC 2005b).

Taking stock in between: need for an explicit framing step

Science policy scholars and public policy-makers have increasingly come to recognise that scientific assessments to inform policy making are conditioned by various kinds of prior up-stream non-scientific 'framing assumptions', which can influence the type and nature of risk assessment conclusions (Millstone et al. 2008, Dreyer and Renn 2009, IRGC 2005a).[53] Framing has recently been acknowledged by the Codex Alimentarius Commission referred to as risk assessment policy. In the view of the CAC, framing constitutes an explicit and essential first step in the risk assessment process (CAC 2007).

Framing encompasses a mutual understanding of the risk issues involved but also includes (Millstone et al. 2008) for example:

- which types of disciplinary approaches to bring to bear on a problem,
- which types of changes and effects are deemed relevant and within the scope of the assessment and which are beyond its **scope**
- how to respond to, and explicitly acknowledge scientific uncertainties

[53] The concept of 'risk assessment policy' or framing is not a new issue. It first emerged in the 1983 US National Research Council's (NRC) report (known as the 'Red Book') which interpreted the concept as referring to policy judgments that arise during risk assessments and confront risk assessors, beyond purely scientific issues (NRC 1983). 20 years later, this concept is being rediscovered partly as a response to contradicting risk assessments.

- which **kinds of evidence** are included and which discounted,
- how the selected evidence is to be interpreted,
- how much of different kinds of evidence may be necessary or sufficient to sustain different types of judgements

Framing (or risk assessment policy) issues are important for several reasons. Often, when different risk assessors, especially in different institutional settings or national jurisdictions reach different conclusions, they do so because they are adopting distinct risk assessment policies rather than because some committees provide more or less scientific answers than others. They are, therefore, often not providing conflicting answers to common and agreed sets of questions concerning shared and agreed bodies of evidence. Often they are answering different questions because they make different risk assessment policy assumptions and consequently are considering different sets of data. Even when the sets of questions and sets of data coincide, different risk assessment policy assumptions may entail that they interpret those data in different ways. Making a wider range of risk assessment policy issues explicit, and deciding them in transparent ways, can provide resources with which disputes can appropriately be understood and addressed, both within and across jurisdictions.

Framing has mainly been discussed in the context of risk assessment, though it holds very useful insights relevant for SOIA. Risk assessment policy was an answer to the different ways to conduct risk assessment and to interpret risk data. It can be seen as an attempt to make the set screws for risk assessment visible and open to public scrutiny. As discussed in the first section of this chapter, there are obvious parallels and similarities between risk assessment and SOEIA, including its advisory and scientific character, the controversial nature of concepts, scope, criteria and data interpretation described above and in preceding sections of this chapter. Even the framing questions listed above that were derived from empirical studies on risk assessments are of clear value for framing a SOEIA. Hence, an explicit framing step for SOEIA would be both pertinent and necessary.

Framing is, for instance, also considered in SIA. The Inter-organizational Committee on Principles and Guidelines for Social Impact Assessment (2003, p. 234 cf. Dreyer et al. 2009) highlights the role of framing when it asks: “If you cannot cover the social universe, on what should you focus?”

Support for such a step also comes from recent studies in integrative risk governance.

Framing steps in the SAFEFOOD model of inclusive risk governance

Dreyer and Renn (2009) proposed broadening the formal framing step in their concept of food safety governance to also include socioeconomic issues. The framing step would also include deliberations on the need for a socioeconomic assessment and would also set the frame for such an assessment.

The authors proposed to follow a two-step procedure which would allow for identifying concerns and for triggering and scoping of subsequent assessment steps. First, the need for what they called ‘concern assessment’ has to be clarified (Dreyer et al. 2009, Ely and Stirling 2009);[54] essentially a “social scientific analysis of the concerns of affected and interested parties and the wider public which focuses on risk-related concerns but seeks to grasp also wider concerns which are not directly related to a given risk and its implications such as, for instance, conflicting views of what might be meant by sustainable development in the agro-food area” (Dreyer et al. 2009).

[54] Concern assessment has also been proposed as a novel step to risk governance by the International Risk Governance Council (IRGC, 2005a).

A concern assessment would be required in cases of socio-political ambiguity. Indicators of socio-political ambiguity include (ibid.)

- "Institutional level: where there is disagreement between regulatory agencies and/or Member States, are there aspects of these institutional conflicts ostensibly unrelated to scientific uncertainty?

- Social amplification phenomenon: with regard to the news media, are there signs that the threat in question and/or the source of this threat are subject to a pronounced degree of amplification?

- Societal level: at the level of society as a whole, are there signs of adverse effects in terms of social justice in the distribution of threat or in terms of manifest political mobilisation on the part of particular public constituencies?"

If any of these indicators apply, a concern assessment would be conducted.

The results of the concern assessment could trigger and frame a more refined and detailed assessment of possible social implications, i.e. a social impact assessment.

For example, if a concern assessment with regard to the use of biotechnologies in agriculture showed strong concerns in relation over increasingly privatised ownership of key varieties of staple crops through an expansion of the possibility of patenting and licensing biotechnology inventions, this could trigger an investigation of how changing ownership structures would likely affect seed costs and options for breeders and farmers to access knowledge and use new technologies to develop new crop varieties. Further, the analysis could also aim at understanding social change in the agri-food sector more generally, for instance by investigating the likeliness and implications of different evolving "agri-food paradigms" (Gill 2007: 18 cf. Dreyer et al. 2009).

Need for an impact assessment policy

From the arguments described above there is a clear need to establish a formal framing step for SOEIA. Such a step could clarify the cornerstones of the assessment as regards the scope, approaches, endpoints and methods used, but also how to deal with uncertainties, data quality, and the opportunities for public perception. In order to highlight this to be an explicit step where not only expert advisors but also decision makers have a say, and in analogy to the CAC terminology this step is called impact assessment policy.

Public participation

Public participation in the context of risk assessment is meanwhile well established though the extent, design and precise role differ between contexts. Public participation is linked to transparency as a precondition for public scrutiny. Public and stakeholder participation have been gradually extended since the inception of EFSA (e.g. stakeholder consultative platform, annual conference, public consultations on specific scientific subjects, public events).

The COGEM report considers public participation as an important criterion with respect to the social column of sustainability but does not provide reference to procedural issues of socioeconomic issues (COGEM 2009). The Norwegian guidance does not address these procedural issues (NBAB 2000/2003), presumably because the procedures including the opportunities for public and stakeholder participation are determined elsewhere.

Participation as envisaged in this section is based on two assumptions: First on the core assumption of inclusive risk governance that all stakeholders have something to contribute to the process of risk governance and that their inclusion improves the final decisions rather than impedes the decision-making process or compromises the quality of scientific input (IRGC 2005b). Second, that SOEIA is envisaged as an expert assessment process in symmetry to risk assessment. For the issue of this report, two different processes can be distinguished: First the process of designing and implementing a framework for SOEIA and, second, the conducting of SOEIA itself.

In social science literature, public participation is usually assigned with three key functions

- Providing relevant information and knowledge
- Bringing in a broad range of societal views and values (when impacts and management options where to be evaluated)
- Enhancing legitimacy and accepting the process

Ample opportunity for participation of stakeholders and interested public is proposed over the whole process of designing and implementing a SOEIA, here the three functions of participation would clearly apply.

Moreover and in-line with the proposals of the SAFEFOODS project it is proposed to establish mechanisms for participation in the framing stage and in the evaluation steps of conducting SOEIA. Risk governance literature has frequently highlighted that framing needs input from and mutual understanding by a broader range of stakeholder. Another key step for public input is when risk assessments and management options are being evaluated and possible trade-offs are being considered. Here the values and views are of particular importance.

Dreyer et al. (2009) proposed that such a concept for public and stakeholder participation would also work for assessing broader societal concerns and socioeconomic impacts. Importantly, the authors suggested that the extent and design of the participation exercise should be handled more flexible. In case of socio-political ambiguity and/or potential for social conflict and mobilisation, more elaborate participation programmes are proposed. This concept of gradually increasing participation based on characteristics of the issue at stake is based on the IRGC framework on inclusive risk governance (IRGC 2005a, b). With risk assessment, complexity, uncertainty and ambiguity trigger more elaborate participation (see also Figure 2). These characteristics could also play a role in assessments of socioeconomic issues.

Notably, this proposal is not only targeting exploratory assessment exercises for example in case of new technologies, it is also proposed to be part in case of established assessment processes. This proposal would require a change of the present practice. Public and stakeholder participation is largely channelled to new, controversial and overarching risk issues and is not envisaged in routine risk assessment processes. The only opportunity is the commenting period on EFSA Draft Opinions. Here the proposal is to open up the framing and evaluation stage for public participation. Public participation does not necessarily comprise resource-intensive face-to-face consultation. It would also be possible to envisage using the internet.

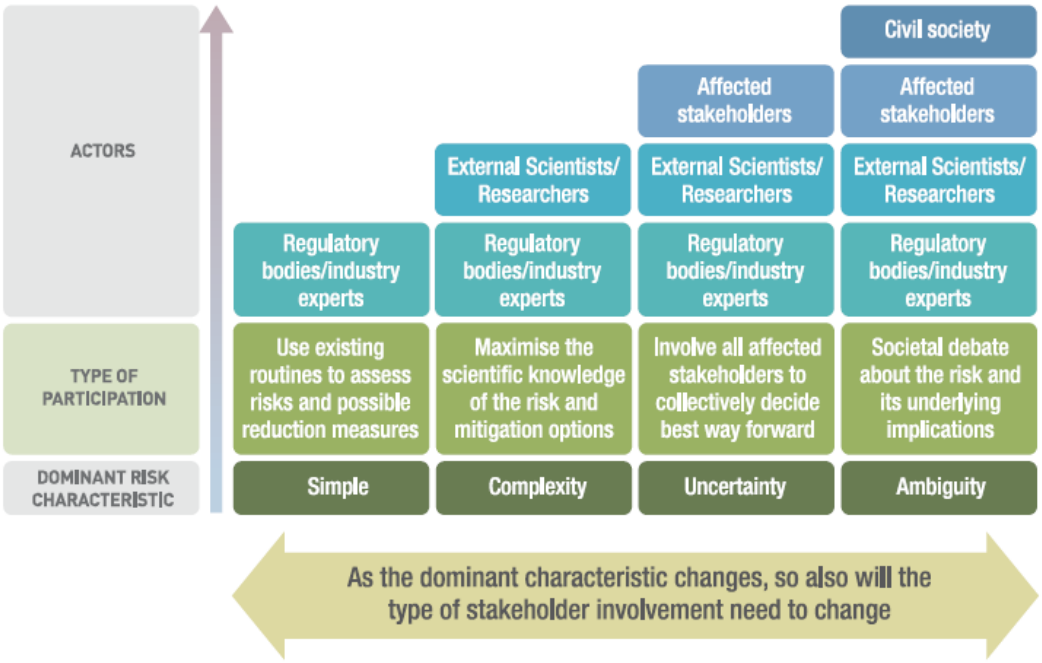


Figure 2: IRGC structure for stakeholder involvement. Source: IRGC 2005b.

Specifity of socioeconomic data

An important question is if socioeconomic data have characteristics which differ from risk data and if this can play a role for procedures in an assessment framework.

GMO risk assessments are largely based on event-specific information in order to capture possible unintended impacts of the particular genetic construct. Even minor differences at the molecular level could be relevant for risk characterisation; e.g. change of protein sequence or additional open reading frames could give rise to proteins with harmful properties.

Socioeconomic data are not event-specific

SOEIA, in contrast, is more specific for a given crop, trait or application, e.g. socioeconomic impacts of BT maize or herbicide tolerant soybean for the food/feed chain or popular trees with modified lignin for biomass conversion. A possible exception to this general rule is if socioeconomic impacts are considered as a second order effect if health and environmental risks turn into hazards.

On the other hand, well established socioeconomic impacts of specific crop/trait combinations might be subject to reconsiderations in case of relevant changes of the trait, e.g. new types of trait combinations via gene stacking. Other examples are major changes in the range of pests in case of BT crops; major changes of the efficiency of the herbicide in case of herbicide tolerant crops or energy crops with altered enzymatic properties to facilitate biomass conversion, and second generation GM crops with modified ingredients aiming at providing health benefits to consumers, e.g. lack/lower levels of certain allergens. Hence, there could be a need to consider existing data base for SOEIA for their relevance for a particular case that will then potentially be followed by reconsideration or by additional and more specific socio-economic data.

A SOEIA dossier (complementing risk assessment dossiers) might therefore include a range of more general data specific for a given crop and/or trait combination considering perhaps also the most frequent types of applications. Such information could be prepared independent of a particular

market application and by a dedicated body (see also chapter "Challenges for EU institutional arrangements"). This more general information could then be complemented by more specific-data on the particular case/event if necessary.

Socio-economic data are context specific

It has already been argued in preceding sections that baselines and key concepts which are important references in a SOEIA could differ between countries based on geographic, socio-cultural, ethical, or political reasons. It was further argued that impact dimensions and methods could therefore also differ between countries. Consequently, SOEIA conducted in these different contexts might lead to different results and conclusions.

It can be assumed that EU Member States will agree on cornerstones for SOEIA (baselines, key concepts, impact dimensions etc.). This would allow preparing SOEIA data relevant to all Member States. The introduction of an explicit framing step as proposed in section "Taking stock in between" will also be helpful in this regard.

Nevertheless, even in case of an agreed 'impact assessment policy' the results might differ between regions. This becomes especially visible in case of cultivation of GM crops. Both European Member States and regions within Member States differ considerably in terms of geographic and agricultural factors as well as in their rural development. For instance, socioeconomic dimensions of the establishment of avoidance strategies and separate supply chains might differ a lot between geographic contexts e.g. in case of cultivating Bt maize in Spain and Austria, but might also differ between different Spanish regions.

Guidance and standards

As discussed in the preceding sections, full agreement of normative baselines, key concepts, impact dimensions, criteria and methods will be difficult to achieve and can be expected on a limited range of aspects only. Nevertheless, a document could be developed aiming to provide general guidance in what is accepted by all Member States. Such guidance could, for instance, be structured according to crop/trait/application and could be further updated for new types of GMOs. It could also serve as reference for further EU harmonisation.

Furthermore, in achieving international harmonisation, best practice documents could be developed by OECD.[55] In analogy to the crop specific documents on biology, such a document could inform about crop specific socioeconomic 'footprints' in OECD Member States. In a similar vain it would be possible to develop trait specific documents.

Best practice documents could also consider best-practice documents which provide examples for approaches and methods which receive widespread recognition – similar to what is presently done by the International Life Science Institute (ILSI) for GMO risk assessment.[56]

A particular challenge is how to cope with the context specifity of socioeconomic considerations (see also section "How any assessment starts: clarifying normative baselines and key reference concepts"). Thus, there will be a need to contextualize socioeconomic considerations, e.g. for specific

[55] Task Force for the Safety on Novel Foods and Feeds (http://www.oecd.org/about/0,3347,en_2649_34391_1_1_1_1_1,00.html), Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (http://www.oecd.org/about/0,3347,en_2649_34387_1_1_1_1_1,00.html).

[56] http://www.ilsi.org.

crop/trait combinations. One way to approach this problem is to explore if it would be possible to identify categories of socioeconomic regions exhibiting similar characteristics. Member States could also prepare background documents describing their socioeconomic regions.

Relationship to GMO risk assessment

First, there is not always a clear-cut distinction between SOEIA and health and environmental risk assessment. As illustrated in Box 2 (p. 64), the scope of environmental risks has already been widened to include impacts which are partly targeting socioeconomic effects, e.g. resistance management strategies aiming at avoiding pests to become resistance against Bt. Furthermore, socio-economic impacts might emerge from health and environmental impacts. These overlaps are not necessarily a problem. It indicates that EFSA has already widened the scope of its assessments beyond issues of safety and nutritional value to include technical evaluations relevant for agronomic and agro-ecological reasons. It can be assumed that a body dedicated to assess socioeconomic impacts will reduce the pressure to include such issues under an environmental assessment. Borderline issues might, nevertheless, continue to occur and it might make sense to clearly acknowledge and characterise these issue and then to allocate them either to a socioeconomic or to a health and environmental risk assessment (and to provide a justification).

Second, health and environmental risk assessment is invariably conditioned by non-scientific framing assumptions which can themselves be influenced by socio-economic factors (see for instance Millstone et al. 2004, 2008).

The latter point is clearly addressed by the introduction of an explicit framing step (see section ”Taking stock in between: need for an explicit framing step”). Acknowledging the interdependencies of the first point would require a clearinghouse function in the framing step. In fact the concept for integrated risk governance (IRGC 2005a) in particular as it is being tailored to governing EU food safety (see also Figure 3 for a graphical representation) envisages such a function for the framing step (Dreyer and Renn 2009; Dreyer at al. 2009; König et al. 2010).

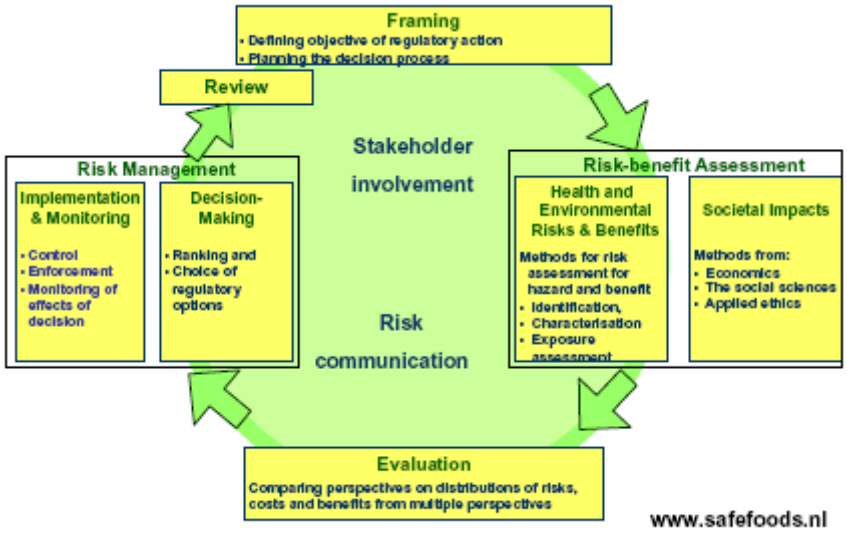


Figure 3: Food safety governance proposed by SAFEFOOS project. Source: König et al. 2010.

Summary

The analysis in this chapter is based on essential similarities between risk assessment and socioeconomic assessment (subsequently referred to as socioeconomic impact analysis, SOEIA). First, SOEIA is conceptualised as scientific advice on policy making, though largely based on social science. Second, this scientific advice can be expected to meet EU standards established for good governance and expert advice in policy contexts. Third, a SOEIA framework could be designed in symmetry to risk assessment. Fourth, the need for an elaborate framework which allows for both public participation and public scrutiny also comes from the inherent similarities of the conflicts. Both the assessment of health and environmental risks and the socioeconomic considerations led to contradicting results and conclusions and stir fierce debates among stakeholder groups as well as in the scientific literature. Given this similarities of both types of scientific advice, the concepts on inclusive and integrative risk governance can also be employed.

Setting an assessment means to clarify normative baselines, key concepts, criteria, impact dimensions, 'endpoints', and methods. Taking the example proposed by the Netherlands Commission on Genetic Modification (COGEM) report it is shown that conventional agriculture and sustainable development might have different meanings in Austria and the Netherlands. Such context specifity is likely to translate into divergence in scope, impact dimensions and criteria. Issues of scope could also be limited by international legislation, e.g. if considering not only impacts on Member States or EU territory but also on third countries. Different proposals have been made for criteria, impact dimensions and endpoints though, quite a few specifically covering a broader range of socioeconomic issues. Recent examples come from COGEM and Norwegian Biotechnology Advisory Board (NBAB) and from a German report. It remains unclear how and to what extent these proposals have been checked against empirical evidence on socioeconomic impacts described in scientific literature and public reports. This is, however, important as there is considerable evidence which needs to be systematically collected and scrutinised in order to verify and possibly develop the criteria proposed. Existing reviews do not seem to be comprehensive enough or seem to be biased in one or another direction. Putting together impact dimensions, endpoints, criteria and methods is a valid endeavour, however, it is still highly questionable if anything like a definitive checklist can be obtained. Researchers of social impact analyses widely disagree on what constitutes social impacts and which variables should be included in assessment criteria.

Austrian stakeholders highlighted impact dimensions relevant for Austria given its specific agroeconomic and sociocultural context: small-scale agriculture with a very high proportion of farmland located in disadvantaged (mainly mountainous) regions, very high proportion of organic farms; strong resistance from consumers and the general public to adopt GM crops and derived food/feed. Hence, serious short-term and long-term impacts can be envisaged on conventional and organic producers and the entire food chain including consumers and seed producers, thereby affecting costs and gains for farmers, food producers and retailers, market shares and position, as well as competitiveness. It is also perceived to conflict with Austrian agriculture policy goals.

Setting up a framework and approaches for socioeconomic assessment of GMOs is breaking new ground, though this does not necessarily mean to start from scratch. Existing impact assessment approaches could be explored, e.g. social impact analysis and environmental impact assessment.

Given the need to clarify and agree on normative baselines, key concepts, criteria, impact dimensions, 'endpoints' and methods it is proposed to establish a distinct framing step which would provide for framing deliberations between expert advisors (here: mainly social scientists) and policy makers (here: risk management, i.e. the European Commission and the Member States). The importance of such a framing step has been acknowledged for risk assessment not only in the scientific literature but also in policy contexts, e.g. recently by the Codex Alimentarius Commission. This framing step could be designated as 'impact assessment policy' in analogy to the term 'risk assessment policy' used by the Codex. Generally agreed procedural and substantive aspects of

impact assessment policy can and should be included in guidance documents. Trait/crop/application-specific guidance in analogy to the crop-specific OECD Consensus or Biology documents could also be considered. This framing stage could also have a clearing house function to allocate issues to either the scientific or the socioeconomic assessment. Over time the scientific risk assessment has been widened to include environmental impacts such as resistance management which are particularly important from an agronomic point of view. Such information might (also) be considered in the course of a socioeconomic assessment.

Public participation is considered important, in particular in the framing and evaluation step (when the expert advice is being considered and weighted by decision makers). The degree of public participation might be flexible depending on the issues at stake.

It is also important to consider the characteristics of socioeconomic data and the differences compared to data from scientific risk assessment. Socioeconomic data are crop/trait/application-specific but not necessarily event-specific. Thus there is no need to produce extensive socioeconomic data for each particular event. Supplementary event-specific information might only be relevant if important characteristics of the crop/trait/application combination are being affected. On the other hand, socioeconomic data can be specific for a particular geographical, climate, agro-economic and socio-political context and such data cannot be directly applied to other contexts. This is complicating the establishment of trait/crop/application-specific guidance documents and putting the value of socioeconomic data from other contexts into perspective.

Wider policy challenges

This chapter describes other issues which might be important in discussing and implementing a socioeconomic assessment in GMO authorisation. The first section identifies some issues requiring clarification at an early stage in order to provide some cornerstones for a broader debate and for policy development. The following section provides some evidence on stakeholder perceptions linked to the issues. The final section briefly describes issues of accountability, administrative burden, and technology access.

Confounding factors

GMO risk assessment has gone a long way in Europe to arrive at a 160 page guidance document (EFSA 2006) which is the most detailed guidance on GMO risk assessment worldwide. Still, there is ongoing controversy. A consideration of socioeconomic aspects of GMOs, in contrast, is starting from scratch. A scoping document would therefore be urgently needed to allow for a proper debate at the EU level. This document should make a number of important clarifications including:

- The relative role of SOEIA in the GMO authorisations procedures should be clarified - in particular for the main issue at stake – the possibility for Member States to restrict GM crop cultivation in their own territory (opting-out). Some Member States and interview stakeholders are considering a SOEIA in combination with the so called “opt-out” proposal by the Dutch government.[57] Would opting out be possible based on the results of a SOEIA? If there were no links between these strands of the debate and if no other changes were envisaged, SOEIA might be perceived as just another information package on which Member States could disagree.

- Would the scope of SOEIA be limited to cultivation in the EU (as for instance proposed by the Netherlands) or much wider to include all types of GMOs (as for instance requested by environmental NGOs)?

- Would SOEIA be a standard requirement? If not, what actually would trigger a socioeconomic assessment? König (2009) proposes that the precautionary principle would be a possible trigger for broadening the scope to include a SOEIA.

- Would it be possible to object an EC proposal for market approval by referring to socioeconomic impacts?

  In fact, a recent case indicates that socioeconomic grounds are gaining more weight vis-à-vis scientific arguments in decision making on GMOs. In May 2009, Portugal informed the EC about the intention to declare the autonomous region of Madeira a GMO-free region. The ban covers seeds and propagating material from all GMO plant varieties authorized under Directive

[57] In fact, this was originally proposed by the Netherlands. In March 2009, the Netherlands’ delegation proposed at the Agriculture Council that Member States should have the right to decide for themselves on the cultivation of GMOs, and suggested that such decisions could be based upon socio-economic criteria (dubbed as ‘opting-out’). The Dutch government’s goals are to ease political pressure on GMO procedures; to give Member States more policy options at the national level; to speed up EU procedures for new authorisations. Its intention is to address the perceived problems of the authorisation procedure being seen as inefficient, slow and unpredictable, and discussions of technical issues being entwined with discussions of political issues (Jarvis 2009). Later on in 2009, the Netherlands changed their policy and stopped pushing for an opting-out solution. At the Council of Environmental Ministers on 25 June 2009, Austria proposed that socioeconomic aspects could form a basis for individual Member States’ opting-out (http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf).

2001/18/EC or Regulation 1829/2003. Portugal argues, that Madeira has an immense plant genetic wealth, which is of scientific and economic value. Two reasons were given: first, coexistence between GM crops and conventional and/or organic crops in Madeira is considered impossible; second, as the effects of introducing GMOs into nature are rated as not have been adequately studied, Portugal concludes that the introduction of GMOs could have dangerous consequences for Madeira's environment. EFSA assessed whether the scientific evidence submitted by Portugal relates to the protection of the environment in Madeira and concluded that there is no new/relevant scientific evidence to justify the ban. EFSA did not assess the agronomic justification as this is considered outside the remit of EFSA (EFSA 2010)[58]. The EC did not formally issue a decision on this notification within the legally required time period by 4 May 2010 which according to Article 140 of the Lisbon Treaty allows Portugal to adopt this Decree (BMG person. Communication). Thereby the EC de-facto acknowledged the socioeconomic justification.

- To whom should the responsibilities fall to produce socioeconomic data?

Without having more clarified these matters it will be difficult to proceed with the issue. It therefore does not surprise that the views of the ministerial roundtable of the Conference on GMOs in European Agriculture and Food Production diverged as to how socio-economic aspects could be included at the EU level – even in more general terms (Ministry of Agriculture, Nature and Food Quality; Ministry of Housing, Spatial Planning and the Environment 2009).

Stakeholder views

If at all and how a socioeconomic impact assessment can be established in GMO authorisation will also depend on acceptance by stakeholders. Not surprisingly stakeholders have responded in very different ways. The idea of socioeconomic assessment was favourably perceived by environmental NGOs – though they are considering a broad scope (Greenpeace International, Friends of the Earth Europe, Corporate Europe Observatory, X-Y Solidarity Fund 2009). An official position from the EU biotechnology industry is still lacking, though some industry representatives have already made clear that they will oppose this idea (Katzek 2009).

Stakeholder views on the assessment of social, economic, and ethical impacts

Clues about stakeholder perception can be derived from the work of Wentholt et al. (2010). The authors conducted a two-round Delphi survey with some 50 stakeholders on the proposed framework of food safety governance which includes assessment of social, economic, and ethical impacts which revealed the agreement of stakeholders to the broadening of assessment criteria beyond health and environmental risks. Overall, the proposed collection of assessment data beyond health received a strong support. Even food industry does not seem to oppose the broadening of the assessment scope (Rawling 2009). In the EU context, agreement was highest for assessing economic impacts (67-81%), slightly lower for ethical impacts (61-76%) and lowest for social impacts (55-73%) (see also Table 11). In general, the support was lower for benefit data than for risk data.

[58] Testbiotech. GMO free region Madeira (Portugal). http://www.testbiotech.org/en/node/299.

Table 11: Percentage of participants agreeing to the collection of different types of risk and benefit assessment data.

Type of impact	Participant stakeholder group	Round 1[a] Risk data	Round 2 Risk data	Benefit data
Health impact[b]	EU	93	100	95
	Non-EU	100	100	58
Environmental impact	EU	90	95	81
	Non-EU	63	58	50
Social impact	EU	73	60	55
	Non-EU	53	42	33
Economic impact	EU	80	71	67
	Non-EU	63	42	50
Ethical impact	EU	76	68	61
	Non-EU	58	50	42

a) Data on benefit assessment was only collected in the second round, based on responses of participants in the first round.

b) The exact phrasing of the item regarding risks was: "health impact ('traditional' risk assessment)" and for benefits it was: "health impact".

Colour code: green: 100-90%, light-green: 70-89%, yellow: 50-69%, orange: less than 50%.

Source: Wentholt et al. 2010; modified.

Clearly, these results cannot be directly applied for the case of socioeconomic impact assessment of GMOs. This survey was conducted in the broader context of food safety governance. It did include but not specifically consider GMOs. Another difference is the proposal of a governance framework in the context of an EU research project whereas the issue here is a specific policy initiative. Nevertheless, the results suggest that the majority of EU stakeholders can be expected to be supportive of a socioeconomic assessment of GMOs.

Views from Austrian Stakeholders

The assumed overall support of socioeconomic assessments of GMOs is also reflected in the responses of Austrian stakeholders collected in the course of ten semi-structured interviews.[59] In no case, however, an agreed view or position paper was available or under preparation - stakeholders seem to adopt a wait-and-see approach. This is not surprising given that the discussion on socioeconomic considerations is still in an early phase.

Most stakeholders interviewed have been considering socioeconomic impacts of GMOs before though in various depth and not necessarily in a systematic way. For organic farmers, the consideration of socioeconomic aspects is key and also underlying the ban of GMOs in the EU legislation on organic farming. Some interviewees highlighted that even without any cultivation of GM crops in Austria there has been a need to grapple with socioeconomics given the need to avoid almost any GMO contamination. Reasons given are the strong rejection of consumers being

[59] For the interview guidance and the list of interviewees see Annex.

interpreted as a kind of zero-tolerance for GMOs in food stuff, for seeds there is national legislation requiring GM contaminations not exceeding 0.1%, and in case of organic farming – strict tolerance thresholds of 0.1% have been set by national associations.

What's happening on the EU level is being closely observed – hence there is awareness of the Council initiative to consider socioeconomic impacts. Stakeholders are in principal largely positive about this initiative. As one interviewee puts it, "the fact that so far socioeconomic aspects have not been considered is at the heart of the problem". So far, none have yet started to deal with the issue in more detail. Some interviewees consider it as too early to get more engaged with this issue – as it is still unclear how this proposal will be interpreted and possessed and how it will be implemented by the Commission. Another reason given is – as long as one can continue with its GM free practice – there is no need to deal with this issue in detail.

When asked for possible problems concerning the implementation of socioeconomic assessments most interviewees highlighted problems related to the

- Value of studies as references: even more than risks assessments, studies depending on assumptions and models which can heavily affect the outcome. As interviewees puts it "each study can be refuted based by another one" or "study results will even more easily please the principal".

- Need to specify, detail and agree on concepts, criteria and methods, interpretation

- The majority of the interviewees pointed to the need for stakeholder /public participation both in the development of criteria and in conducting socioeconomic assessments. Other issues mentioned comprise:

- How to evaluate socioeconomic effects ex-ante – what relevance for data from other countries growing GM crops, e.g. USA, Canada?

- Likely to drag out even more GMO application procedures: existing studies on socioeconomic issues lead to contradicting results; will require extensive debates

- Compatibility to EU legislation

- Compatibility to national legislation: what would that mean e.g. for a farmer willing to cultivate crop? Could a positive socioeconomic analysis be considered as favourable evidence (e.g. in case of the Austrian Vorsorgegesetze)?; could national court cases refer to this type of evidence?;

Other issues

Accountability

The present impasse in GMO authorisation allows pursuing a "blame avoidance" strategy (Weaver 1986). National policy makers can vote against authorisations or abstain from voting – in order to please their national constituency while predictably receiving a default positive decision on the GMO by the EC. The Commission thereby takes the blame, while national doors for agriculturally biotechnology are being kept open. This might change if the authorisation was amended according to the reform proposals – in particular if also an opt-out clause was implemented. As Jarvis (2009) puts it, "for Member State politicians, the proposed reforms would put decisions that are currently taken

behind closed doors in Brussels into the hands of ministers and administrations of national government. Lines of accountability would change."

Administrative burden

Administrative burden for Member States pursuing a stricter coexistence policy might increase following GM crop cultivation in these Member States' territory. For Austria, the administration of the provincial coexistence laws ('Vorsorgegesetze') is expected by some stakeholders to be demanding (see preceding section).

Given the context-specifity of SOEIA, Member States are likely to play an important role in conducting and/or contributing to and/or scrutinizing SOEIAs. As discussed elsewhere in this report, even scope, criteria, baselines, and data for the assessment could be country or even region specific. If Member States are to conduct country-specific SOEIA in the context of possible opt-out clauses, there may also be a need to establish a firm national legislative basis. It is unlikely that applicants can be required to conduct SOEIA for each national/regional context. On the other hand, if Member States for instance were asked to complement general SOEIA data with specific data for their territory (if they feel the need to do so), the burden for national administration could increase quite sharply. Given the need to collect data from provinces or regions, even a dedicated body might be considered - especially in Member States with a federal system or more autonomy for provinces and regions (for a similar view see Jarvis 2009).

Unreasonable regulation? - revisiting an old theme

One argument frequently put forward in the public debate on agricultural biotechnology is on appropriateness of regulatory burdens; i.e. the notion that GM crops are being strictly regulated and only authorised after passing a thorough risk assessment, whereas crops from conventional breeding are not being assessed at all. Though this argument has apparent flaws it worked very well in the public arena. With respect to socioeconomic considerations a similar point could be made. GMOs are being tested for e.g. their sustainability and might even be rejected on these grounds, whereas similar conventional crops would be accepted though they would not even meet the same criteria if being assessed (COGEM 2009, Jarvis 2009). The European Group on Ethics (EGE), in fact, proposed that all products of new and existing agricultural techniques and not just GMOs would be tested for their sustainability (EGE 2002). In the context of socioeconomic assessment this argument might be even more powerful if the approaches for assessing GM impacts are not different from those assessing conventional crops.

Repercussions on access to technology

If applicants were required to provide extensive and even context specific data in the context of a socioeconomic impact assessment, the risk arises that such information would not be provided for markets which are not considered significant by applicants (Jarvis 2009). Rosendal (2008), in fact, assumes that this is the main reason behind the apparent lack of such data in the dossiers though sustainability criteria had been included in the Norwegian law a long time ago.

Summary

This chapter briefly discusses other aspects still relevant for policy development.

The most important aspect is the need to set the stage for a broader debate on the EU level. A scoping document should be composed which clarifies some cornerstones of a socioeconomic assessment of GMOs. These clarifications should include the relationship to the parallel debate on allowing Member States to ban cultivation on their own territory (opt-out); whether socioeconomic impacts should only be considered in case of cultivation and restricted to the EU only or all GMOs and extended to impacts on third countries; whether socioeconomics would be routinely assessed in each case and – if not – what would trigger such an assessment; whether it would be possible to object to an application based on socioeconomic grounds; to whom the responsibilities would fall to provide socioeconomic data.

Another important question is how stakeholders will respond if this is becoming a broader debate. There is preliminary evidence from literature that a majority of stakeholders would positively receive the consideration of socioeconomic aspects with the biotechnology industry possibly opposing such a move. Almost all Austrian stakeholders interviewed in the course of this study also expressed a positive view. At this early stage, Austrian stakeholders have not yet taken any official position or view as there is still a lack of clarity whether at all and how socioeconomic considerations might become relevant. The majority highlighted prior occupancy with the issue of socioeconomics given the specifics of the Austrian context: lack of tolerance of consumers for trace amounts of GMOs; the threshold for GMOs in seeds, and organic food products being as low as 0.1%.

Other aspects not directly related to a socioeconomic assessment framework are

- Changing lines of accountability – in particularly if linked to opting-out: blame avoidance strategies ('no' votes or abstaining while predictably receiving a positive decision by the EC) might no longer be sustained.

- Administrative burden for Member States with strict coexistence laws is likely to increase in any case: if there is cultivation of GM crops in these countries, efforts will increase for implementing national legislation and control. In case of an opt-out clause based on socioeconomic reasons, Member States might be required to provide extensive socioeconomic data for their specific geographic and socio-cultural contexts.

- The appropriateness of regulation might again be subject to criticism if GM crops were rejected on socioeconomic grounds, while conventional varieties with a similar socioeconomic 'profile' would not be assessed at all and continue to be marketed.

- Applicants might not provide extensive and context specific data for less important markets – this is one explanation why Norway has so far not received additional socioeconomic information along with the risk assessment dossiers.

Characteristics of the Austrian context

This chapter briefly describes some characteristics of the Austrian agricultural and policy context in order to illustrate the context specificity of socio-economic impacts. A comprehensive and systematic investigation of specific characteristics is beyond the scope this study.

Structure of agriculture

Austria has a very distinct agricultural structure. 79,1% of the total agricultural area is located in so called disadvantaged regions of which almost 90% are classified as mountainous regions. Among EU Member States, Austria has one of the highest proportions of mountainous regions. The majority of Austrian farmers are small holders and more than 93% of the farms are run by families. This structure makes it difficult to compete with large scale agricultural farms located in favourable regions; it is however a plus for landscape care (Lebensministerium 2009; 2010).

Two characteristics are particularly relevant for coexistence of conventional/organic and GM crops. Individual fields are very small, with an average plot size of some 1.7 hectares[60]. Second, the high proportion of organic farming: in 2009 20,870 farms, which corresponds to 15.2% of all farms, were managed organically. This comprises a 18.5% share for organic farming of total arable land[61] (Lebensministerium 2010). These proportions are by far the highest among all EU Member States. In some Austrian regions the share of organic farms is exceeding 30%, with 52%(Hallein) being the highest. In the province of Salzburg 42% of all farms are organic farms (see Figure 4).

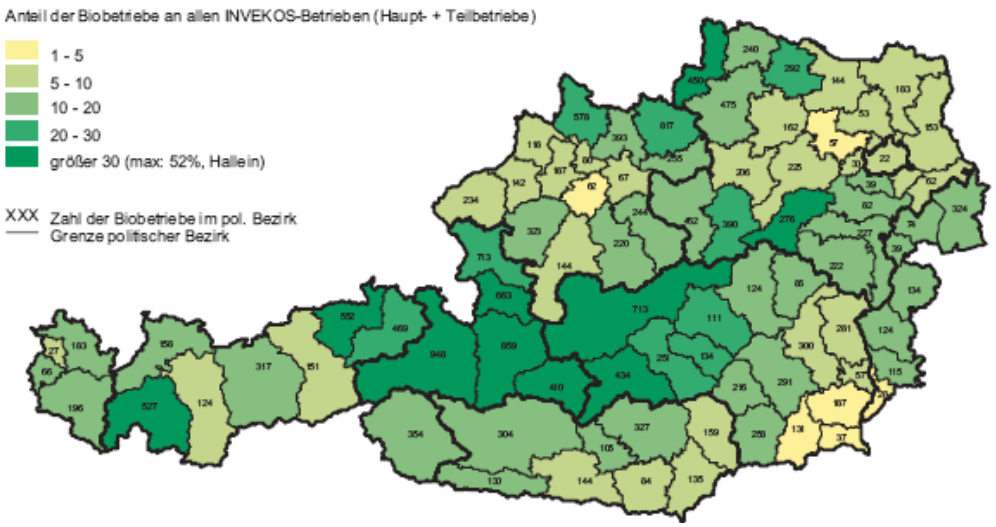


Figure 4: Proportion of organic farms in according to administrative districts in 2009. Source: Lebensministerium 2010.

[60] BMLFUW.

[61] Including areas of organically managed alpine pasture.

Agricultural policy context

Austrian agricultural policy started to support environmental measures in agriculture in the late 1980ies. In 1991, the first nationwide programme to support organic farming was launched (Gleirscher 2008).The Agricultural Act of 1992 specified the agricultural policy goal to consider social and ecological aspects, as well as regional balance. The Act highlighted that structural improvements should especially be environmentally and socially sound and compatible to a peasant agriculture. Natural resources, soil, water, and air should be protected in a sustainable way (Landwirtschaftsgesetz 1992).

Multifunctionality of agriculture was and is important for maintaining agriculture and cultural landscape care in mountainous regions and borderline regions. Several authors have described characteristics of Austrian agriculture well beyond the pure productivity function (cf. Schmid and Sinabell 2004):

- Production function, supply of services
    - food, feed, fibre, biomass, energy carriers
    - tourism, secondary activities, community services, waste management, recycling
    - food security, animal welfare
- Spatial function, viability of rural economies
    - rural infrastructure, street network, provision of land, open landscape
    - direct and indirect employment, rural value added, direct sales, buffer function on labour market, support system for rural dwelling
- Ecological and landscape aesthetical functions, viability of rural environment
    - landscape stewardship, landscape management, provision of cultural landscapes
    - maintenance of natural resources, biodiversity, deer feeding, genetic resources
- Protection function and regeneration of natural resources
    - groundwater recharge, maintenance of surface water courses
    - protection of the environment, protection against natural hazards
- Socio-cultural function, cultural role of farmers
    - rural life style, maintenance of historical objects and local traditions

The Austrian National Sustainable Development Plan also highlights the multifunctionality of agriculture (Federal Ministry of Agriculture, Forestry, Environment and Water Management 2002). GMOs are perceived to negatively affect these goals – in particular with regard to organic agriculture (Berlakovich 2009).

In 1995, the first agri-environmental programme was launched following EU accession. In 1997 more than 90% of the total agricultural area was covered by agri-environmental measures. A similar high share has been maintained ever since, e.g. 94% in 2008, 89% in 2009. In 2009 73% of all farms participated in the agri-evironmental programme (ÖPUL). Austria has the highest percentage of participation in EU agri-environment programmes (some 17%)[62].

Recent Austrian policies support an economically sound, competitive peasant agriculture, high-quality food, environmentally friendly production methods, sustainable and small-scale production, etc. Austrian policy makers have promoted a strategy of 'quality instead of quantity', given the high proportion of less-favoured areas and small-scale farms. They emphasise support for alternative production and marketing systems. The Austrian National Strategy emphasises the importance of maintaining Austrian small-scale agriculture.

Within the new Austrian 2007-13 RDP, measures for land management and improving the environment aim at strengthening the farmers' willingness to keep or to introduce production methods which protect or improve the environment, the cultural landscape, the rural areas, the natural resources, the soils and genetic diversity. Axis 3 measures (quality of life and diversification of the rural economy) support joint projects of farmers and non-farmers; cooperation between agriculture and other sectors; vertical cooperation between direct selling activities, catering and tourism.[63]

Organic agriculture has been supported by national funding since 1991 with the number of organic farmers continuously growing ever since (see Figure 5).

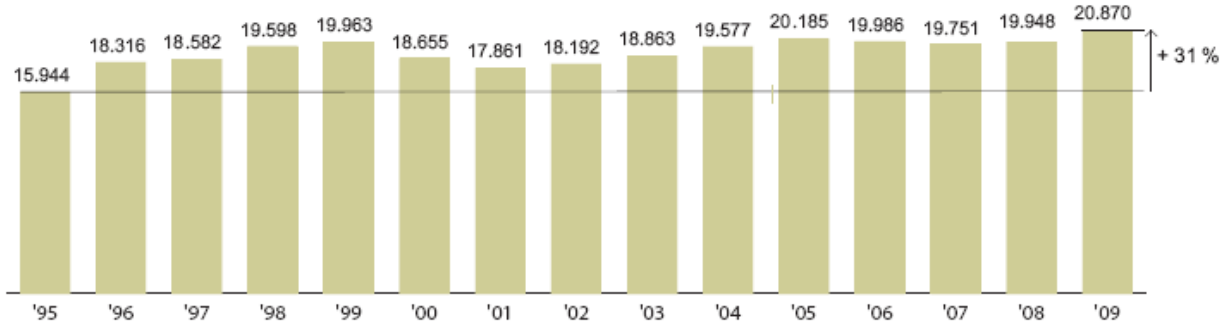


Figure 5: Number of organic farms in Austria from 1995 to 2009. Source: Lebensministerium 2010.

Organic Farming Action Programmes support such expansion, e.g. aiming to reach 20% of the total arable land by 2010 (Lebensministerium, no publication year indicated; Lebensministerium 2010). Elsewhere the policy goals were described as "socio-ecological, sustainable agriculture with a clear organic priority".[64]

Support for alternative agriculture comes from dedicated CSOs, top-level chefs, restaurateurs, organic/alternative farmers, their respective organisations and consumers. All seek regional, original specialities, many of which are perceived as being more sustainable, healthy and more natural than

[62] http://ec.europa.eu/agriculture/envir/report/en/2078_en/report.htm.

[63] http://ec.europa.eu/agriculture/envir/report/en/2078_en/report.htm.

[64] http://www.bmlfuw.gv.at/article/articleview/71768/1/13752/.

conventional products. Furthermore, there are efforts to support local and/or alternative networks on the regional and communal level; some regions and municipalities try to implement sometimes ambitious projects using their own budgets.

Absence of benefits

Present generations of GM crops are perceived not to provide relevant advantages over conventional crops. This type of crops is discussed to convey farm level benefits, in particular increased yield/reduction of yield loss, but has so far failed to provide significant advantages to Austrian farmers. The corn borer, for instance, is not a significant problem in Austria and can be controlled by conventional and preventive means. Hence, there is little incentive to cultivate Bt-maize. Overall the contribution of GM technology to yield increase seems to be limited. Figure 6 shows the breeding progress for yielding maize in the USA (with GM maize varieties) and in Austria (without GM varieties). From this comparison it appears that the use of genetic engineering does not lead to increased yield.

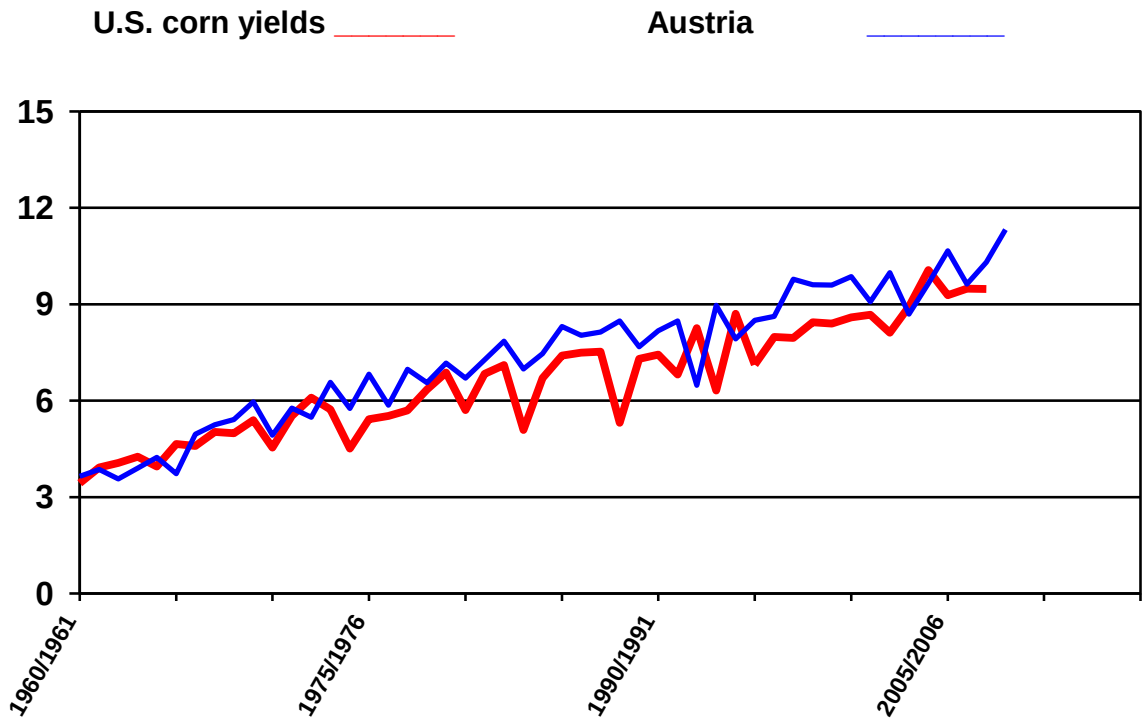


Figure 6: Breeding progress in maize yields. Source: Gurian-Sherman (2009a); BMLFUW

Coexistence

The difficulties and obstacles for coexistence of GM, conventional, and organic crops in Austria were investigated on a crop-specific basis by several authors (e.g. Müller 2003, Pascher and Dolezel 2005, Pascher et al. 2006) and frequently highlighted by policy makers. General factors complicating coexistence in the Austrian context are:

- Average plots are very small (1.7 hectares[65]) and typically scattered over an area
- The high percentage of organic farms (15.2% with some regions exceeding 35% as described above)
- Strong consumer demand for GM-free food (discussed further down in this chapter)

Both GM-free and organic food products require not to exceed thresholds of 0.1% according to national guidelines (Austrian Codex) or association's standards resp.[66] A growing number of food producers is marketing certified GM-free food. One example is rapeseed oil. Partially refined or cold-pressed rapeseed oil has become more and more popular in Austria given its health benefits. All relevant vegetable pure oil brands are GM-free. RAPSO, the biggest and most successful brand, uses oil from oilseed rape cultivated by some 1,500 contract farms and produced by small and decentralized oil mills. RAPSO field plot size range between 0.5 and 2.5 hectare (Reiner 2009, Pascher and Dolezel 2005).

Beyond legal and private standards there is a strong consumer preference for GM-free conventional food which is reflected by the efforts of big retailers and food producers to avoid *any* GMO contamination. Hence, in order to maintain organic and GM-free food supply in Austria coexistence measures would have to be much more rigorous and comprehensive compared to other countries. Isolation distances would need to make sure that the resulting food would not be labelled (that means to be beyond the 0.9% labelling threshold set by EU-Regulation 1829/2003). Organic food producers, producers of conventional GM-free food and many conventional producers in Austria, require much lower thresholds, though. For seed production this would be even more difficult because seeds containing more than 0,1% of GM material cannot be legally marketed in Austria.

The difficulties for coexistence can be illustrated by taking the example of isolation distances. Pascher and Dolezel (2005) simulated cultivation of GM maize and GM rape using different adoption scenarios in selected regions of Austria.[67]

A number of EU Member States have established isolation distance for GM maize of 200 or 300 m with some considering larger distances of 800 m and more (e.g. Hungary, Poland, Luxembourg). In case of rape and given its biological properties and the biogeographical context in Europe larger isolation distances would have to be considered. Very few EU Member States have yet proposed isolation distances ranging from 300 to 3000 m. [68]

Simulations show that even in case of moderate isolation distances and lower adoption rates considerable impacts can be expected due to loss of arable land for cultivation of conventional and organic maize/rape. The magnitude of the loss is thereby clearly depending on a range of different factors, e.g. crop type, pattern of fields, landscape structure, and isolation distances.

For GM rape, anticipating a low adoption of 10% and an isolation distance of 200 m, loss of conventional oilseed rape cultivation area would be up to 36%. In case of a larger isolation distance

[65] BMLFUW.

[66] http://www.bio-austria.at/.

[67] Three regions were selected for each crop including the most important regions for rape cultivation (in the provinces of Lower Austria, Upper Austria, and Burgenland). The maize scenarios were selected from Styria, Burgenland, and Lower Austria.

[68] http://www.biosicherheit.de/.

(500 m) up to 73% would be lost. In case of higher adoption rates loss would rise to 84% (200 m) and would reach 100% in all three regions in case of 500 m isolation distance. For maize estimated loss would amount to 76% in case of a 10% adoption rate and 200 m isolation distances but would easily reach 100% in case of 50% adoption rate. If differentiated isolation distances are anticipated (for feed maize, food maize, and organic maize) impacts would be lower in the 10% adoption scenario and in a similar range in the 50% adoption scenario (see also Figure 7).

A reduction in area loss could be achieved if plots would be clustered and/or closed production areas for GM and non-GM crops would be established. These measures would, however, require considerable changes in agricultural practice and structure.

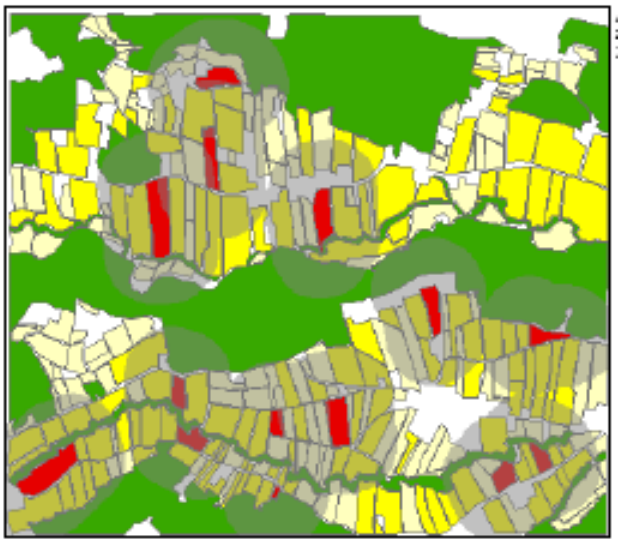
A  B 

Figure 7: Simulated loss of cultivation area for conventional rape (A) and maize (B) due to coexistence measures.

A: rape; scenario: Sigmundsherberg, Lower Austria; adoption rate of GM rape: 10%; isolation distance: 500 m; GM rape fields scattered over the area. Estimated loss: 73.5%.

B: maize; scenario Mehlteuer, Styria; adoption rate of GM maize: 10%; isolation distance: 200/300 m. Estimated loss: 76%/82%.

Red colour indicate plots with GM crops; green colour plots with woods, and yellow colour indicate rape or maize fields resp. Light yellow colour indicates plots with other crop cultivation. Grey zones indicate isolation distances.

Source: Pascher and Dolezel (2005).

Overall Pascher and Dolezel (2005) concluded that in case of rape, coexistence is considered not feasible whereas in case of maize, coexistence is also likely to fail without drastic changes in agricultural structure.

Two other examples might help to further illustrate direct and indirect socio-economic impacts on particular branches. In these examples, the efforts and costs for coexistence, segregation and control measures - once GM crops can be grown commercially in Austria – is likely to be detrimental – in particular in the case of small scale producers.

For egg production, free-range systems have become a standard in Austria and cage eggs are no longer permitted. This type of egg production works well in a traditional farming system. It relies on grain feed from the farm, which mainly consists of cereals such as wheat, rye, or corn. GM-free eggs and egg-products[69] are popular in Austria and consumers are willing to pay a premium. Eggs are supplied from these small-scale farms. A key factor is that these farms are able to supply GM free maize as feed (Reiner 2009).

Another example is the production of GM-free milk. A number of producers (e.g. Kärntnermilch, Stainzer Milch, Obersteirische Molkerei, Tirol Milch) have focused on the production of milk labelled as GM-free. These producers are depending on GM-free feed in order to meet the labelling requirements.

Public perception and consumer demand

A national opinion poll on GMOs and GM food in 1997 launched by opponents of GM technology was very successful and received more than 1.2 million signatures. Since then, public acceptance of GM crops and GM food has been continuously ranking very low compared to all other EU Member States (see Table 12 and Figure 8). Even industrial GM crops which receive higher levels of support in many EU Member States compared to GM crops for food/feed use are largely rejected by a majority of the Austrian publics (see Figure 9). A retrospective analysis over time shows that these low levels are quite stable (Table 12). A recent survey has shown that Austrian consumers are highlighting fresh, healthy and regional food and are rejecting GM food (GfK Austria 2010). Overall sales of organic products are estimated to be about 1 billion €. Despite the economic crisis sales were growing 5% in 2009 indicating strong consumer preference (Bio Austria 2010).

The low level of public acceptance for GM crops is mirrored by a general consensus of political parties and major stakeholder organisations to proceed with a GM free policy.

Table 12: Outright support and risk tolerant support for GM food across EU25

EU Member State	1996	1999	2002	2005-2007
Spain	80	70	74	74
Malta	-	-	-	66
Portugal	72	55	68	65
Czech Republic	-	-	-	64
Ireland	73	56	70	55
Italy	61	49	40	54
Lithuania	-	-	-	54
Netherlands	78	75	65	48
United Kingdom	67	47	63	48
Slovakia	-	-	-	48
Finland	77	69	70	46

[69] GMO-free animal products according to the Austrian Food Codex have to be fed with non-GM feed.

EU Member State	1996	1999	2002	2005-2007
Belgium	72	47	56	45
Denmark	43	35	45	42
Hungary	-	-	-	37
Poland	-	-	-	36
Slovenia	-	-	-	33
Sweden	42	41	58	32
Estonia	-	-	-	31
Germany	56	49	48	30
France	54	35	30	29
Austria	31	30	47	25
Luxembourg	56	30	35	20
Latvia	-	-	-	19
Cyprus	**-**	**-**	**-**	**19**
Greece	49	19	24	12

Source: Gaskell et al. (2006,modified).

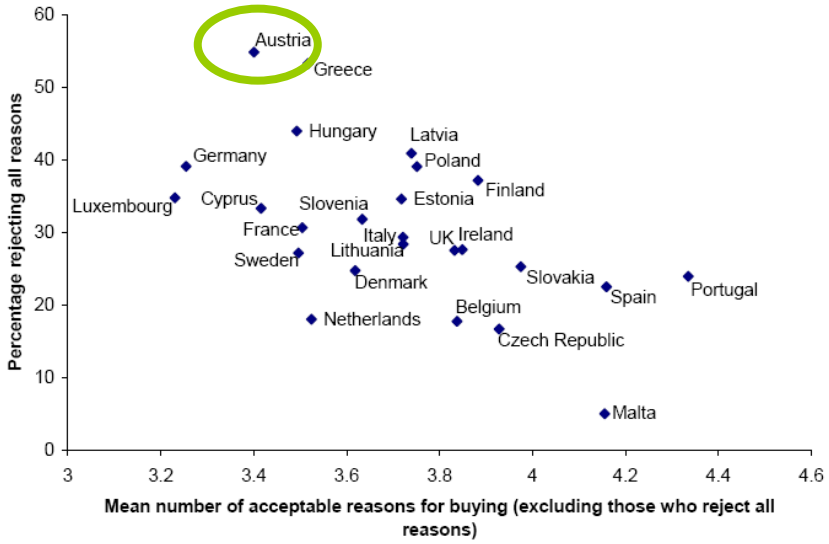


Figure 8: Acceptable reasons for buying GM crops. Source: Gaskell et al. (2006).

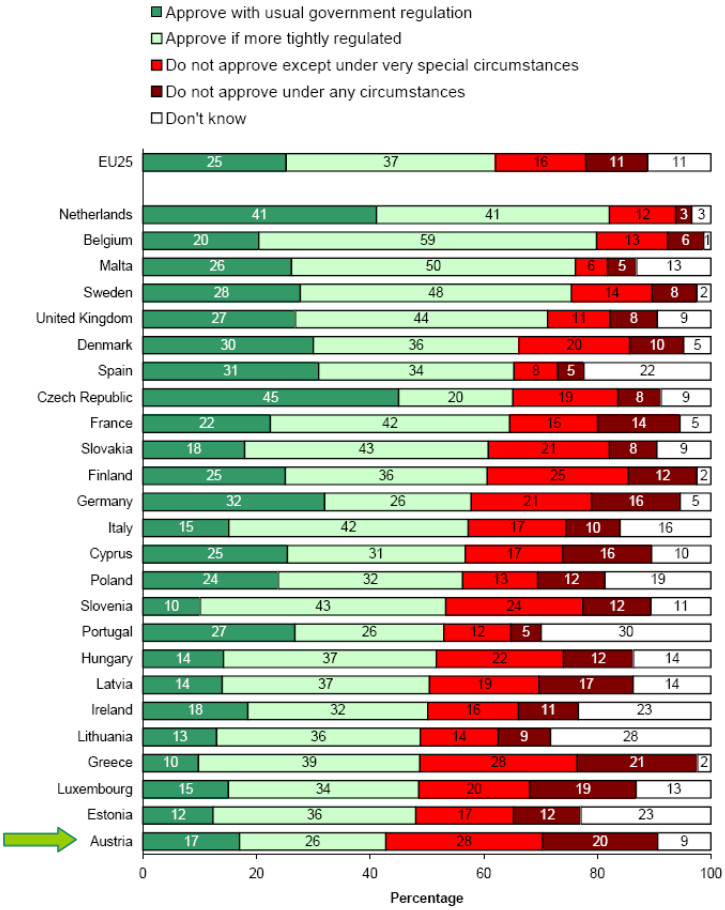


Figure 9: Support for industrial GM crops. Source: Gaskell et al. (2006).

GM-free policy

Policy documents frequently highlight GM-free agriculture as an important aim in agricultural policy.[70] All nine Federal Provinces (Bundesländer) have established strict coexistence rules as measures to maintain GM-free agriculture.[71] Federal Provinces, regions, and rural communes have launched a number of voluntary initiatives for GM-free agriculture, e.g. the "Austrian Charter for the Non-Use of Genetic Engineering"[72]. GM-freeness is frequently considered an important aspect of high-quality and healthy food (Kellner 2004). GM crops are excluded from healthy and sustainable food supply for reasons of environmental threats and market monopolies. For instance, some guidance documents for and some policy measures on (public) procurement imply that conventional food should be GM-free (e.g. Kellner 2004; Wiener Abfallwirtschaftskonzept 2007). In these cases, reference is given to the definition of GM-free specified by the Austrian National Food Codex Commission.

[70] Government Programme 2008 – 2013. http://www.landnet.at/filemanager/download/55993/; Lebensministerium http://www.landnet.at/article/articleview/55037/1/17818;

[71] E.g. Lebensministerium 2008. http://www.landnet.at/article/articleview/39938/1/5988/

[72] E.g. Lebensministerium 2006. http://www.landnet.at/article/articleview/43565/1/5838/.

The role of organic agriculture and GM-free in rural development

Given its tremendous success, organic agriculture in Austria has become more then just another branch of agriculture occupying a market niche. The organic movement has effectively transformed conventional agriculture in Austria and thereby contributed to ecological modernisation of agriculture at large. This is reflected by the high participation in agri-environmental programmes and by the way organic agriculture is providing an important role model for agricultural policy (Schermer 2008; 2005). Moreover, the organic movement has also changed rural development by encouraging what has been called "endogenous " or "neo-endogenous" regional development" (Schermer 2006, 2003). Organic agriculture has frequently become a core element with organic farmers constituting core groups in bottom-up rural development initiatives. These initiatives are frequently aiming to establish an organic region[73] (in German: "Bioregion"). Such organic regions typically comprise several rural communes and sometimes also larger regions. In a very general sense these initiatives are linking both organic production and organic products to regional characteristics (Schermer 2003, Kratochvil 2004). Sustainable regional development and organic agriculture act as strategic partners for mutual benefit (Kratochvil 2004, Schermer and Kirchengast 2008).

As a specific feature organic regions are linking both actors along the food chain (producers, food processors, and retailers) and different sectors (e.g. agriculture, gastronomy, tourism, energy production) (Schermer 2003). A number of positive impacts are associated with such initiatives: creating and keeping value added in a particular region; establishment of regional brands which are perceived outside the region; creation of new jobs in the region; improvements of regional infrastructure and food supply; improvements with respect to regional self-support, improvements of quality of life in the region; encouragement of active participation of the regional population; creation of regional self-images; improvements in regional self-governance; protection of natural resources (Kratochvil 2004). Meanwhile a more detailed concept of what is considered an organic region has been proposed in order to guide and facilitate the establishment of such regional initiatives (Schermer 2008).

In 2002 Schemer (2003) described 20 regions and more than 30 initiatives. These numbers have been growing ever since supported by the LEADER programme and other rural development programmes. Some initiatives are less region and more product/market oriented (Kratochvil and Schermer 2008). Some consider them to be broader than organic (indicated by the term 'Ökoregion') others established a focus on the culinary heritage[74]. While organic agriculture is not the dominating/core element in all cases principles of sustainable development and sustainable agriculture (in particular of Agenda 21) are widely shared in almost all initiatives.

Many of these regional development initiatives have adopted GM-free as an additional criterion, as GM is associated with industrialised and intensive agriculture, globalisation and standardised food products, all of which are considered to contradict underlying principles of sustainable development. Even initiatives and regions which are not dominated by organic farming frequently declare themselves as GM-free (e.g. region Almenland, Bioregion Murau). From interviews conducted by the author of this study in the course of another project[75] it appears that the notion of GM-free has already become firmly embedded in the beliefs and attitudes of many farmers, producers and

[73] The German term "Bioregion" is translated by Schermer (2003) as "eco-region". This translation does, however, not allow to differentiate "Bioregion" and "Ökoregion", hence, the term "organic region" is preferred.

[74] http://www.genuss-region.at/.

[75] http://www.faanweb.eu/.

retailers outside of the organic community. It is considered to be even more important if cultivation of GM crops will become more widespread ((Hoppichler and Schermer 2006). Hence, GM-free regions, GM-free production/products are meaningful to larger parts of the population. Given the difficulties of coexistence outlined above any cultivation of such crops in or nearby such regions could be disruptive to such initiatives. Members of such rural development initiatives perceive cultivation of GM crops as jeopardizing their economic basis and sociocultural regional identity.

Socio-economic impacts mentioned by stakeholders

Views on socioeconomic impacts of cultivation of GM crops in Austria were collected in the course of ten semi-structured interviews.[76] In no case, however, an agreed view or position paper was available or under preparation - stakeholders seem to adopt a wait-and-see approach. This is not surprising given that the discussion on socio-economic considerations is still in an early phase. Hence, the impacts anticipated in the interviews have to be interpreted with extra care.

All interviewees highlighted that considerable socio-economic impacts are to be expected if GM crops are cultivated in Austria. As general reasons, the specifics of the Austrian agricultural context and the strong rejection of GM foods by consumers were mentioned.

The majority of interviewees pointed to impacts from avoidance strategies, contamination and the loss of GM-free status as being particularly detrimental.

Societal resistance and protests

The mere announcement of cultivation of GM crops might be sufficient to trigger strong resistance protests from large societal groups – as one interviewee phrased it “there will be a public outcry”. If GM cultivation is imposed by EU policy, this will reinforce anti-EU attitudes.

Impacts on growers of conventional and organic crops and the overall food chain

Most respondents highlighted the impact of GMO cultivation in Austria on conventional and organic farming. Austrian farms and their plots are very small (average plots size of some 1.7 hectares[77]) and are often scattered over a region. About half of the Austrian farms are located in so called disadvantaged regions (mainly mountainous regions). Multifunctionality of the Austrian agriculture was also highlighted. At present, domestic maize seed production [comment: until recently the only GM crop authorised for commercial cultivation], strict controls of seeds and the bans on cultivation effectively ensure GM free agriculture. Serious problems are expected if GM crops are to be cultivated in Austria. Given the specifics of Austrian agriculture and topography and the requirement to avoid any contamination, coexistence is not expected to work in practice. Farmers who want to stay GM-free would be required to consider extensive isolation distances – one interviewee mentioned several hundred meters up to one thousand meters. This would reduce production surface and considerably impact the economics of conventional or organic farms.

Avoidance strategies are likely to result in tensions and conflicts between neighbour farmers, within the agricultural system and among all actors along the food chain, and might also lead to court cases. Liability problems are expected to occur which by some are associated with enhancing legal uncertainties. The order of magnitude of all these problems is expected to depend on the crop

[76] For the interview guidance and the list of interviewees see Annex.

[77] BMLFUW.

though most interviewees focused on maize when responding - it is expected to be lower in case of soybeans and much higher in case of rape.

Given the consumer demand for GM-free food products, food producers would avoid having anything in stock with a GM label on it and are therefore carefully selecting their suppliers.

At present, some 90% of the hybrid maize seeds used are produced domestically. Given the conditions described above, GM-free seed production is considered feasible only in case of a legal protection of certain regions used for seed production.

The requirement to establish separate logistics or to relocate seed production and the impacts described above are expected to translate into extra costs for growers, processors and retailers which will have to be partly passed over to consumers. Moreover, as one interviewee puts it "avoidance strategies cannot be calculated based on the 0.9% [labelling] threshold because the market does not accept any GMOs". Extra costs can be borne more easily by larger farms or companies and are more likely to facilitate concentration in the agricultural sector and along the food chain. Organic producers are particularly affected. Income of organic farmers is expected to drop. In the long run, cultivation of GM crops in Austria is expected to affect the structure of both the agricultural sector and rural areas in general. Agricultural practice could shift more towards intensive farming. Given the absence of potential gains, one interviewee highlighted a "striking imbalance of efforts and costs" given the absence of gains.

Jeopardising market niche and competitiveness

The status of a de-facto GM free country (even no field trials) and the Austrian seed legislation have led to an increased demand for Austrian GM-free conventional maize seeds resulting in a 3-4-fold increase in production and a proportion of about 50% for export e.g. of seeds for the organic market to France and Germany. Following cultivation of GM crops in Austria, Austria would no longer be perceived as a guarantee for GM-free seeds. Contamination risks would not differ from e.g. East European countries which could economically produce seeds at lower prices.

Image at risk

Several stakeholders argued that a cultivation of GM crops would be detrimental for the image of Austria linked to good quality of life, organic food, sustainable agriculture, healthy food, identification and importance of regions, wellness etc. GM-freeness is considered by some to be an important characteristic of high-quality food products. This could not only impact the export of food products but also tourism.

Impact mentioned by a few or one interviewee only

On agro-food sector

- Does not correspond to the Austrian goal in agricultural policy embedded in the national legislation
- Yield
- Employment effects, costs per workplace lost
- Effects on agricultural practice

- Possible driving out of business of certain types of farming (e.g. organic rape in Canada)
- Effects on EU policy goals for biodiversity
- Costs for administering coexistence
- Efforts for resistance management
- Insurance costs for farmers
- Effects on farm enterprises aiming at agro-biodiversity
- Social pressure on the first farmers intending to grow GM crops
- Effects on landscape, agriculture and leisure industry
- Liability issues, e.g. near borderlines between Member States
- Pesticide prices
- Effects on bee keepers

On consumers

- Freedom to choose for consumers
- Consumer demands and benefits
- Food sovereignty

Broader environmental effects

- Protected areas
- Effects on genetic biodiversity

Other

- (Fairness of) distribution of costs and benefits
- Costs for risk research and coexistence research

All interviewees suggested assessing all dimensions of socioeconomic impacts mentioned in the interviews.

Summary

Austria has a very distinct agricultural structure compared to other EU Member States. It has one of the highest proportions of farms in mountainous regions (more than 70%) - dominated by small-holders - and by-far the highest proportion of organic farms (15.2% corresponding to a share of 18.5% of total arable land). Since the late 1980ies, Austrian agricultural policy has highlighted sustainable and multifunctional agriculture (landscape management, tourism, biodiversity, rural

development, socio-cultural aspects etc.) and strongly promoted ecological measures, organic farming and organic food, regional food supply, local and regional farmer-business initiatives etc. This is also mirrored in Austria's National Sustainable Development Plan. Austria has the highest percentage of participation in EU agri-environment programmes (some 17%). National policies foresee to continue with this policy and to expand organic farming to 20% of total arable land by 2010.

Present generations of GM crops are not perceived to provide relevant benefits, a fact that is partly linked to the low infestation rates with pests such as the corn borer. Yield increase over the last few decades in case of maize compares and even exceeds the numbers from the USA.

Coexistence of GM and conventional/organic crops is being considered very difficult for two main reasons. First, the small-scale agriculture with an average plot size of some 1.7 hectares and plots typically scattered over an area. Policies in place support small-holder structures and less intensive farming as important in mountainous regions for the maintenance and management of cultural landscapes, tourism and rural development in general. Second, there is strong pressure to avoid any GM content in food exceeding 0.1%. This threshold is embedded in standards of the organic farmers association and in legal requirements for food labelled as GM-free. Beyond that many food processors and retailers are striving to avoid any GM content because of public demand. In fact, the acceptance of GM crops and food in Austria has been continuously ranking very low and lowest compared to other EU Member States.

As a consequence, coexistence measures would have to be much stricter and more comprehensive compared to other geographical contexts. For instance, according to simulation experiments with rape and maize considerable loss of conventional/organic crop land of 36 to 100% could be anticipated in order to allow for sufficient isolation distances.

The organic farming movement has also triggered ecological modernisation in Austrian agriculture with many farmers adopting ecological measures even if not farming organically. Organic farmers are frequently key actors in bottom-up initiatives of rural development which have become more and more important, especially in disadvantaged regions. These initiatives are typically comprising of several rural communes and could also cover larger regions. They are frequently linking regional actors along the food chain and other business sectors such as gastronomy, tourism and energy production. High quality food and specialities from sustainable production are being linked to regional characteristics. Many of these initiatives – even if not subscribed to organic farming – have adopted sustainability standards for farming, food-production and supply with GM-freeness as one of the key criteria. Members of such rural development initiatives, therefore, perceive cultivation of GM crops as a threat to their economic basis and sociocultural regional identity.

Overall, these characteristics have led to strict coexistence legislation by all Federal Provinces and the establishment of numerous initiatives promoting GM-free regions and GM-free food supply.

Austrian stakeholders consulted in the course of this study highlight these agro-economic and socio-cultural specifics. Hence, serious short-term and long-term impacts can be envisaged on conventional and organic producers and the entire food chain including consumers and seed producers, thereby affecting costs and gains for farmers, food producers and retailers, market shares and position, as well as competitiveness. It is also perceived to conflict with Austrian agriculture policy goals.

Conclusions and Recommendations

The 2008 EU Council initiative to include socioeconomic consideration in GMO market authorisations brings new inputs into the GMO debate. The twofold novelty lies in the characteristics of socioeconomic information and in the consideration of not only risks but also benefits. The Council conclusion did not specify *how* socioeconomic impacts should be considered. Basically, there seem to be two policy options:

Option 1: *socioeconomic information will be considered at a political level*, without formally integrating its assessment into the case-by-case authorisation procedures.

Option 2: s*ocioeconomic assessments will be conducted alongside risk assessments in individual authorisation procedures*: this option does not mean that a fully fledged socioeconomic assessment would have to be conducted for each individual event. A basic set of socioeconomic data could be generated for individual traits/crops/applications or their respective combinations which will be supplemented by event specific information if necessary.

The challenges for implementation will depend on the particular policy option. In any case it can be expected that socioeconomic assessment will be conducted at the EU level and scrutinized by all Member States and interested stakeholders. For the purpose of this analysis it is presumed that an assessment procedure will be established.

Challenges arise from the need to comply with international legislations, in particular with the WTO and the Cartagena Protocol on Biosafety (CPBS). As the analysis in chapter “Challenges from international regulations” shows, there seems to be ample scope for considering socioeconomic impacts under WTO legislation. Scope also seems to exist in case of the CPBS, though the meaning of relevant provisions has not been specified so far. The WTO legislation seems to be particularly relevant as major GMO producers are Parties to the WTO but not necessarily Parties to the CPBS.

Challenges are also identified with respect to the institutional location of socioeconomic impact assessment. There is no obvious body at the EU level to take over such a task. Given possible legal restrictions and the lack of acceptance by stakeholders and Member States, EFSA is unlikely to host a fully fledged socio-economic impact assessment unit. More likely, EFSA will be charged to evaluate certain aspects, e.g. GMO benefit claims in analogy to health claims. Another scientific panel in analogy to the European Group of Ethics composed of unpaid independent scientists will only be able to deal with this issue in very general terms. Hence, there is a need to establish a new body or unit dedicated to evaluating socioeconomic impacts more broadly and incorporating inputs from Member States.

Socioeconomic impact assessment might be favourably perceived by a majority of stakeholders. Its appealing strengths are that it makes visible and allows to explicitly address aspects which have previously played a major role but remained opaque in the decision making process. However, socioeconomic impact assessment *per se* is unlikely to overcome the policy impasse on GMO authorisation. It might just enrich the vocabulary of and add new topics to the controversy. Controversies very similar as those over the last 15 years in risk assessment can be expected for two reasons. First, a broader analysis of impacts will provide quantitative and qualitative data, the generation of which will be invariably conditioned by basic assumptions, models and methods used for quantifying economic impacts etc. which are already a matter of controversy. Consequently, studies investigating impacts ex-ante might be even more controversial. Second and related to the first point, knowledge generation in social science is guided and interpreted along coexisting theoretical concepts none of which is dominant. Thus, social science might provide to be less

authoritative than the science for risk assessment. The guidance which will be needed to structure such assessments will take a long time for agreement. Eventually, such deliberations could turn out to be another proxy for actors who are generally prone or opposed to GMOs or GMO cultivation.

In order to establish socioeconomic impact assessment as a robust and transparent assessment process it would be necessary to draw on lessons from risk assessments and to consider widely shared principles of good governance and for expert advice on policy making. A socioeconomic impact assessment conceptualised as social science advice into GMO decision making (here: into risk management comitology) can therefore also be informed by concepts of integrated and inclusive risk governance. Against this backdrop it becomes clear that any socioeconomic assessment needs clarification of a number of cornerstones including scope, normative baselines, criteria, and possibilities for public participation as well as impact dimensions and impacts to be considered. Any robust assessment aiming at a transparent and more legitimate assessment requires mutual understanding and agreement by expert advisors, decision makers and stakeholders of these cornerstones. Insights from risk governance studies have shown that this is done best in a dedicated framing step which– in analogy to risk assessment - can be considered as setting an 'impact assessment policy'. It might also require a kind of clearing house mechanism to clarify which issue to go to the scientific risk assessment and which to the social science impact assessment.

While these measures are important and a necessary precondition for a robust assessment procedure, they are nevertheless not sufficient to overcome the impasse and above-mentioned problems. An unprecedented move in EU history but perhaps most effective would be to move towards renationalisation of decision making in GMO cultivation allowing Member States to opt-out from the EU-wide authorisation for cultivation. GM crops could then be banned on a Member State's territory. As a matter of fact, this would lift the pressure on risk assessment and socioeconomic assessment and both types of assessments can be expected to function more smoothly and in ways they are intended to do. Such opt-outs could be justified, e.g. by socioeconomic assessments conducted at the national level and reviewed by e.g. the Commission or by other sound political reasons (implementing the policy guidelines of EC President Barroso (EC 2010).

There is another important characteristic of socioeconomic assessment which enhances complexity and therefore requires attention. Socioeconomic impact data and assessments can/will quite often be specific for a particular country or region:

- *impacts can differ depending on the geographical, agro-economical, political, and socio-cultural context*: socioeconomic impacts are context specific; impact data and conclusions

- *what is being perceived as negative/positive impacts can differ depending on the geographical, agroeconomical, political, and socio-cultural context*: normative baselines and impact dimensions might be context specific and difficult to agree at the EU level

- *impact assessment will depend on data/information only available in countries/regions*

The context specificity of both data and assessments is not entirely new. Environmental risks of GMOs have been complicated by geographical, climate and other context factors, e.g. when considering the results of field trials for countries with a different climate/geographical environment, when considering baselines for environmental monitoring, identifying indicator species for identifying environmental harm, but also in the type of agriculture considered to be a normative reference: conventional industrialised agriculture or organic agriculture. With socioeconomic data and assessments, context specificity is assumed to be even more important, more complex, and more difficult to tackle.

Another type of challenges which will occur is the problem of weighing. If different bodies of knowledge are being produced, e.g. on socioeconomic risks, socioeconomic benefits, environmental risks, environmental benefits etc., decision making will be better informed but require weighing between these issues. Risk governance studies conceptualise this important step as risk/benefit evaluation and suggest broader participation depending on the issue at stake.

General recommendations

Based on the results and conclusions of this analysis, a number of recommendations can be derived.

Clarifications and agreement on the EU level is needed

- on the cornerstones for socioeconomic assessment in order to set the state for developing a proper framework – this would include possible links to the opt-out proposal. Such a scoping paper would provide a frame of reference for a broader discussion involving a broad range of experts and stakeholder groups

- on the possible legal restrictions and leeway to widen the scope of EFSA to also consider socioeconomic impacts; more broadly the possibilities and leeway under EU law for considering socioeconomic issues need to be explored and defined

- how to envisage a kind of base set of socioeconomic data for individual crops/traits/applications in order to facilitate and speed-up assessment

More research is required on

- assessment criteria, concepts, methods which can be employed in socioeconomic assessment

- how the various existing concepts of impact analysis can provide useful insights, e.g. social impact assessment

- how concepts of integrated risk governance, for instance the one developed by the SAFEFOODS project could inform the establishment of a socioeconomic impact assessment; this would for instance include an attempt to identify and characterise in more detail the differences between socioeconomic assessment and knowledge and scientific risk assessment – in other words how to tailor concepts essentially developed for dealing with scientific data and assessments to meet the specific characteristics of social science data and assessments

- recent WTO case law which could provide some more guidance on what kind of socioeconomic considerations would be in-line with SPS, TBT, or GATT

- how to envisage a centralised multilevel assessment framework which allows for gathering and evaluating ‘contextualised’ socioeconomic information from individual Member States

- how key stakeholder groups and the publics at large perceive such an implementation

Recommendations for policy development in Austria

For more than two decades, Austria has provided substantial inputs into the development and improvement of the EU regulatory regime for GMOs thereby considerably shaping EU policy. In that way, Austria has frequently highlighted the specifics of its agro-environmental context in particular in the context of environmental risk assessment and monitoring. The apparent rationale of Austrian GMO policy was to strive for a regulatory regime which would not jeopardise Austria embarking on sustainable agriculture without GMOs. According to this rationale it would be both pertinent and appropriate to also provide significant inputs into the EU discussion on socioeconomics. Such inputs, though, require the development of particular expertise and specific knowledge.

The particular measures recommended would, however, depend on next steps taken by the European Commission – e.g. if and how the Commission will link the issue of socioeconomics to the so called opting-out debate. The measures proposed in the following are anticipating that a socioeconomic assessment will play an important role – either in GMO authorisation procedures in general or for considering opting-out measures:

- Launch a process for policy development which allows for inputs of a broad range of stakeholders

  Such a process could be initiated by stakeholders and expert workshops. This would help to raise awareness among Austrian stakeholders and the general public. It would also be important to consult with experts and stakeholders from France and Norway who have already institutionalised a socioeconomic assessment for GMOs. It would also be pertinent to consider the establishment of an expert panel in order to provide advice policy makers during the entire process. In the course of such a participatory process it would also be possible to discuss and assess aspects linked to the issue through the lens of socioeconomics, e.g. the issue of novel breeding methods or other innovations in the pipeline (see examples further down). This issue is challenging the boundaries between conventional breeding and GMOs, between techniques accepted for sustainable farming and those considered unsustainable.

- Indentify and conduct research on impact dimensions and possible impacts of GM cultivation *specifically relevant for Austria*

  Over the last three decades, Austria has successfully developed, established and broadened niches in agricultural development (organic products, specialties) which allowed for alternatives to the dominant paradigm of intensive agriculture and globalised food production and supply. These developments helped not only to maintain agriculture and cultural landscape in mountainous regions, but also to strengthen more sustainable developments all of which were important for tourism. Together these developments provide scope for entrepreneurs and bottom-up initiatives favouring farmer-business cooperation. Agricultural efficiency and productivity is less dominant - the success of such initiatives is partly built on and has reinforced the links to regional and local traditions and (rediscovered) cultural heritage. Still, these developments are fragile and need attention and support. They are to some extent depending on consumer trust and credibility and functioning social networks in rural communities. Any cultivation of GM crops is therefore likely to impact the economics of farmers, initiatives and regions focusing on more sustainable and traditional forms of agriculture.

  Some impacts might be related to increased costs for operators due to coexistence and segregation measures. Others might be caused by indirect effects, e.g. facilitating concentration

in the seed industry, problems for small-scale and decentralised production and logistics. Again other impacts might not be related to coexistence at all.

This research would also provide a better basis to consider the relative importance and role of context specific national and regional vs. centralised and cross EU data and assessments.

- Based on the research described above

    - Identify best practice models, approaches and methods appropriate for measuring and assessing the impacts *identified as relevant for Austria*. This is particularly important for ex-ante assessments which will have to be applied in Austria.

    - Clarify and characterise the relevant normative baselines and criteria: existing policies relevant to sustainable development, agriculture, rural development, regional development, environmental protection, biodiversity etc. should be systematically reviewed to prepare a synopsis which can then work as a basis used in the assessment.

  The questions outlined above are most appropriately addressed by transdisciplinary approaches combining participatory research and stakeholder consultations. This would allow to access important knowledge of practitioners, to reveal differences in the normative baselines and to increase legitimacy of the process and the outcomes.

Even if socioeconomic consideration eventually played a less important role in routine EU GMO authorisation, they might by very relevant for assessing technological innovation already in the pipeline e.g.

- GM crops with altered composition claiming health benefits
- GM crops for industrial uses
- GM crops for energy production
- Novel breeding methods
- GM fish.

Some of these issues could become relevant for Austria. It might therefore be pertinent in any case to proceed with exploring socioeconomics and socioeconomic assessment of GMOs.

References

Alemanno, A. 2008. Science & EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review. EUROPEAN RISK GOVERANANCE - ITS SCIENCE, ITS INCLUSIVENESS AND ITS EFFECTIVENESS, Connex Report Series No. 6, E. Vos, ed., February 2008. Available at SSRN: http://ssrn.com/abstract=1007401.

Barrow, C. 2000. Social impact assessment. An introduction. London, Arnold and New York: Oxford University Press.

Becker, H. & Vanclay, F. 2003. The international handbook of social impact assessment. Cheltenham, Colchester, United Kingdom: Edward Elgar Publishing.

Benbrook, C. 2009a. Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years. Critical Issue Report. The Organic Center. http://www.organic-center.org/reportfiles/13Years20091126_FullReport.pdf.

Benbrook, C. 2009b. The Magnitude and Impacts of the Biotech and Organic Seed Price Premiums. Critical Issue Report. The Organic Center. http://www.organic-center.org/reportfiles/Seeds_Final_11-30-09.pdf.

Berlakovich, N. 2009. Nachhaltige Landwirtschaft und kleine Betriebsgrößen im agrarischen Welthandel berücksichtigen. Tagung des International Policy Council, 11 May 2009, Salzburg. http://www.bmlfuw.gv.at/article/articleview/75618/1/26603.

BIO 2009a. BIO debunks myths in anti-industry report. Press Release 4/14/2009.

BIO 2009b. Re: MKE Notice#2009-125 dated 9 April 2009. Letter from BIO to the Minister of Knowledge Economy, Republic of Korea, 29 April 2009. www.bio.org/foodag/action/20090429.pdf.

BIO AUSTRIA 2010. Presseaussendung 26.4.2010. http://www.bio-austria.at/content/download/26062/193345/file/BIO_AUSTRIA_Presseaussendung_%20Umsatzzahlen%202009_26042010.pdf.

BÖLW (ed.) 2009. Schadensbericht Gentechnik. Berlin: Bund Ökologischer Lebensmittelwirtschaft.

Brookes, G. & Barfoot, P. 2006. Global impact of biotech crops: Socio-economic and environmental effects in the first ten years of commercial use. AgBioForum 9:139-15.

Brookes, G. & Barfoot, P. 2010a. Global impact of biotech crops: environmental effects, 1996-2008. AgBioForum 13 (1):76-94.

Brookes, G. & Barfoot, P. 2010b. GM crops: global socio-economic and environmental impacts 1996-2008. Dorchester: PG Economics Ltd. http://www.pgeconomics.co.uk/pdf/2010-global-gm-crop-impact-study-final-April-2010.pdf.

Brookes, G. Yu THE, Tokgoz, S. & Elobeid, A. 2010. The Production and Price Impact of Biotech Corn, Canola, and Soybean Crops. AgBioForum 13(1): 25-52.

Cabinet Office 2003a. Field Work: Weighting up the Costs and Benefits of GM crops. London: Cabinet Office.

Cabinet Office 2003b. Field Work: Weighting up the Costs and Benefits of GM crops. Analysis Papers. London: Cabinet Office.

CAC 2007. “Working Principles for Risk Analysis for Food Safety For Applications By Governments” CAC/GL 62-2007. Codex Alimentarius Commission.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000. http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

CEC 2001. European Governance. A White Paper.COM 428, 25.7.2001, Brussels.

CEC 2002. Communication from the Commission on the collection and use of expertise by the Commission: principles and guidelines. “Improving the knowledge base for better policies”. COM 713, 11.12.2002, Brussels.

CEC 2007. Accompanying document to the SECOND REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT on the experience of member states with GMOs placed on the market under Directive 2001/18/EC.{COM(2007) 81 final}. COMMISSION STAFF WORKING DOCUMENT. SEC(2007) 274, 5.3.2007, Brussels.

CEU 1997. Council of the European Union. 2045. Council - Agriculture, Press Release: Brussels (19-11-1997) - Press: 343 - Nr: 12241/97, Brussels.

CEU 2008. Council of the European Union: Council Conclusions on Genetically Modified Organisms (GMOs): 2912th Environment Council meeting, Brussels, 4 Dec. 2008.

CGRFAO (FAO Commission on Plant Genetic Resources) 2002. Ninth Regular Session, Rome, 14 – 18 October 2002, Towards an International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources. CGRFA-9/02/18/Annex (CPGR/93/9) (The attached document was originally issued as CPGR/93/9). ftp://ftp.fao.org/ag/cgrfa/cgrfa9/r9w18ae.pdf.

Codex Alimentarius Commission 2007. Thirtieth Session, FAO Headquarters, Rome, Italy, 2–7 July 2007, ALINORM 07/30/REP, http://www.codexalimentarius.net/download/report/684/al30REPe.pdf.

COGEM 2009. Socio-economic aspects of GMOs. Building blocks for an EU sustainability assessment of genetically modified crops. COGEM Report CGM/090929-01. COGEM.

Day, C. 2007. Enhancing impact assessment. Closing speech of the Secretary General of the European Commission at the European Commission Impact Assessment –Discussion with Stakeholders, Brussels.

Dreyer, M. & Renn, M. (eds) 2009. Food Safety Governance: Integrating Science, Precaution and Public Involvement, Springer, Berlin.

Dreyer, M., Renn, O., Cope, S., & Frewer, L.J. 2009). Including social impact assessment in food safety governance. Food Control. doi: 10.1016/ j.foodcont.2009.05.007.

Dreyer, M., Renn, O., Ely, A., Stirling, A., Vos, E., & Wendler, F. 2008. A general framework for the precautionary and inclusive governance of food safety. Final report of the EU-project SAFE FOODS, work package 5, deliverable 5.8. Stuttgart: DIALOGIK. <http://www.dialogik-expert.de/en/forschung/A%20General%20 Framework%20for%20the%20Precautionary%20and%20Inclusive%20Governance% 20of%20Food% 20Safety.pdf>.

EC 2000. European Commission: White Paper on Food Safety. COM (1999) 719 final. 12.01.2000, Brussels.

EC 2002a. Commission Communication on the operating framework for the European regulatory agencies, COM (2002) 718. Brussels: European Commission. <http://ec.europa.eu/governance/docs/comm_agence_en.pdf>.

EC 2004. National Sustainable Development Strategies in the European Union - A First Analysis by the European Commission, Commission Staff Working Document, April 2004. http://ec.europa.eu/sustainable/docs/sustainable_development_strategies.pdf.

EC 2005. Impact assessment guidelines, SEC (2005) 791. Brussels, 15.6.2005.

EC 2006. EU policy on biotechnology. Belgium. http://ec.europa.eu/environment/biotechnology/pdf/eu_policy_biotechnology.pdf.

EC 2009. Questionnaire about the socio-economic implications of the placing on the market of GMOs for cultivation. http://ec.europa.eu/environment/biotechnology/pdf/questionnaire_socio_eco.pdf.

EC 2010. Commission announces upcoming proposal on choice for Member States to cultivate or not GMO's and approves 5 decisions on GMO's. Press release IP/10/222. Brussels, 2 March 2010. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/222&format=HTML&aged=0&language=EN&guiLanguage=en.

EFSA 2006. Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use by the Scientific Panel on Genetically Modified Organisms (GMO). The EFSA Journal 374: 1-115. http://www.efsa.europa.eu/en/scdocs/doc/374.pdf.

EFSA 2007a. Risk-benefit analysis of foods. Methods and approaches. EFSA Scientific Colloquium. Summary Report. EFSA.

EFSA 2007b. Assessing the environmental impact of genetically modified plants - EFSA Scientific Colloquium - 20-21 June, Tabiano, Parma, Italy. Pressemitteilung. http://www.efsa.europa.eu/de/press/news/gmo070704.htm.

EFSA 2007c. REPORT OF THE SPECIAL ADVISORY FORUM MEETING ON EU GMO RISK ASSESSMENT. 13 November 2007. http://www.gmsafood.org/documents/dosyalar/report_gmo_af_meeting.pdf.

EFSA 2007d. BRIEFING NOTES FOR DISCUSSION GROUPS. EFSA Scientific Colloquium 8. Environmental Risk Assessment of Genetically Modified Plants -Challenges and Approaches. 20-21 June 2007 Tabiano (PR), Italy. http://www.efsa.europa.eu/de/events/documents/colloque070620-ax2.pdf.

EFSA 2008. EFSA's 8th Scientific Colloquium - Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches, 20 - 21 June 2007, Tabiano, Italy.http://www.efsa.europa.eu/EFSA/Scientific_Document/comm_colloquium8_2008_en.pdf?ssbinary=true

EFSA 2009a. Guidance on human health risk benefit assessment of foods. Scientific Opinion. EFSA Scientific Committee. European Food Safety Authority (EFSA), Parma, Italy. http://www.efsa.europa.eu/en/consultations/call/sc100226-ax1.pdf.

EFSA 2009b. Frequently Asked Questions (FAQ) related to the EFSA assessment of Article 14 and 13.5 health claims applications. http://www.efsa.europa.eu/cs/BlobServer/Report/nda_report_ej1339_FAQ_on_Health_Claims_fin694 al_EN.

EFSA 2009c. 11th PLENARY MEETING OF THE EFSA EXPERT ADVISORY GROUP ON RISK COMMUNICATIONS (AGRC). 19 October 2009. http://www.efsa.europa.eu/en/events/event/agrc091019-m.pdf.

EFSA 2010. Scientific Opinion on a question from the European Commission related to the notification by Portugal, pursuant to Article 95 (5) of the EC Treaty, for the prohibition of cultivation of Genetically Modified Plants in the Autonomous Region of Madeira. EFSA Journal 2010; 8(2):1500. http://www.efsa.europa.eu/en/scdocs/doc/1500.pdf.

EGE 2008. Ethics of modern developments in agriculture technologies; Proceedings of the round table debate (18 June 2008).

Ely, A. & Stirling, A. 2009. The Process of Assessment. In M. Dreyer, O. Renn (eds), 'Food Safety Governance: Integrating Science, Precaution and Public Involvement', Springer, Berlin, 2009, pp 56-70.

EU 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal L 031, 01/02/2002 P. 0001 – 0024.

EU 2006. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/ 67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Communities, L396, 1–849. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L: 2006:396:0001:0849:EN:PDF>.

EuropaBio 2009. Socio-economic impacts of green biotechnology. EuropaBio. http://www.europabio.org/positions/GBE/PP_080110-Socio-economic-impacts-of-GM-Crops-GMO.pdf.

Falck-Zepeda, J.B. 2009. Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake? AgBioForum, 12(1): 90-107. http://www.agbioforum.org/v12n1/v12n1a09-falckzepeda.pdf.

Federal Ministry of Agriculture, Forestry, Environment and Water Management 2002. The Austrian Strategy for Sustainable Development: An Initiative of the Federal Government.

FOE 2006. Who benefits from GM crops? Monsanto and the corporate-driven genetically modified crop revolution. Amsterdam: Friends of the Earth International.

FOE 2008. Who benefits from GM crops? The rise in pesticide use. Amsterdam: Friends of the Earth International.

Fransen, L., La Viña, A., Dayrit, F., Gatlabayan, L., Santosa, D.A. & Adiwibowo, S. 2005. Integrating socio-economic considerations into biosafety decisions: The role of public participation. Washington, DC: World Resources Institute.

Gaskell, G., Stares, S., Allansdottir, A., Allum, N., Corchero, C., Fischler, C., Hampel, J., Jackson, J., Kronberger, N., Mejlgaard, N., Revuelta, G., Schreiner, C., Torgersen, H. & Wagner, W. 2006. Europeans and Biotechnology in 2005: Patterns and Trends, Final report on Eurobarometer 64.3, A report to the European Commission[1]s Directorate-General for Research, Brussels, July 2006. http://ec.europa.eu/public_opinion/archives/ebs/ebs_244b_en.pdf.

Geslain-Lanéelle, C. 2007. Letter from 16 February 2007 (Ref.: JK/gf (2007) out 1992408) to Prof. Vittorio Silano.

GfK Austria 2010. Österreichische Ernährungsstudie 2010. Berichtsband 23.11.2009 – 21.01.2010. http://www.gfk.at.

Gill, B. 2007. Property claims in GM and non-GM crops: Intellectual property rights versus brand property rights in postindustrial knowledge societies. Under review in International Journal of Agricultural Resources, Governance and Ecology.http://www.lrz-muenchen.de/Lehrstuhl_Beck/d/gill/publika/GM_prop.pdf>.

Gleirscher, N. 2008. Policy instruments in support of organic farming in Austria. International Journal of Agricultural Resources, Governance and Ecology 7 (1-2): 51-62.

Glowka, L. 2003. Law and modern biotechnology. Selected issues of relevance to food and agriculture. FAO Legislative Study 78. FAO: Rome. ftp://ftp.fao.org/docrep/fao/006/y4839e/y4839e00.pdf.

Greenpeace 2009. Testimonials of Contamination. Why co-existence of GM and non-GM crops remain impossible. Report. Amsterdam: Greenpeace.

Greenpeace International, Friends of the Earth Europe, Corporate Europe Observatory, X-Y Solidarity Fund 2009. NGO joint response to the conference 'GMOs in European Agriculture and Food Production', Scheveningen 25-26 November 2009. http://www.foeeurope.org/GMOs/NGO%20joint%20response.pdf.

GTG 1994. Gentechnikgesetz (GTG). Bundesgesetz, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen und die Anwendung von Genanalyse und Gentherapie am Menschen geregelt werden (Gentechnikgesetz - GTG) und das Produkthaftungsgesetz geändert wird. StF: BGBl. Nr. 510/1994, zuletzt geändert durch BGBl. I Nr. 13/2006.

Gurian-Sherman, D. 2009a. Failure to yield. Evaluating the performance of genetically engineered crops. UCS. http://www.ucsusa.org/assets/documents/food_and_agriculture/failure-to-yield.pdf.

Gurian-Sherman, D. 2009b. Commercialised GM crops and yield. Nature Biotechnology 27(9): 801-802.

Gurian-Sherman, D. 2009c. The Real Scoop. http://www.ucsusa.org/food_and_agriculture/science_and_impacts/science/the-real-scoop/the-real-scoop.html.

HCB 2010. Notice of the High Council of Biotechnology (HCB) on the application file for permission EFSA/GMO/NL/2009/72 - maize MON89034xNK603. Recommendation of the Economic, Social and Ethical Committee. http://www.ogm.gouv.fr/.

Heatherly, L., Dorrance, A., Hoeft, R., Onstad, D., Orf, J., Porter, P., Spurlock, S. & Young, B. 2009. Sustainability of U.S. Soybean Production: Conventional, Transgenic, and Organic Production Systems. Spec. Publ. 30. Council for Agricultural Science and Technology, Ames, IA. www.cast-science.org. Sponsored by the United Soybean Board. www.unitedsoybean.org.

Hoppichler, J. & Schermer, M. 2006. Gentechnikfreie Gebiete: Grundlagen, Ansätze und Chance für benachteiligte Regionen. Ländlicher Raum 11. http://www.laendlicher-raum.at.

IAASTD 2008a. Agriculture at a Crossroads, Volume I: The Global Report. International Assessment on Agricultural Knowledge, Science and Technology for Development. http://www.agassessment.org/reports/IAASTD/EN/Agriculture%20at%20a%20Crossroads_Global%20Report%20(English).pdf.

IAASTD 2008b. Agriculture at a Crossroads. Executive Summary. The Synthesis Report. International Assessment on Agricultural Knowledge, Science and Technology for Development. http://www.agassessment.org/reports/IAASTD/EN/Agriculture%20at%20a%20Crossroads_Synthesis%20Report%20%28English%29.pdf

Inf'OGM – Citizens' Watch Group for Information Relating to GMOs 2008 (ed.). The French law on GMOs: "balanced" or biased? Montreuil: Inf'OGM.

IRGC 2005a. White paper on risk governance: Towards an integrative approach. Geneva: International Risk Governance Council (IRGC).

IRGC 2005b. An introduction to the IRGC risk governance framework. Geneva: International Risk Governance Council (IRGC).

Isaac, G.E. 2002. Agricultural biotechnology and transatlantic trade: Regulatory barriers to GM crops. Oxon, UK: CABI Publishing Inc.

Isaac, G.E. 2004. The interaction between levels of rule making in international trade and investment: The case of sanitary and phytosanitary measures. Discussion paper presented at the Workshop on the Interaction Between Levels of Rule Making in International Trade and Investment UNU CRIS/LSE ITPU Project, December, Brussels, Belgium.

Jarvis, A. 2009. A Way Forward for GM Cultivation in Europe? EEDP Programme Paper 09/03. www.chathamhouse.org.uk.

Katzek, J. 2009. Warum die Erfassung sozioökonomischer Kriterien bei der Zulassung keinen Sinn macht. Presentation in the course of the NABU Workshop „Sozioökonomie als neues Zulassungskriterium für GVO", 4.11.2009, Berlin.

Kellner, J. 2004. Der Essenseinkauf im Betrieb. Qualität auf allen Ebenen – gesund, sicher, fair; Einkaufsführer und Ratgeber: bio + fair +regional http://images.umweltberatung.at/htm/besser_essen_im_buero.pdf.

Kratochvil, R. 2004. Beiträge von Bioregionen zur nachhaltigen Regionalentwicklung. In: Kullmann, A. (ed.). Ökologischer Landbau und nachhaltige Regionalentwicklung. Strategien, Erfolge, Probleme, Handlungs- und Forschungsbedarf. Berichte zur IfLS-Tagung am 11. März 2004 in Frankfurt/Main. Institut für Ländliche Strukturforschung, Johann Wolfgang Goethe-Universität, Franfurt/Main, p.66-78.

Kratochvil, R. & Schermer, M. 2008. Regionale Vermarktung in Österreich. Kritische Bestandsaufnahme. Ökologie & Landbau 147(3): 3ß-32.

König, A. 2009. Compatibility of the SAFE FOODS Risk Analysis Framework with the legal and institutional settings of the EU and the WTO. Food Control, doi:10.1016/j.foodcont.2009.11.018.

König, A., Kuiper, H.A., Marvin, H.J.P., Boon, P.E., Busk, L., Cnudde, F.C., et al. 2010. The SAFE FOODS framework for improved risk analysis of foods. Food Control, doi:10.1016/j.foodcont.2010.02.012.

Kvakkestad, V. & Vatn, A. 2008. Regulating the release of GMOs: contrasts between the European Union and Norway. Environment and Planning C: Government and Policy 26: 968-981.

Landwirtschaftsgesetz 1992. BGBl 375/1992 idF BGBl 420/1996.

Lebensministerium (no year indicated). Aktionsprogramm Biologische Landwirtschaft 2008-2010. http://www.landnet.at/filemanager/download/42489/.

Lebensministerium 2010. Grüner Bericht 2010. Bericht über die Situation der Land- und Forstwirtschaft. http://www.gruenerbericht.at.

Lebensministerium 2009. Ländliche Entwicklung 2007-2013. Nationaler Strategieplan Österreichs für die Entwicklung des ländlichen Raums 2007-2013. Revision 2009. 10.6.2009. Lebensministerium: Wien.

Levidow, L. & Carr, S. 2000. UK: precautionary commercialization? Journal of Risk Research 3: 261-270.

Levidow, L. Carr, S. & Wield, D. 2000. Genetically modified crops in the European Union: regulatory conflicts as precautionary opportunities. Journal of Risk Research 3: 189–208.

Lockie, S. 2001. SIA in review: Setting the agenda for impact assessment in the 21st century. Impact Assessment and Project Appraisal, 19(4), 277–287.

Loefsted, R. 2004. The swing of the regulatory pendulum in Europe: From precautionary principle to (regulatory) impact analysis. The Journal of Risk and Uncertainty, 28(3), 237–260.

Millstone, E., van Zwanenberg, P., Levidow, L. & Spök, A. 2008. Risk Assessment Policies: Differences Across Jurisdictions. Seville: IPTS, Joint Research Centre.

Millstone, E., van Zwanenberg, P., Marris, C., Levidow, L. & Torgersen, H. 2004. Science in Trade Disputes Related to Potential Risks: Comparative Case Studies. Seville: IPTS, Joint Research Centre.

Ministry of Agriculture, Nature and Food Quality; Ministry of Housing, Spatial Planning and the Environment 2009. GMOs in European Agriculture and Food Production. Conference report of the international conference on GMOs in European Agriculture and Food Production, 25-26 November 2009, The Hague, The Netherlands. http://www.minlnv.nl/txmpub/files/?p_file_id=47648.

Ministry of Environment 2001. Begrunnelse for de norske forbudene mot omsetning av EU-godkjente genmodifiserte organismer. [Basis for the Norwegian decision to prohibit marketing of EU-approved genetically modified organisms]. http://www.regjeringen.no/nb/dep/md/tema/naturmangfold/genteknologi-/begrunnelse-for-de-norske-forbudene-mot-.html?id=411955.

Ministry of Environment 2005a. Regulations relating to impact assessment pursuant to the Gene Technology Act. Laid down by Royal Decree of 16 December 2005 pursuant to section 11, cf section 8, of the Act of 2 April 1993 No. 38 relating to the production and use of genetically modified organisms, etc. Submitted by the Ministry of the Environment. http://www.regjeringen.no/nb/dep/md/dok/lover_regler/forskrifter/2005/regulations-relating-to-impact-assessmen.html?id=440455.

Ministry of the Environment 2005b. Regulations relating to impact assessment pursuant to the Gene Technology Act 2005. Appendix 4 Evaluation of ethical considerations, sustainability and benefit to society, cf section 17 of the regulations. Forskrift, 16.12.2005. http://www.regjeringen.no/nb/dep/md/dok/lover_regler/forskrifter/2005/regulations-relating-to-impact-assessmen.html?id=440455.

MOP 4 Decision BS-IV/16. BS-IV/16. Socio-economic considerations (Article 26, paragraph 2). http://www.cbd.int/decision/mop/?id=11695.

Müller, W. 2003. Concepts for Coexistence. Final Report to the Federal Ministry of Health and Women, Austria. Forschungsberichte der Sektion IV, No.7/2003.

Nischwitz, G., Moldenhauer, H., Röhrig, P., Potthof, C., Volling, A. & Ober, S. 2009. Berücksichtigung von sozioökonomischen Kriterien bei der Zulassung von GVO in der EU. Vorschläge zur Erfassung von sozioökonomischen Faktoren in Deutschland. Bremen: IAW.

Noiville, C. 2009. The Haut Conseil des biotechnologies : towards a new assessment of GMOs in France. Presentation held at the Conference GMOs in European Agriculture and Food Production, 25-26 November 2009, The Hague, The Netherlands.

Norwegian Biotechnology Advisory Board (Rogne, S. & Linnestad, C.) 2000/2003. Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms: implementations of the concepts set out in the Sections 1 and 10 of the Norwegian Gene Technology Act. The Norwegian Biotechnology Advisory Board: Oslo.

Norwegian Gene Technology Act. Ministry of the Environment. Act of 2 April 1993 No. 38 with subsequent amendments, most recently by Act of 17 June 2005 No. 79. http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031.

OECD 2006. Good Practices in the National Sustainable Development Strategies of OECD Countries. Paris: OECD. http://www.oecd.org/dataoecd/58/42/36655769.pdf.

Palmer, A. 2006. The WTO GMO dispute.: implactions for developing countries and the need for an appeal. Paper prepared for GeneWatch UK, the RSBP, Forum for Biotechnology and Food Security and the GM Freeze.

Parrot, W. 2009. An analysis of “Failure to Yield” by Dough Gurian-Sherman, Union of Concerned Scientists. http://mulch.cropsoil.uga.edu/~parrottlab/Response%20to%20UCS.pdf.

Pascher K., Narendja, F. & Rau, D. 2006. Feral oilseed rape—investigation on its potential for hybridisation. Final Report to the Federal Ministry of Health and Women, Austria. Forschungsberichte der Sektion IV, No.3/2006.

Pascher, K. & Dolezel, M. 2005. Koexistenz von gentechnisch veränderten, konventionellen und biologisch angebauten Kulturpflanzen in der österreichischen Landwirtschaft - Handlungsempfehlungen aus ökologischer Sicht. Im Auftrag des Bundesministeriums für Gesundheit und Frauen, Wien, Forschungsbericht der Sektion IV, No.2/2005.

Pauwelyn, J. 2009. The GMO Debate Under the Rules of the World Trade Organization. Presentation held at the Conference GMOs in European Agriculture and Food Production, 25-26 November 2009, The Hague, The Netherlands.

PG Economics Ltd 2009a. Union of Concerned Scientists report on GM crop performance is misleading. Briefing Note. 17 April. http://www.pgeconomics.co.uk/pdf/UCSresponseapr2009.pdf.

PG Economics Ltd 2009b. Impact of genetically engineered crops on pesticide use: US Organic Center report evaluation by PG Economics. Briefing Note 19 Nov.

PG Economics Ltd 2009c. The magnitude and impacts of the biotech and organic seed price premium: US Organic Center report assessment by PG Economics.

Qaim, M. 2009. The Economics of Genetically Modified Crops. Annual Reviews in Resource Economy 1: 665-693.

Raney, T. 2006. Economic impact of transgenic crops in developing countries. Current Opinion in Biotechnology 17:174-178.

Rawling, R. 2009. An Industry Perspective on the Governance Framework. In M. Dreyer, O. Renn (eds), ‘Food Safety Governance: Integrating Science, Precaution and Public Involvement', Springer, Berlin, 2009, pp 231-238.

Reiner, H. 2009. Socioeconomic Aspects in the Food and Feed Chain of GMO Corn, Rapeseed, Soybean and other Food Plants in Austria. Project Report GZ: 70420/0128-II/B/9/2009.

Renda, A. 2006. Impact assessment in the EU. The state of the art and the art of the state. Brussels: Centre for European Policy Studies.

Rosendal, G.K. 2007. Competing Knowledge Claims and GMO Assessment by the Norwegian Biotechnology Advisory Board. FNI Report 5/2007. Fridjo Nansen Institute.

Rosendal, G.K. 2008. Interpreting Sustainable Development and Societal Utility in Norwegian GMO Assessments. European Environment 18: 243-256.

Schenkelaars Biotechnology Consultancy & Risk & Policy Analysts Ltd 2004. Study – Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology Article 31 (7a, 7b and 7d) of Directive 2001/18/EC. Study contract no. B4-3040/2003/359058/MAR/C4. FINAL REPORT. 06.04.2004.

Schermer, M. 2005. „Ökologische Modernisierung“ durch Biologischen Landbau in Österreich? [Ecological modernisation by organic farming in Austria?] 8. Wissenschaftstagung Ökologischer Landbau- Ende der Nische, Kassel, 01.03.2005-04.03.2005. In: Heß, J und Rahmann, G (Hrsg.) Ende der Nische, Beiträge zur 8. Wissenschaftstagung Ökologischer Landbau, kassel university press GmbH, Kassel.

Schermer, M. 2003. “Bioregionen” in Östereich- der Versuch einer Typologie. Ländlicher Raum 03: 14-16, http://www.laendlicher-raum.at.

Schermer, M. 2008. Organic policy in Austria: greening and greenwashing. Int. J. Agricultural Ressources, Governance and Ecology 7(1/2): 40-50.

Schermer, M. & Groier, M. 2008. Bioregionen als Modell für nachhaltige regionale Entwicklung. Abschlussbericht über Tätigkeiten und Ergebnisse im Zeitraum Februar 2005 – November 2007. http://www.dafne.at.

Schermer, M. & Hoppichler J. 2004. GMO and sustainable development in less favoured regions – the need for alternative paths of developments. Journal of Cleaner Production 12: 479-489.

Schermer, M. & Kirchengast, C. 2007. Der Beitrag des Biolandbaus zu einer territorialen Entwicklung. 9. Wissenschaftstagung Ökologischer Landbau. http://orgprints.org/view/projects/wissenschaftstagung-2007.html.

Schermer, M. & Kirchengast, C. 2008. Eco-Regions: how to link organic farming with territorial development. 16th IFOAM Organic World Congress, Modena, Italy, June 16-20, 2008. http://orgprints.org/view/projects/conference.html

Schmid, E. & Sinabell, F. 2004. Modelling multifunctionality of agriculture – concepts, challenges, and an application. DP-08-2004. http://www.boku.ac.at/wpr/wpr_dp/dp-08-2004.pdf.

Schomberg, R. von 1998. An appraisal of the working in practice of directive 90/220/EEC on the deliberate release of genetically modified organisms. Draft Final Report to the Scientific and Technological Options Assessment Unit (STOA) of the European Parliament. January 2.

Seifert, F. & Torgersen, H. 1997. How to keep out what we don’t want: an assessment of ‘Sozialverträglichkeit’ under the Austrian Genetic Engineering Act. Public Understanding of Science 6: 301-327.

Sharma, A.B. 2008. GEAC calls for socio-economic survey of Bt brinjal. The Financial Express May 24, New Delhi, India. Available on the World Wide Web: http://www.financialexpress. com/news/GEAC-calls-for-socio-economic-survey-of-Bt-brinjal/313798/.

Smale, M., Zambrano, P. & Cartel, M. 2006. Bales and Balance: A Review of the Methods Used to Assess the Economic Impact of Bt Cotton on Farmers in Developing Economies. AgBioForum 9(3): 195-212.

Smale, M., Zambrano, P., Falck-Zepeda, J. & Gruere, G. 2008. The economic impact of transgenic crops in developing countries: a note on the methods. International Journal of Biotechnology 10 (6): 519-515.

Strauss, M. 2009. EU Council Conclusions on GMO Risk Assessment. In: Bundesministerium für Gesundheit (ed.). Regional Aspects in Precautionary GMO Decision Making Conference in Vienna, 26-27 March 2009, p 79-82. http://www.bmgfj.gv.at/cms/site/attachments/2/7/8/CH0810/CMS1249634364362/kern_conference_proceedings_bmg_ohne_impressum.pdf.

The Interorganizational Committee on Principles and Guidelines for Social Impact Assessment 2003. Principles and guidelines for social impact assessment in the USA. Impact Assessment and Project Appraisal, 21(3): 231–250.

Then, C. & Lorch, A. 2009. Schadensbericht Gentechnik. Berlin. Bund Ökologische Lebensmittelwirtschaft (Hrsg.): Berlin, http://www.boelw.de/uploads/media/BOELW_Schadensbericht_Gentechnik090318.pdf.

Torgersen, H. & Seifert, F. 2000. Austria: precautionary blockage of agricultural biotechnology. Journal of Risk Research 3: 209–217.

Torgersen, H., Seifert, F. & Waldhäusl, M. 1995. Die Sozialverträglichkeitsbestimmung von gentechnischen Produkten. Forschungsberichte –Sektion III 6/96. Wien: Bundesministerium für Gesundheit und Konsumentenschutz.

UNEP (n.p.y.i.). Socioeconomic Considerations. http://www.cbd.int/biosafety/issues/others.shtml.

UNEP 1995. International Technical Guidelines for Safety in Biotechnology. http://www.unep.org/biosafety/Documents/Techguidelines.pdf.

UNEP 2008a. Socio-Economic Considerations - Compilation of views and case-studies concerning socio-economic impacts of living modified organisms. UNEP/CBD/BS/COP-MOP/4/INF/1. http://www.cbd.int/doc/meetings/bs/mop-04/information/mop-04-inf-01-en.pdf.

UNEP 2008b. Socio-Economic Considerations (Article 26, Paragraph 2). Note by the Executive Secretary. UNEP/CBD/BS/COP-MOP/4/15.

UNEP-GEF 2006. A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects. Prepared by the UNEP-GEF Biosafety Unit. December 2006. http://www.unep.org/biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf.

Vanclay, F. 2003. International principles for social impact assessment. Impact Assessment and Project Appraisal, 21(1), 5–12.

Vik, N. 2009. Socio-economic considerations in GMO decision making – the Norwegian Gene Technology Act. In: Bundesministerium für Gesundheit (ed.). Regional Aspects in Precautionary GMO Decision Making Conference in Vienna, 26-27 March 2009, p 35-42. http://www.bmgfj.gv.at/cms/site/attachments/2/7/8/ CH0810/CMS1249634364362/kern_conference_proceedings_bmg_ohne_impressum.pdf.

Vos, E. & Wendler, F. 2009. Legal and Institutional Aspects of the General Framework. In M. Dreyer, O. Renn (eds), 'Food Safety Governance: Integrating Science, Precaution and Public Involvement', Springer, Berlin, 2009, pp 83-110.

Weaver, R.K. 1986. The Politics of Blame Avoidance. Journal of Public Policy 6(4): 371-98.

Wentholt, M.T.A., Rowe, G., König, A., Marvin, H.J.P. & Frewer, L.J. 2010. The views of key stakeholders on an evolving food safety governance framework: Results from a Delphi study. Food Policy 34: 539-548.

Wiener Abfallwirtschaftskonzept 2007. Ist-Zustand der Wiener Abfallwirtschaft (Langfassung) November 2007.

Winham, G.R. 2009. The GMO Panel: Applications of WTO Law to Trade in Agricultural Biotech Products. European Integration 31(3):409-429.

World Commission 1987. Our common future.

WTO (no publication year indicated). SPS Agreement Training Module. http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm.

Zarrilli, S. 2005. INTERNATIONAL TRADE IN GMOs AND GM PRODUCTS: NATIONAL AND MULTILATERAL LEGAL FRAMEWORKS. POLICY ISSUES IN INTERNATIONAL TRADE AND COMMODITIES STUDY SERIES No. 29. UNCTAD.

Annex

Figures

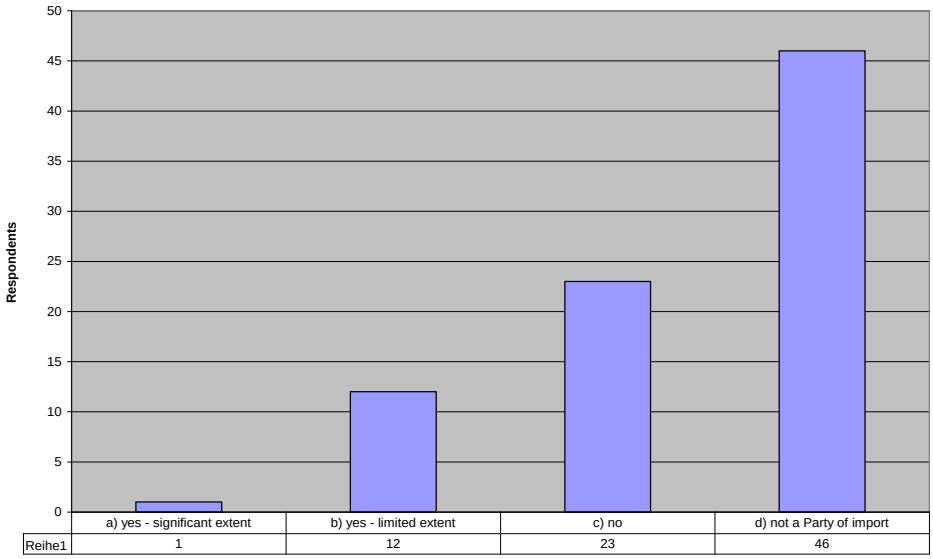


Figure 10: Number of responses in the first national reports (deadline: 2007) to the CPBS to question No 60 ("If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1")). Source: http://www.cbd.int/biosafety/parties/reports.shtml?report=NR-CPB-01.

About half of the countries responded that they have not been a Party of import. 13 countries responded to have taken into account socio-economic factors in decisions on import of GMOs:

EU: Italy, Netherlands, Spain, Germany.

Non-EU: Armenia, Cambodia, China, Colombia, Mauritius, Philippines, South Africa, Syrian Arab Republic, Uganda.

23 countries responded not to have taken into account socioeconomic factors:

EU: Belgium, European Community, France, Hungary, Ireland, Portugal, Romania, United Kingdom.

Non-EU: Australia, Brazil, Cameroon, Costa Rica, Dominican Republic, Egypt, Ghana, Indonesia, Japan, Kenya, Mexico, Palau, Papua New Guinea, Thailand, Venezuela.

EU Members States responding yes, refer to national coexistence rules.[78]

[78] See first national reports of these countries.

Tables

Table 13: Economic and social implications: influence on concerned economic operators

Upstream
Farmers
farmers cultivating GM crop;
conventional crops;
organic crops;
beekeepers;
seed producers producing GM seeds;
seed producers producing conventional seeds;
seed producers producing organic seeds;
Seed industry
plant breeders;
multiplying companies;
seed producing farmers;
seed distributors;
Downstream
Consumers;
Cooperatives and grain handling companies;
Food and feed industry;
Transport companies;
Insurance companies;
Laboratories;
Innovation and research;
Public administration;
Economic context;
Internal market;
Specific regions and sectors.
Agronomic sustainability
Biodiversity, flora, fauna and landscapes;
Renewable or non renewable resources;
Climate;
Transport / use of energy.

Table 14: Socioeconomic impacts differentiated according to the area.

Farmers

- farmers' revenues (output prices and agricultural yields);
- farmers' production costs;
- labour flexibility;
- quality of the harvest (e.g.mycotoxines);
- cost of alternative pest and/or weed control programmes;
- price discrimination between GM and non-GM harvest;
- availability of seeds and seed prices;
- dependence on the seed industry;
- farmers' privilege (as established by Article 14 of Regulation (EC) No 2100/94 on Community plant variety rights) to use farm-saved seeds;
- the use of agriculture inputs: plant protection products, fertilisers, water and energy resources;
- health of labour (possible changes in the use of plant protection products);
- farming practices, such as coexistence measures and clustering of GMO and/or non-GMO production;
- cost of coexistence measures;
- conflicts between neighbouring farmers or between farmers and other neighbours;
- labour allocation- insurance obligations;
- opportunities to sell the harvest due to labelling;
- communication or organisation between the farmers;
- farmer training;
- beekeeping industry.

Seed industry

For cultivation

- employment, turn over, profits;
- the production of seeds (easiness/difficulty to find seed producers, easiness/difficulty to find areas to produce these seeds…);
- marketing of seeds;
- the protection of plant breeders' rights; - the protection of plant genetic resources.

For marketing of GM seeds: on the seed industry and its structure (size of companies, business concentration, competition policy)?

- for plant breeders;
- for seed multiplication;
- for seed producers;
- for the availability of conventional and organic seeds;
- creation/suppression of barriers for new suppliers;
- market segmentation.

Stakeholder interviews

Interviews conducted

Phone interviews were conducted with senior level officials from the organisations/institutions listed below.

1. Austrian Chamber of Agriculture
2. Austrian Seed Association
3. BIO AUSTRIA
4. Chamber of Commerce - food industry
5. Environment Agency Austria
6. Federal Chamber of Labour
7. Federal Institute for Less Favoured Mountainous Areas
8. Global 2000
9. Raiffeisen Ware Austria (plant breeding and seed production)
10. Via Campesina Austria

Interview guidance

The semi-structured interviews were guided by the questions listed below.

1. In what particular way have you/your institution/your organisation dealt with socioeconomic impacts of GMOs in general and with the Council initiative in particular?
2. What is your view on the proposal to consider socioeconomic impacts in GMO market authorisation?
3. What kind of socioeconomic impacts do you expect in case of GM crop cultivation in Austria – which impacts do you consider as particularly relevant for Austria?
4. Which impacts should be assessed and considered in the context of market authorisations of GM crops?
5. Considering the implementation of socioeconomic assessments: any ideas about a possible way forward and about problems to expect?
6. Which institutions should assess socioeconomic impacts? EU or national institutions? Which role to consider for EFSA?

7. What kind of link do you see between the debate on socioeconomics and the proposal of opting-out (allowing Member States to ban or discontinue cultivation of GM crops in their own territory)?

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Der EU-Ministerratsvorschlag, bei der Marktzulassung von GVOs sozioökonomische Aspekte zu berücksichtigen, bringt neue Gesichtspunkte in die festgefahrene Diskussion um die EU-Gentechnikregulierung. Allerdings gibt es bislang mit der sozioökonomischen Bewertung von GVOs in regulatorischen Zusammenhängen nur sehr wenig Erfahrung. Vor diesem Hintergrund untersucht die vorliegende Studie die vielfältigen Probleme, die sich für ein solches Unterfangen stellen, skizziert mögliche Pfade für die weitere Vorgangsweise und gibt Empfehlungen für Forschung und Politikentwicklung.