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Considerations for a precautionary approach in GMO Policy

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CONSIDERATIONS FOR A PRECAUTIONARY APPROACH IN GMO POLICY

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SUMMARY

The report at hand addresses the application of the precautionary principle in GMO policy at the EU level. Wherever possible, experience in the EU with the implementation of the precautionary principle in related regulatory fields is considered in comparison. Reference points for the recommendations by the authors are a critical analysis of the Communication of the European Commission on the precautionary principle, published in 2000 and of the current regulatory system for GMOs in the EU. Additionally, the report takes into account the results of two expert workshops and interviews conducted with experts and regulators in the course of the study.

Although the focus is on developments in the EU and its Member States, international developments concerning the application of the precautionary principle and the impact of EU developments at an international level are also considered.

The authors suggest a comprehensive precautionary approach in EU GMO regulation by implementation of three sets of improvements:

- elaborate guidance on application of the precautionary principle in GMO policy,
- prepare a thorough review of the current approach to applying the precautionary principle in GMO policy by way of cases studies, and
- implement improvements to the current EU regulatory system for GMOs with regard to aspects which are relevant for a comprehensive application of the precautionary principle. This includes improvements at all steps of the regulatory process, i.e. risk assessment, risk management and risk communication and stakeholder involvement.

Suggestions concerning policy considerations

The Commission Communication as an important general guidance should be clarified and elaborated with regard to GMO regulation, e.g. by publishing a supplementary document to the Communication to clarify the precautionary approach in GMO policy. Such guidance could be drafted in cooperation by risk assessors, risk managers and regulators. Additionally the authors suggest that the regulatory system should be developed further to better accommodate the relevance of regional differences in environmental conditions for the evaluation of GMO applications. This should be achieved by strengthening Member States' responsibilities in analogy with recent amendments to pesticide regulation.

Suggestions concerning the review of current practices

A review of the current risk assessment process for GMOs should be done to indicate whether the used system is in line with a precautionary approach. This review should identify improvements which could support the application of the precautionary principle and increase the transparency concerning the current application of the precautionary principle by risk managers. In practical terms elements like a precautionary scientific approach, which comprehensively addresses associated uncertainties, and an evaluation phase for improved interaction between risk assessors and risk managers are suggested. Furthermore the

authors suggest that case studies should be conducted to evaluate and illustrate specific issues which are critical for the application of the precautionary principle in GMO regulation.

Suggestions to broaden the scope of application of the precautionary principle

Specifically the current framing of the risk assessment approach for GMO applications should be broadened to include a cost/benefit assessment comprising social, ethical and environmental aspects and integrate experiences with the application of the precautionary principle in related regulatory fields, e.g. by best practice analysis with regard to the applied risk assessment approaches. Additionally evidence-based methods should be applied to analyse the significance of scientific data used in risk assessments and Biosafety research programmes of the European Community be developed to address the investigation of long-term or complex environmental effects. The authors of the report also suggest increased involvement of stakeholders in the design of the risk assessment approach for GMOs, i.e. in the definition of the issues that should be addressed by the scientific risk assessment.

ZUSAMMENFASSUNG

Im vorliegenden Bericht wird die Anwendung des Vorsorgeprinzips in der europäischen GVO-Politik einer kritischen Betrachtung unterzogen. Dabei werden auch Erfahrungswerte mit der Anwendung des Vorsorgeprinzips in anderen Regelungsbereichen der EU-Umweltgesetzgebung genutzt.

Als Ausgangspunkt für die Erarbeitung von Verbesserungsvorschlägen dient eine kritische Analyse der Richtlinien der Europäischen Kommission für die Anwendung des Vorsorgeprinzips (Communication of the European Commission on the precautionary principle) aus dem Jahr 2000, sowie die Analyse der derzeitigen Zulassungsverfahren für GVOs in der EU. Bei der Formulierung von Verbesserungsvorschlägen wurden darüber hinaus die Ergebnisse von zwei Projektworkshops und von zusätzlich durchgeführten ExpertInneninterviews berücksichtigt.

Obwohl der Fokus der Arbeiten auf die europäische Politikebene gerichtet ist, werden internationale Entwicklungen mit Relevanz für die Anwendung des Vorsorgeprinzips in der EU berücksichtigt. Ebenfalls in Betracht gezogen wird die Auswirkung von Europäischen Initiativen im Hinblick auf die Anwendung des Vorsorgeprinzips auf der internationalen Ebene, beispielsweise bei Verhandlungen im Rahmen des Cartagena Protokolls über die biologische Sicherheit.

Der Bericht beschreibt notwendige Elemente für eine umfassende Berücksichtigung des Vorsorgeprinzips in der europäischen GVO-Gesetzgebung und enthält konkrete Vorschläge für Verbesserungen in folgenden Bereichen:

- Verbesserung der Richtlinien für die Anwendung des Vorsorgeprinzips in der Regulierung von GVOs
- Eingehende Überprüfung der derzeitigen Praxis der Anwendung des Vorsorgeprinzips im Rahmen von Zulassungsverfahren von GVO mittels Fallstudien
- Verbesserung der Gesetzgebung im Hinblick auf Elemente, die für die Anwendung des Vorsorgeprinzips von wesentlicher Bedeutung sind. Die diesbezüglichen Vorschläge zielen auf alle Teilbereiche von Zulassungsverfahren: Risikoabschätzung, Risikomanagement und Entscheidungsfindung, sowie Risikokommunikation und Einbindung aller Gruppen von Betroffenen (Stakeholdern).

Im Detail werden im Bericht folgende Vorschläge gemacht:

Vorschläge für die weitere Verbesserung des europäischen Rechtsrahmens für GVOs

Die Richtlinien der Europäischen Kommission zur Anwendung des Vorsorgeprinzips sind eine wichtige Grundlage, müssten aber in Bezug auf die GVO-Gesetzgebung klarer ausformuliert werden. Das könnte beispielsweise mit einer zusätzlichen Publikation erreicht werden, die spezifisch auf die Problematik der Anwendung des Vorsorgeprinzips in der GVO-Regulierung eingeht und die in Zusammenarbeit mit ExpertInnen aus den Bereichen Risikoabschätzung, Risikomanagement und von Behörden entwickelt werden sollte.

Zusätzlich sollte der bestehende Gesetzesrahmen weiterentwickelt werden, um besser als bisher auf die regionalen ökologischen Unterschiede in der Bewertung von GVOs eingehen zu können. Im Einklang mit der derzeitigen Diskussi-

on unterstützen die Autoren, dass rasch die rechtlichen Grundlagen geschaffen werden, um eine stärkere Entscheidungsverantwortung der EU-Mitgliedsländer betreffend den Anbau von GVOs sicherzustellen. Das sollte in Analogie zu der kürzlich verabschiedeten Änderung der Verfahren für Pestizid-Zulassung umgesetzt werden, die bei der Zulassung spezieller Produkte den Mitgliedsstaaten ebenfalls mehr Verantwortung überträgt.

Vorschläge für eine Evaluation der aktuellen Praxis der GVO-Regulierung

Die derzeitigen Verfahren der Risikoabschätzung sollten unbedingt evaluiert werden, ob sie die Anwendung des Vorsorgeprinzips erlauben. Diese Evaluierung sollte im Einklang mit der laufenden Weiterentwicklung der Risikoabschätzung Ansätze zur Verbesserung identifizieren und eine Umsetzung im Sinne einer besseren Anwendbarkeit des Vorsorgeprinzips unterstützen. Konkret werden dazu ein vorsorgeorientierter wissenschaftlicher Ansatz, der Unsicherheiten bestmöglich beschreibt, und die Einführung einer verbesserten Schnittstelle (Evaluierungsphase) zwischen Risikoabschätzung und Risikomanagement empfohlen. In einer solchen Evaluierungsphase könnten die ExpertInnen, welche die Risikoabschätzung durchführen, und RisikomanagerInnen/EntscheidungsträgerInnen die notwendige Diskussion über Ergebnisse und Konsequenzen der Risikoabschätzung führen. Darüber hinaus schlagen die Autoren vor, dass im Rahmen von Fallstudien kritische Aspekte in Bezug auf die Anwendung des Vorsorgeprinzips in der GVO-Regulierung detailliert untersucht werden.

Vorschläge zur Verbreiterung des derzeitigen Ansatzes zur Umsetzung des Vorsorgeprinzips

Einerseits sollte bei der Bewertung von GVO-Anwendungen neben der naturwissenschaftlichen Risikoabschätzung auch eine sozioökonomische Abschätzung der Kosten und Nutzen durchgeführt werden. Diese sollte neben Umweltaspekten auch soziale, wirtschaftliche und ethische Kriterien mit umfassen und auf den in verwandten Regulierungsbereichen gemachten Erfahrungen aufbauen. Dazu müssten die verwendeten Ansätze zur Umsetzung des Vorsorgeprinzips im Rahmen einer best-practice Untersuchung genauer analysiert werden.

Darüber hinaus sollten bei der Risikoabschätzung verstärkt Evidenz-basierte Methoden eingesetzt werden, um die Aussagekraft der verwendeten Daten besser einschätzen zu können. Für die bessere Untersuchung von komplexen Langzeitwirkungen von GVOs sollten darüber hinaus spezifische Forschungsprogramme auf EU-Ebene initiiert und durchgeführt werden.

Die Autoren schlagen darüber hinaus auch die bessere Einbindung von Betroffenen (Stakeholdern) vor, insbesondere beim Prozess bei dem Umfang und Design der Risikoabschätzung definiert werden.

1 INTRODUCTION

This report is addressing the application of the precautionary principle in GMO policy at the EU level. It follows up the results of the discussions held in 2006 at the international conference on "The Role of Precaution in GMO Policy" in Vienna. Furthermore it takes into account the ongoing discussion about the application of the precautionary principle in EU environmental policy in different regulatory fields. The Communication of the European Commission on the precautionary principle (EC 2000), which was introduced into this debate, is one of the reference points for the analysis of the considerations in the report at hand. Additionally, it takes into account current discussions on the further development of GMO policy at the EU level, which also implicate the question of the application of the precautionary principle. Such discussions are held in expert groups recently convened by the European council and the President of the European Commission, as well as in the course of a process aimed at improvements in GMO regulation, which was initiated by the European Commission in 2006 and among others involves the European Food Safety Agency (EFSA).

Wherever possible, experience with the implementation of the precautionary principle in related regulatory fields is considered in comparison. Although the focus is on developments in the EU and its Member States, international developments concerning the application of the precautionary principle and the impact of EU developments at an international level are also considered.

1.1 Background of the discussions on the precautionary principle in GMO regulation

The precautionary principle has become an important element in various (environmental) legislative acts and agreements since its introduction in the Rio Declaration on Environment and Development in 1992. Such legislations were introduced at the international, European and national levels for a number of regulatory issues, e.g. for chemicals and novel foods, as well as GMOs. The GMO legislation at the EU level and the Cartagena Protocol on Biosafety at the international level embrace the precautionary principle as an important aspect.

In the EU the precautionary principle is one of the guiding principles of current legislation, as stipulated e.g. in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The transposition of Directive 2001/18/EC (and the preceding Directive 90/220/ECC) into national law led to the establishment of national biosafety frameworks in EU Member States, some of which also embrace the precautionary principle.

In the year 2000 the European Commission published a "Communication from the European Commission on the precautionary principle" (referred to as "Communication" in this report) to guide the application of the precautionary principle introduced into various pieces of European legislation (EC 2000). This Communication is still of high relevance for the implementation of the precautionary principle in GMO policy, since the European Commission did not publish another general or more specific document on the matter to replace the Communication. It was examined and discussed in detail during the present project.

However, even after some 18 years of experience at the EU level, the application of the precautionary principle in GMO regulation proved to be a challenging matter. A number of open questions and difficulties concerning the implementation of the precautionary principle are apparent at the EU-level as well as at the national levels. Major difficulties were also seen with the implementation of the precautionary principle at the international level. These issues were discussed during the Austrian EU Presidency in the year 2006 at an international conference held in Vienna in April 2006 (BMGFJ 2006).

The importance of further progress concerning this matter was stressed in conclusions by the Presidency following the EU Environment Council meeting in June 2006. These conclusions were supported by many Member States in deliberations at the EU level. Some of these Member States, e.g. Italy, specifically addressed questions related to the implementation of the precautionary principle in GMO regulation in EU fora (COUNCIL OF THE EUROPEAN UNION 2006).

In parallel, the European Commission started a process to introduce improvements in risk assessment practices and to improve the scientific consistency and transparency of decision-making for authorisation procedures of GMOs (EC2006).

The role of the precautionary principle in decisions on GMO products was also an issue in consultations between EFSA and Member States.

At the international level certain aspects related to the application of the precautionary principle in GMO regulation was discussed in the proceedings of the in the “EC: Biotech” case by a Panel of the WTO. The outcome showed that further initiatives for the implementation of the precautionary principle at an international level are needed to ensure consistency of the European and international regulatory frameworks for GMOs, and to achieve that Multilateral Trade Agreements and Multilateral Environmental Agreements, like the Cartagena Protocol on Biosafety, are indeed mutually supportive as far as the application of the precautionary principle is concerned.

1.2 Terminology used in this report

Differences in the terminology and use of definitions are an issue which has accompanied any discussion of the precautionary principle since its introduction, making any discussion of the subject complicated. Therefore, in the following, the use of important terms in the context of this report is clarified to avoid such misunderstandings.

The term “Risk analysis” is used according to the definitions provided by the Codex Alimentarius (CAC 2003) and at the EU level by Regulation (EC) 178/2002. The term describes a process consisting of three interconnected components: risk assessment, risk management and risk communication:

- ‘risk assessment’ is used to describe the scientifically based process of hazard identification, hazard characterisation, exposure assessment and risk characterization.

- 'risk management' is used to describe the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and risk management options.
- 'risk communication' describes the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

In a legal sense the ´precautionary principle´ is understood according to the basic definition given in Principle 15 of the Rio Declaration. The EC Communication on the Precautionary Principle (EC 2000) also takes into account this definition of the precautionary principle.

The practical application of the precautionary principle in EU legislation on GMOs is based on many considerations which have to be taken into account during the overall process of risk analysis. In this report we therefore use the term ´precautionary approach´. However, this is not done to put forward a different definition of the precautionary principle, but to stress that the application of the precautionary principle needs to be considered in the overall context of risk analysis. Such a precautionary approach requires that management measures are based on the application of the precautionary principle by risk managers as described above.

1.3 Results and open questions of the Conference "The Role of Precaution in GMO Policy"

In April 2006 participants at the international expert conference "The Role of Precaution in GMO Policy" discussed legal, scientific and practical aspects of the role of the precautionary principle in GMOs regulation in the EU. A panel of speakers from the European Commission, the EFSA GMO panel, national competent authorities, the scientific community and other stakeholders (industry and NGOs) addressed the issues and presented them for discussion with stakeholders from EU Member States and EU institutions as well as stakeholders from civil society.

The results of the conference can be summarised as follows:

- A broad consensus exists on the recognition of the precautionary principle as an important principle in the European legislative framework for GMOs. It is seen as a useful means of achieving the required protection goals, with a view to the uncertainties which may be identified during the risk assessment of GMOs. However, in terms of concrete application, no sufficient common approach to the implementation of the precautionary principle has been achieved since the introduction of GMO legislation.
- The concrete application of the precautionary principle may have important consequences in relation to unresolved scientific questions concerning the risk assessment of GMOs. An improved, harmonised and generally compre-

hensible risk assessment procedure as the basis for a reliable system of GMO regulation both nationally and across the EU is seen as an important prerequisite for the application of the precautionary principle in the decision-making process for GMO applications. The standard should be an unambiguous scientific database, compiled using appropriate, robust methods, as opposed to arguments based on assumptions.

- It was also emphasised that the precautionary principle can serve as a driving force of scientific innovation. This again relates to the scientific basis for risk assessment, but goes beyond it and relates to the wide-ranging context in which decisions on the application of GMOs are taken. In this framework the role of the social and economic sciences is as important as is the role of the natural sciences. These disciplines therefore need to be considered accordingly.
- A general demand is seen for transparent implementation involving the stakeholders concerned, in order to ensure that decisions on GMOs are transparent, acceptable and proportionate. Along with the risk assessment mechanism itself risk communication must be improved to ensure appropriate public participation. In this context the dialogue between the European Commission, the European Food Safety Authority and the EU Member States needs to be strengthened.

1.4 Objectives of the present study

The study at hand was conducted with the following aims:

- The results of the project should stimulate further discussion of the practical application of a precautionary approach, building on the notion that there is a broad consensus on the recognition of the precautionary principle as one of the fundamental aspects that define the European approach to GMO legislation.
- The results of the project should identify current viewpoints with respect to the different concepts related to the precautionary principle nationally (e.g. within Scientific Committees and authorities) and at the EU level (i.e. within EFSA and the GMO Panel). These results should address the difficulties to establish a common understanding towards implementation of a precautionary approach.
- The project should also intensify the dialogue of stakeholders at the national level, at the EU level and between these levels. Furthermore suggestions for a way forward involving these stakeholders should be devised and discussed.

2 OUTLINE OF THE PROJECT STRUCTURE

In the course of the project relevant issues were discussed with a group of knowledgeable experts from relevant stakeholder groups at two consecutive workshops and in expert interviews in the following sequence of events.

- At a first workshop in November 2007 the results of the assessment of the current situation as summarised by an input paper were discussed by experts. This workshop was convened to bring together persons with an in-depth knowledge of the problems and challenges of GMO risk assessment and regulation as well as experts for precautionary policies in related regulatory fields. The results of the first workshop were used to define the issues selected for a round of expert interviews.
- As a next step a number of in-depth interviews were conducted in autumn 2008 with additional experts to reveal additional insights into critical issues for further application of the precautionary principle. The interviews targeted stakeholders in European countries and European institutions involved in GMO regulation.
- At the second workshop in November 2008 the results of the first workshop and the expert interviews were further discussed. The objective was to arrive at conclusions and suggestions for possible ways forward with regard to application of a precautionary approach. Furthermore workshop participants discussed the best ways to introduce the results as an input to the ongoing debates on further implementing the precautionary approach.
- The results of workshop discussions and expert interviews are compiled and introduced in the political discussions on further development of the precautionary approach, concentrating on the EU-level.

2.1 1st Expert Workshop, November 2007

For initial discussion of the current situation regarding implementation of the precautionary principle an expert panel was convened in November 2007 for a first workshop.

The participants invited were present in their personal capacity. Experts from academia, EU Member States authorities, EFSA, and Umweltbundesamt were invited. A list of participants is attached to the report as Annex 1. The meeting was chaired by Umweltbundesamt.

The workshop participants were supplied with an input paper which also contained a list of questions which were addressed at the workshop. The complete paper is attached as Annex 2.

The main results of the workshop comprised

- General issues concerning the application of the precautionary principle in GMO policy, such as
  - Strategies of further implementation of the precautionary principle
  - Common definition and understanding of the precautionary principle with a view to controversies concerning these issues

as well as inputs for the following:

- Implementation of the precautionary principle in environmental regulation at EU-Level, specifically
  - Progress made since publication of the EC Communication on the precautionary principle
  - Differences in approaches to application of the precautionary principle in GMO policy at the EU-Level
  - Deficiencies in current applications of the precautionary principle in GMO policy at the EU-Level
- International framework for the precautionary principle in GMO policy, specifically
  - Which policy fora are relevant for the implementation of the precautionary principle at the international level and what are the obstacles to a common understanding towards the precautionary principle at the international level
- Implementation of the precautionary approach in GMO Risk Assessment, specifically
  - A common understanding of the precautionary approach within the Risk Assessment (RA) framework
  - The precautionary principle as an issue of scientific research
- Challenges in communication on improvements of implementation of the precautionary principle, specifically
  - Target groups to be addressed for questions regarding application of a precautionary approach

A summary record of the workshop is attached to the report as Annex 3.

2.2 Expert Interviews, Autumn 2008

In-depth interviews were conducted with 16 experts from different EU countries and Switzerland who have a profound background in GMO regulation or questions related to the application of the precautionary principle in different fields, or who are familiar with both. The interviews were targeted at analysing the relevance of the Communication of the European Commission on the precautionary principle for GMO regulation.

The participants answered the questions in their personal capacity. Interviews were conducted with experts from academia, EU Member States authorities, the EFSA GMO panel. A list of participants is attached to the report as Annex 4.

The participants received information on the ongoing project as well as a questionnaire for preparation. The questionnaire is attached as Annex 5. The text of the questionnaire was slightly edited for clarification according to suggestions from interview partners without changing the substance of questions.

Answers were compiled in interview records, which were sent to the experts for comments and approval. The records were used for further analysis and the input from the interviews was drawn on for drafting Chapter 3 and 4.

2.3 2nd Expert Workshop, November 2008

For the discussion of the draft suggestions for a way forward regarding application of the precautionary approach an expert panel was convened in November 2008 for a second workshop. Some of the experts invited had already attended the first workshop, while some others had been interviewed during the stakeholder interviews. These experts were joined by colleagues who did not participate in previous steps in the project.

The participants invited were present in their personal capacity. Experts from academia, EU Member States authorities and European institutions were invited. A list of participants is attached to the report as Annex 4. The meeting was chaired by Umweltbundesamt (Environment Agency Austria).

The workshop participants were supplied with the draft report, giving an outline of the authors' suggestions with respect to potential improvements concerning the application of the precautionary approach.

As a result of the workshop the draft report was amended according to suggestions by participants, which were discussed at the workshop. Comments were made concerning specific suggestions contained in Chapter 4 of the draft report, as well as with regard to issues of communication of the report and introducing the suggestions into the political debate.

3 RELEVANT ISSUES FOR APPLICATION OF A PRECAUTIONARY APPROACH

The following issues were addressed in the expert interviews. They highlight areas of importance regarding the application of the precautionary approach in GMO policy as identified by the interviews. Specifically controversial issues were considered, since they pinpoint topics which need to be further discussed for identifying possible ways forward to better implementation of the precautionary principle.

The interviews were analysed qualitatively by the project team. The objective was to identify different viewpoints and to indicate areas of commonality as well as controversy. The experts' answers of are not directly quoted and are given without the experts' names in the text.

Questions were based on the Communication of the EC on the precautionary principle (EC 2000, referred to as "Communication" in the following text) to highlight current needs for update and review of the concept as outlined in the Communication.

3.1 GMO Legislations providing the framework for application of the precautionary principle

The regulatory framework for GMOs in the EU allows for the application of the precautionary principle by the competent authorities of Member States and authorities at the European level (EFSA, EC), which is one of the basic requirements of implementation of the precautionary principle.

However, the relevant pieces of legislation (Directive 2001/18/EC and Regulation (EC) 1829/2003) are regarded to be different in their potential for providing for application of the precautionary principle by some experts. Whereas Directive 2001/18/EC was deemed to be in line with the framework for application of the precautionary principle as outlined in the Communication, the implementation of Regulation (EC) 1829/2003 was thought to provide less opportunities for Member States to apply the precautionary principle.

The fact that the current EU legislations embrace the precautionary principle was regarded as important, but not sufficient. The way how the precautionary principle is applied was deemed equally important. This latter issue is seen as very problematic by some experts. Since the legislations themselves are not containing specific guidance for application of the precautionary approach, additional guidance is considered necessary. The Communication is seen by most of the experts as a very relevant document in that respect.

3.2 Impact of the precautionary principle in GMO policy

The general implementation of the precautionary principle in GMO policy initiates and supports the need for an adequate risk assessment of GMOs as a first step, before risk management and decision making.

Observations by members of scientific advisory committees at the EU level as well as on the national level suggest that the precautionary principle should be taken into account as a general principle for GMO assessment as well as for other fields (e.g. food safety, biocontrol). However, it is just one of a number of considerations, which is important for the work of these committees regarding GMO regulation. The discussion of the precautionary principle in GMO policy needs to be placed in the context of the overall debate on how to develop further the framework for GMO regulation, which involves various important issues besides the precautionary principle.

Difficulties arise from the situation that the precautionary principle is implemented in the regulatory system as well as in the political system. Therefore different groups of stakeholders are involved representing different interests. This situation leads to controversies, which currently seem to be major obstacles to a common understanding with regard to the application of a precautionary approach.

3.3 Difficulties for the application of a precautionary approach in GMO regulation

The difficulties for application of a precautionary approach in GMO regulation, which were identified during the expert interviews, can be grouped into two categories.

The first group relates to specific aspects of the technology and the characteristics of the GMO products themselves, whereas the other group is targeting problems arising from the way how these products are dealt with in the regulatory process.

Examples of difficulties belonging to the first group are e.g.

- The assessment of GMOs is complicated due to the fact that they are alive and because of the biological characteristics associated with GMOs, e.g. reproductive and transfer capabilities, capabilities to spread and persist, etc. Once certain GMOs have established in the environment, they may persist even in case further release is terminated.
- Effects of GMOs, specifically environmental effects, are complex and difficult to assess (e.g. long term and indirect risks). Assessment demands an elaborate knowledge basis and a multidisciplinary approach.
- For some aspects, quantification is difficult or even impossible. Modeling and prognosis are important tools for the assessment of environmental effects of GMOs, but some effects can still only be assessed by using reductionist approaches.

- Likewise, the costs and benefits of the application of GMOs may manifest themselves over longer time periods and are thus difficult to assess and to compare. Not all effects can be translated into economic values.
- Thus it is difficult to assign criteria for an assessment and decisions may have to be taken in the context of remaining uncertainties.

Examples belonging to the second group are e.g.

- Compared with other policy fields, GMO applications seem to be dealt with in a specific way in the regulatory process. While the EC is supporting the positive assessments of EFSA in its draft decisions, there is opposition on the part of a number of Member States, resulting in most cases in a failure to reach decisions for or against authorization of individual GMO applications. This is reflected in disagreements over assessment opinions and political controversies. The opinion put forward is that one of the reasons why conflicts are hard to resolve can be identified as intransparencies regarding the rationales for decisions (specifically regarding the rationales for voting by Member States).
- GMO issues are associated with a higher political risk for risk managers, because GM technology causes more political and social controversies than other technologies. Decisions on GMO applications seem to be influenced by this background to a higher extent than decisions concerning other technologies.

A general challenge which was mentioned by experts is that the policy environment for the evaluation of GMOs has changed over time since the introduction of GMO regulations and since publication of the Communication. E.g. concerns over biodiversity impacts at a global and not anymore at a local level should be taken into account, the need for increased global food production, climate change effects, economic considerations, etc. should be considered for developing regulations and the way of application of the precautionary approach, as otherwise the regulations would become outdated.

3.4 Impact of the Communication concerning GMO regulation

The merits of the Communication, which were specifically indicated in expert interviews, are that it confirms and elaborates Principle 15 of the Rio declaration. It is thus regarded as a useful contribution to the discussion and an important and valuable document concerning the application of the precautionary principle in GMO regulation. However, some of the experts interviewed indicated that the Communication is not fully sufficient in the present form.

Observations which support this view are:

The Communication is regarded as being very general by most experts. As a general document it does not specify aspects which are important for the application of the precautionary principle in specific fields like GMO regulation (e.g. guidance for the determination whether the chosen level of protection is achieved). Therefore the application of the Communication requires considerations in detail and more clarification with regard to relevant issues (for examples see Chapter 3.5). Thus the application of the principles of the Communication is

dependent on further interpretation, which is approached differently by different institutions in Member States and EU institutions. It is indicated in most interviews that the guidance provided by the Communication is not fully sufficient for application of the precautionary principle in GMO regulation. Additional guidance is needed to provide specifics, but is currently lacking.

The communication introduces a certain terminology which is also used in discourses at the national level, although not in a homogenous way. This is typical of certain EU-level documents, which need to take into account different political cultures and interests prevailing in Member States. The language of these documents appears to be quite rigid, but is open to interpretation concerning practical application. Thus differences in interpretation can be found between Member States, but also within EU institutions itself.

Some experts criticise the Communication in a general and comprehensive way, e.g. indicating that the focus on the science-based approach of the Communication falls short of considering all relevant aspects of application of a precautionary approach. These experts call for revising the overall concept as outlined in the Communication. Other observations point to the fact that some of the recommendations contained in the Communication have not been implemented in GMO regulation, e.g. a reference made in the Communication to the chosen level of protection which may be different depending on the specific environment in different countries or regions.

Other general drawbacks of the Communication which were indicated in the interviews can be summarized as follows:

- It is difficult to operationalise. No agreed criteria are available on how the general rules should be applied in practice.
- The framework of assessment is focused on the dealing with risks rather than on the consideration of risks and benefits in a proportionate way.
- The concept assumes that the problem can be reduced to technical and scientific issues. It does not reflect the need to consider the different cultural backgrounds for decision making which exist in the European Community and the complexity of the subject (in comparison with other regulatory topics). It is incomplete as it does not take into account the balance between risks and benefits.

3.5 Shortcomings of the approach outlined in the EC Communication

According to the opinion of many experts an important drawback of the concept outlined in the Communication is that this concept is too general and open to interpretation and thus vulnerable to being used selectively. According to observations by experts some terms which are of key importance for the application of the Communication, are not adequately specified and are thus interpreted differently in different countries, e.g. “Acceptable level of risk”, “Potentially dangerous effects”, “Reasonable amount of scientific certainty”, etc.

Without clarifications of these issues, the objective of the Communication to foster a common approach to the application of the precautionary principle cannot be achieved. Additionally, some experts hold the view that Member States use this lack of specificity to interpret the precautionary principle according to

political interests. The precautionary principle is thus implicated in decisions on GMO applications in a way which does not keep different decisions in proportion. Comparison with other fields of regulation indicates that the precautionary principle is thus used in a way which is not intended by the Communication.

The Communication is focused on the implementation of the precautionary principle for risk management and assumes that risk assessment is supplying the necessary information to risk managers for the precautionary principle to be applied. The analysis of expert opinions shows that this is seen controversially.

On the one hand the intention outlined by the Communication is supported. According to the expert opinion, the framework is suitable and sufficient for application in GMO regulation. Additionally, this approach is considered to be in line with relevant international agreements including Multilateral Trade Agreements (e.g. WTO agreements).

By contrast, observations from other experts indicate that the implication of the precautionary principle for risk management is dependent on a precautionary approach, which requires specific consideration of the precautionary principle at all individual steps of the regulatory process. This regards the overall design of the decision-making process, and specifically the design of the risk assessment (see also Chapter 3.7).

3.6 Shortcomings of current application of the precautionary principle in GMO regulation

The following observations indicate shortcomings as identified by the experts participating in the interviews:

In the view of some experts the reasons for decisions on individual GMO applications are not explained in a transparent way by risk managers. This complicates the assessment of the justifications for the decisions and may foster the notion that certain decisions are taken for political reasons. Additionally, risk managers are implicating the precautionary principle only in very general terms in individual decisions on certain GMO products. Risk managers do not sufficiently explain in their decisions whether and how they applied the precautionary principle. A need to improve transparency accordingly was identified.

Controversial views prevail regarding the question whether the precautionary principle needs to be applied with regard to GMOs. Some experts indicated that there was no need to apply the precautionary principle in decision-making because no relevant adverse effects have been identified for GMOs. Other experts argued that the precautionary principle was not applied due to insufficiencies of the risk assessment (with respect to scope, the information considered, conclusions drawn and the treatment of uncertainties).

According to the observations by some experts, the principles outlined in the Communication were not systematically implemented. This regards both decisions where the precautionary principle has been implicated (e.g. to restrict application of GMOs) as well as decisions not to apply the precautionary principle. A reason why application is selective could be the fact that specifications are missing in the Communication. A lot of observations indicated that the terminology as well as the practical approaches are not defined at a necessary level of specificity.

The difficulties that were identified concerning the application of the precautionary principle are:

- A common approach to application would be necessary, but is not achievable.
- Current guidance for risk assessment does not strengthen the precautionary approach.
- Controversies around the application of the precautionary approach are framed as scientific disputes. Discussions are not taking into account that science cannot address controversies related to the application of different levels of protection, as determined by different countries.
- Differences arise from different perceptions of the risks, since there is no adequate system for quantifying risks and no common level of protection.
- Weaknesses in risk communication were indicated by a number of experts and regarded as one of the reasons for political unease with GMO regulation.

3.7 Scope of application of the precautionary principle in GMO regulation

According to the Communication, the precautionary principle shall be considered in a structured approach to the process of risk analysis in GMO regulation and specifically at the risk management stage. This notion was supported by a number of experts, which indicated that the precautionary principle should be considered by risk managers during decision making. According to an observation, this is the only interpretation that would be consistent with the principle as outlined in the Rio Declaration.

According to this interpretation, risk assessment needs to be seen as a separate step, which would not be guided or influenced by the precautionary principle itself. Only after a scientific opinion is established would the precautionary principle need to be involved in considerations concerning decisions and options for risk management.

However, a number of experts indicated that this view might be a simplification of the GMO regulation process. Specifically, it may not incorporate all necessary considerations regarding the application of the precautionary principle. According to these arguments, a meaningful implementation of the precautionary principle needs to be based on an approach which also targets other aspects of the overall process, like risk assessment and risk communication. Specifically aspects which rest on normative commitments (judgments, assumptions, the framing of processes contingent on social values) should be considered in such an approach.

The application of the precautionary principle thus becomes an overarching policy principle and a point of reference e.g. for situations where uncertainties in the scientific risk assessment need to be considered. This approach would therefore apply among others to the framing of risk assessment processes, the participation of stakeholders regarding the design of risk evaluation, the way of conducting a cost and benefit assessment and the presentation and evaluation of the results of the risk assessment. Therefore this approach concerns not just the practice of risk assessment but also its importance for regulation and policy.

The Communication is not explicitly addressing these implications, but refers to the above mentioned precautionary approach.

The interconnection between risk assessment and risk management is an important aspect in the context of the discussion as to how a precautionary approach shall be applied. This is stressed by experts in the interviews specifically with regard to GMO regulation.

Important issues with relevance for risk management are how the risk assessment is structured and which risks are considered during risk assessment. However, it was pointed out that not all risk aspects concerning GMOs can be assessed by means of a scientific risk assessment. As another important issue the degree of evidence which is deemed necessary to conduct an assessment, is indicated.

In the course of risk assessment hazard characterisation should comprehensively identify risk hypotheses and all plausible risk hypotheses should be investigated scientifically to establish whether the associated risk is negligible. According to specific observations by interview partners, it is questioned whether this is currently done in GMO assessment. A number of experts indicated therefore the need to continuously update and revise the available guidance for the assessment of GMOs and to develop additional guidance. A need for improvement in certain fields (e.g. assessment of the effects of GMOs on non-target organisms) is indicated.

It was observed additionally that certain management decisions demand specific information which needs to be established during the risk assessment (like issues connected to case-specific monitoring of GMOs). Thus interaction between risk assessors and risk managers is deemed necessary to be able to translate the assessment results into risk management decisions.

3.8 Consideration of uncertainties

Uncertainty in all its types is a relevant factor in the application of the precautionary approach. Due to the biological characteristics of GMOs and their (environmental) effects, which are complex and difficult to assess, uncertainty is an unavoidable factor in the scientific assessment of effects of GMO applications. The Communication states that uncertainties have to be identified at each stage of the evaluation and communicated appropriately together with the results of the assessment.

Whether uncertainties are addressed adequately at present is discussed controversially between stakeholders.

With regard to the requirement contained in the Communication the interviews identified a number of different shortcomings in the current practice of risk assessment of GMO applications. The following shortcomings were mentioned according to subjective appraisals:

- The approach outlined by the Communication and currently implemented in GMO risk assessment cannot identify all types of uncertainties (scientific uncertainties, ambiguity, ignorance and indeterminacy). The current evaluation of GMOs deals primarily with scientific uncertainty, but is weak on the other types of uncertainties (e.g. ignorance, specifically with regard to proportionality issues and benefits).

- Better knowledge might reduce some uncertainties, but some uncertainties will remain and need to be taken into account during risk management and decision-making.
- Uncertainties are not addressed sufficiently at the step-by-step assessment and due to shortcomings of the current risk assessment regarding the assessment of the impact of GMOs in different environments.
- Shortcomings concerning the communication of uncertainties are indicated by different experts. According to these opinions, efforts to improve the situation have started only in recent years.

Other observations indicated that scientific uncertainties ("known unknowns") are addressed by the current system, and increasing experience will reduce the level of this type of uncertainty further on.

Monitoring is identified as a measure related to the application of a precautionary approach which can be used to address "unknown unknowns". However, it is indicated that monitoring has its limits and cannot be used in all situations. The reasons for these limitations can be methodical or due to decisions that monitoring is not appropriate for a specific type of uncertainty (e.g. for potential risks of medical applications).

The concept of prudence in risk assessment as outlined in the Communication is regarded as necessary, but needs to be better specified according to several observations. Specification of prudence considerations for GMO regulation can increase the accountability of the risk assessment.

3.9 Stakeholder roles

Some experts indicated that the stakeholders involved in GMO regulation should support the further application of the precautionary approach by taking it better into account within their role. This is specifically relevant for necessary cooperation, e.g. at the interface between risk assessors and risk managers when the design of risk assessment systems and the evaluation of risk assessment results come into question, as well as the evaluation of risk management options. Additionally, it is indicated that the responsibility for risk communication has to be taken by the risk managers.

The need to identify and include relevant stakeholders in discussions concerning further development is stressed by a number of experts. Observations indicated that specifically stakeholders who currently have an important part in GMO regulation, like EFSA, should be included in the discussions.

The involvement of other stakeholders who could provide additional input and share experiences made in other regulatory fields is not addressed in a systematic way by lawmakers and risk assessment bodies. Observations indicated that relevant input with regard to implementation of the precautionary principle in GMO regulation from academia (e.g. scientists who are not members of advisory panels), and institutions concerned with the application of the precautionary principle in related fields should be actively pursued.

Some experts pointed to the important role of independent review and highlighted the work done by the European Environment Agency concerning the review of case studies on the application of the precautionary principle (EEA 2001).

A specific observation indicates that, according to the legal framework in certain countries, risk managers have a direct legal responsibility for their decisions, and specifically for taking into account the precautionary principle. Within the system of GMO regulation in the EU such a direct legal responsibility is not assigned to a specific decision-making body and the complex system of responsibilities may have an influence on how decisions are taken.

3.10 Considerations related to cost/benefit analysis of GMOs

The Communication calls for the assessment of the costs of action and inaction based on an examination of the costs and benefits of applications in both the short and long term.

Such an approach is regarded as valuable from all aspects. Some experts even stressed that such an evaluation is urgently needed to make GMO regulation fit for the purpose. The approach is supported, but the need to develop specific guidance for such an approach is indicated.

However, a number of difficulties are pointed out for such an approach:

- Currently the Communication does not specify how to approach the examination of costs and benefits, apart from the recommendation that costs and benefits should be assessed in a broad sense, and not restricted to an economic analysis.
- At present such an approach is not accommodated in current GMO regulations, and thus not included in the assessment foreseen by the regulations for GMOs. This kind of analysis is thus not implemented in practice at present.
- The analysis of costs and benefits is difficult to achieve. It is indicated that it should be done according to scientific analysis. However, not all issues of the problem can be approached scientifically.
- Apart from economic considerations, estimations of non-economic factors (e.g. changes in biodiversity) need to be made. These aspects are difficult to assess and specifically difficult to compare with the economical considerations of a cost/benefit analysis.
- Important issues concerning this analysis are the distribution of costs and benefits between different groups in society and appraisals of whether assessments are realistic in practical terms.

Concerning a practical approach to this analysis, reference is made to approaches developed in the UK (ACRE 2007) and Norway (decision tree approach to the assessment of GMOs).

Furthermore it is indicated that an examination of the costs and benefits of GMO application would enhance comparability with other technological solutions in an environmental impact assessment-like approach. Such an analysis is suggested for new and generic types of GMOs (e.g. GM plants with relevant

changes of general characteristics). These applications could pose new challenges for assessment and regulation and the approach mentioned would complement an in-depth risk evaluation as recommended for these applications. According to expert suggestions, recommendations for such an analysis may be drawn from the experiences with comparative assessments of pesticides and suggestions made by the German Advisory Committee for global environmental changes for the risk management of GMOs (WBGU 1998).

3.11 Development of a scientific basis for the assessment of GMOs

According to most experts, the developments of a scientific basis for the assessment of GMOs are not driven specifically by the precautionary principle. Application of a precautionary approach, however, can identify areas where further research is necessary. The publishing of the Communication by the European Commission is not considered to have specifically boosted efforts for developing science used in risk assessment in a particular way. It was placed into a context of safety research which was already underway.

However, expert opinions differ on the extent and usefulness of biosafety research in the EU. Some experts indicate that quite an effort had been made in the EU at the beginning of the 1980s to support the scientific evaluation of GMOs and to develop the necessary methods. It is specifically noted that, compared with the situation in other countries, more funds and efforts were allocated to safety research in the EU than anywhere else. As a result, the necessary science for assessment would be available. Concerning the results of safety research, one expert notes that for some issues evidence for a scientific evaluation would be available so that having recourse to the precautionary principle would no longer be necessary (e.g. for HGT for antibiotic resistance markers genes).

Other experts indicate that activities in safety research are few in comparison with the research activities undertaken for applied research and development of GMO applications and they deplore that safety research is not supported adequately. Consequently, the notion is put forward that the development of applicable methods to assess environmental effects as well as toxicological effects is not as advanced as it could be.

In this respect it is noteworthy that the steering bodies for research funds are usually not involved in discussions concerning the application of the precautionary principle. Therefore no direct link is established between the identification of research needs and scientific developments.

General criticism is made concerning the overall focus of biosafety research, which is deemed not adequate to support innovative approaches to comprehensive risk assessment.
Another line of criticism targets politically motivated research programmes, which add little to the knowledge already available, and mainly duplicate preceding efforts.

A specific issue is the field of science necessary for the monitoring of GMOs. The need for monitoring is triggered by a precautionary approach. Implicating the precautionary principle can demand specific monitoring and thereby drive development and application of methods for monitoring, e.g. environmental monitoring.

Some of the components of these monitoring systems are not specifically applicable for GMOs, but for a wide range of related issues (neobiota, introduction of non-food plants, etc.)

3.12 Discussion concerning the application of a precautionary approach

There is an ongoing discussion with regard to the application of a precautionary approach in the framework of the general discussion concerning the application of GMOs and specifically GM plants in the EU. The publication of the Communication is considered to have had some impact on these discussions. However, most experts are not sure whether the publication of the Communication itself stimulated the discussion. There is only little published output from the discussions relating to the Communication. As observed from an outside perspective the discussions concerning a precautionary approach mostly did not seem to involve the EC and EFSA, which are main stakeholders in the process of GMO regulation.

Some opinions are indicating that the publication of the Communication was regarded as an end to a discussion process rather than as an input for the start of such a discussion process. Therefore an opportunity was missed to address certain controversial issues of the Communication from the start in an open discussion process. According to another expert, the European Commission itself was very reluctant to enter into a discussion with the aim of amending the Communication during the first years following the publication of the Communication. More recently, some Directorates of the European Commission appeared to be more open to discussions of these aspects.

Regarding these discussions, however, concerns are expressed that the discussions do not address the issues of conflict openly (e.g. safeguard measures based on application of a precautionary approach). Therefore the current discussions are not regarded as adequate for resolving controversial issues or for leading to a change in current positions.

4 SUGGESTIONS FOR A WAY FORWARD

In this chapter recommendations for a way forward concerning further application of a precautionary approach in GMO policy are proposed. These suggestions are based on the results of discussions during the study and on the interviews conducted with experts in the course of the project. The authors want to introduce these suggestions for further discussion at the EU level and as an input for exploring possibilities of improved applications of a precautionary approach.

The suggestions target the following three main areas:

- Policy considerations for implementation of a precautionary approach
- Suggestions for review of current practices of application of the precautionary principle in GMO policy
- Broadening the scope of application of the precautionary principle in order to establish a comprehensive precautionary approach.

To avoid misunderstandings of specific terms with regard to the application of a precautionary, approach Chapter 1.2 of this report outlines how the crucial terms are used by the authors. This relates specifically to the use of the terms “precautionary principle“ and “precautionary approach”, which are interpreted differently in different fora and by different stakeholders, as well as to the definition and scope of the different elements of risk analysis.

4.1 Policy considerations for application of the precautionary approach in GMO policy

4.1.1 The precautionary principle is an important aspect in EU GMO policy

The precautionary principle is an important issue embraced by GMO legislation in the EU. The precautionary principle in GMO regulation is implemented by Directive 2001/18/EC and related legislation. However, the precautionary principle is not the only principle which is considered in GMO regulations. A number of other principles have to be observed, such as the requirement for evaluation of individual applications based on a case-by-case assessment, the respect for ethical principles, the principle that the public should be informed and participate (e.g. in consultations of the public concerning specific types of GMO applications), that GMOs should be traceable at all steps of application and that compliance shall be ensured. The application of the precautionary principle therefore has to be considered in the context of the overall development of GMO regulation.

Consequently, discussions aimed at further developments of the overall framework for GMO policy and individual aspects need to consider requirements for the application of a precautionary approach in turn. Therefore, people professionally involved in the GMO regulatory process on GMOs should be aware of the precautionary principle and of its current state of implementation. The precautionary principle should therefore be actively addressed further in the course of the ongoing debate on the further development of GMO legislation.

Another aspect which has to be taken into consideration is the existence of possible overlaps of different fields of regulation, with respect to the development and use of GMO applications in the EU. An apparent example is the overlap of GMO legislation and legislation on pesticide use for the regulation of herbicide-tolerant GM crops.

Other overlaps, e.g. in the fields of research & development policy, economic policy, etc., are evident. The way of application of the precautionary principle in different regulatory fields and the respective impact on GMO policy need to be evaluated and better taken into consideration. This can only be achieved by a structured and integrative political effort at the EU level which is based on the evaluation of experiences regarding the application of the precautionary principle in the respective policy fields.

Furthermore, the implications of strategic goals, e.g. strengthening innovation processes in the EU set by the Lisbon targets, need to be addressed with a view to potential conflicts with the objectives of EU legislations introducing precautionary approaches towards technologies which are regarded as potentially dangerous.

4.1.2 Review of the Communication of the European Commission on the precautionary principle

Some guidance for the application of the precautionary principle in EU policy is given by the Communication of the EC on the precautionary principle. Therefore the Communication needs to be considered in ongoing discussions concerning the precautionary principle in GMO policy as a relevant point of reference. However, the Communication should not be regarded as a final outcome of the discussion, but rather as an important input which needs to be reconsidered in due course. Therefore the approach which is laid out in the Communication should be reviewed with a view to the developments since the publication and with a view to specific aspects of the policy fields which are concerned, like GMO regulation. Wherever such a critical appraisal identifies issues which are not satisfactorily addressed by the Communication, clarifications should be introduced, e.g. by drafting additional explanatory documents supplementing the Communication.

The aim of critically discussing the Communication is twofold:

- to discuss the Communication in the light of experience gained; and
- to reacquaint stakeholders with the communication, because not all current stakeholders might be fully aware of the Communication and its implications.

The dialogue should involve the European Commission as author of the Communication, competent authorities, scientific advisory committees and technical experts of the competent authorities, and EFSA. Discussions should openly address the problems which are encountered in practice, and be aimed at resolving divergent opinions at an expert level or make transparent any prevailing disagreements. An appropriate format for such discussions will have to be determined by the participants.

The results of case studies on how the precautionary principle is applied in GMO regulation (see Chapter 4.2.3 for details) could highlight different approaches and identify open issues with regard to application of a precautionary

approach. In case the analysis reveals that the guidance given in the Communication is not sufficient, clarifications and specific details could be incorporated in an explanatory document specifying the precautionary approach for GMOs.

Discussions about the Communication should take into account recent developments in other emerging technologies (e.g. nanotechnology for food applications, applications of synthetic biology). A broad group of stakeholders should be included in these discussions.

4.1.3 Clarification of terminology

A number of key issues contained in the Communication are not defined at a necessary level of specificity to offer adequate guidance for the application in GMO regulation. Since providing such guidance is an explicit objective of the Communication itself the need for further clarification is evident. Additional clarification could reduce conflicting interpretation with regard to issues which are crucial for application of a precautionary approach in GMO policy. Clarifications should be introduced concerning e.g. the strength of evidence which is sufficient to justify application of precautionary measures, how uncertainties are considered and taken into account and to describe elements which would constitute a prudential approach in relation to uncertainties identified during the evaluation of GMO applications. Specifically a lot of differences exist concerning the way how risk and uncertainties are expressed by scientific committees. An analysis of such differences was presented e.g. by HARDY (2007). These differences may have important consequences, since they may influence which measures are adopted. Therefore specific clarifications should supplement the general guidance as contained in the Communication.

On the other hand, some issues need to be determined in a case-specific manner and need to be defined in the context of a certain regulatory and political system. For example, the level of protection is regarded as such a key issue which cannot be determined in a universal manner and thus some level of conflicting interpretation with regard to this issue can be expected. However, for these issues transparency is necessary to bring to light the reasons which were guiding the choice of a specific interpretation.

It needs to be explored what is the best means for introducing specific clarifications with regard to application of the precautionary principle in GMO policy. We suggest that an additional document should be drafted by the European Commission in cooperation with Member States and experts.

4.1.4 Guidance for application of a precautionary approach in GMO regulation

To support the application of the general framework for the precautionary principle, a set of specific criteria should be developed to underpin the practical application of the precautionary principle during the evaluation of specific GMOs.

Such criteria were developed e.g. on behalf of the Swiss scientific advisory committee (AMMANN et al. 2007) and as suggestions for the consistent implementation of a precautionary approach by the same committee. This approach was taken in the context that no systematic approach to operationalise the pre-

cautionary principle is at hand which takes into account the specific characteristics which are typical of GMOs and their assessment (biological characteristics, the complex nature of environmental effects, long-term effects which may be difficult to assess, etc.). It is geared to the objectives that the scientific assessment should be comprehensive, assess the consequences of action and inaction, determine and communicate the scientific certainty of the assessment and evaluate alternatives.

In analogy to the suggestions in AMMANN et al. (2007), the development of guidance for a precautionary approach in GMO regulation is suggested with the following aims:

1. Establishing an understanding of the precautionary principle in a certain context, e.g. in Biosafety Commissions
2. Guiding the application of the precautionary principle in Biosafety in a specific regulatory context

Such considerations could be used as checklists for guidance during the evaluation of GMOs.

Guidance for an understanding of the precautionary principle as proposed for Biosafety Commissions should underscore that e.g.

- The level of risk should be reduced as far as possible in order to achieve the desired high level of protection, even when taking into account that it is not possible to eliminate all risks.
- The risk assessment should be conducted taking into account the available evidence. It should be based on scientific caution and present judgment as to when the scientific reasoning is deemed conclusive.
- The risk assessment should be open and transparent and address public concerns regarding emerging risks.
- The risk assessment should identify the potential adverse effects and should identify the potential magnitude of risks as well as the potential magnitude of uncertainties in relation to the level of protection which is applied.
- It should be communicated when the interpretation of evidence is controversial within a specific advisory committee and due account should be taken of minority views, provided the credibility and reputation of this fraction are recognized.
- Initial presumptions of adverse effects should be based on worst case scenarios.
- The precautionary principle should be applied in case of indications of potential adverse effects which are not consistent with the desired level of protection.
- The principles for risk management as outlined by the Communication should be applied (proportionality, consistency, non-discriminatory nature, examination of potential benefits and costs of action or inaction, review of the measures based on new scientific data, measures capable of assigning responsibility for producing the necessary scientific evidence).

Guidance for the application of a precautionary approach could clarify whether measures based on the precautionary principle should be triggered. According to such guidance

- The existing knowledge should be evaluated and rated according to its significance. Based on these considerations, the available information should be considered for decision-making.
- Potential risks should be examined comprehensively and the state of knowledge considered adequately. Measures should take into account whether the knowledge of important risk facts relevant to the assessment is insufficient.
- An analysis of uncertainties should be performed, which identifies relevant kinds and levels of uncertainties. Conclusions should be judged by the level of associated uncertainties. Measures should take into account whether uncertainties can be eliminated in the course of the risk assessment and whether it is possible to determine the degree of risk that adverse effects will manifest (data lacking and/or equivocal and/or inadequate).
- The chosen level of protection should be ensured even in situations of inadequate scientific knowledge. Measures should be taken when scientifically plausible risk hypothesis exist which are based on reasonable grounds.
- The consequences of action and inaction should be assessed as proposed by the Communication.
- Unnecessary delays in decision-making should be avoided and provisional measures taken which should be reviewed in the light of new scientific evidence.

To guide the application of a precautionary approach by respective bodies for the evaluation of GMO notifications in the EU, appropriate guidance should be implemented. The use of such guidance could additionally make decisions more accountable.

4.1.5 Common and regional aspects of GMO Policy

The issue covered in this chapter is of general interest in GMO regulation, but is also highly relevant for a precautionary approach. In the context of a precautionary approach regional specifics should be considered adequately for the evaluation of all potential risks of GMOs. Specifically the general assessment standards for the environmental assessment of GMOs should allow that relevant differences between environmental conditions are taken adequately into account. Differences in receiving environments may translate into the adoption of different levels of protection in different regions. But even a common level of protection would have different consequences, since environmental effects of GMOs are dependent on the specific environmental conditions in a given region or country and thus can vary considerably between different locations in the EU. For decisions which concern the deliberate release and the cultivation of GMOs in the EU these ecological differences between regions should be taken into concern accordingly. This needs to be better acknowledged in decision-making than is currently done and could be achieved by strengthening the responsibilities of the Member States with regard to aspects that are connected to environmental assessment and decision-making. This could be achieved in analogy to the current EU procedures for the authorisation of pesticides according to Directive 91/414/EEC which take into account the different environmental condi-

tions and the responsibilities of countries. According to a precautionary approach, different levels of protection could thus also be considered for the evaluation of GMO use in different environments.

In contrast to other issues related to the evaluation of GMOs, no relevant regional differences can be expected, e.g. for the evaluation of potential adverse effects of GMOs for human health. With respect to such issues, the current EU approach to introduce a common assessment standard which ensures an adequate level of protection is considered adequate.

4.1.6 Implementation of the precautionary principle at the international level

Since the EU is an important political and economic player, other countries, including developing countries, are showing a major interest in EU developments concerning GMO applications and in the application of a precautionary approach in GMO regulation.

EU policy concerning GMO regulation is considered to be very precautious by a great number of other countries. Other industrialized countries like Japan, but also developing countries, show an interest in the EU approach. However, criticism has been raised that the decisions in the EU on GMO applications lack transparency, and that the EU rules are applied inconsistently (e.g. claims by countries like US, Canada and Argentina during deliberations of the WTO panel in the “EC: Biotech” case). In case this criticism cannot be refuted, the application of the precautionary principle in the current system for GMO evaluation could be denounced as arbitrary and based on considerations other than scientific evaluation.

Therefore, specifically with regard to environmental issues, the chosen level of protection needs to be explained and applied in a transparent way. International stakeholders (especially developing countries) need to be actively involved in the discussions about the precautionary principle, identifying differences in interpretation and application, the reasons for such differences and the justifications for specific interpretations.

Such efforts to present the application of a precautionary approach in the EU in a transparent way for other international parties may support the efforts undertaken by the EU to actively promote the concrete application of the precautionary principle in international fora (of Multilateral Trade Agreements like the WTO and the Cartagena protocol). These efforts need to take into account that international agreements have to accommodate different regulatory cultures.

Such considerations do not only apply to the international discussion about the implementation of the precautionary principle in GMO policy. Similar considerations might also apply with a view to other topics, particularly with the assessment of emerging technologies (nanotechnology in foods, synthetic biology applications, biocontrol, etc.). An active role of the EU in international discussions about the significance of the precautionary principle in a broader sense is therefore proposed. Aspects related to GMO technology should be an important focus of the respective efforts.

4.2 Suggestions regarding a review of the current practice of application of the precautionary principle in GMO policy

4.2.1 Transparency of application of the precautionary principle

Observations by experts indicate that the precautionary principle is seldom implicated in specific decisions on GMO applications by risk managers and if so, mostly in a very general way. Notably no reference is made to how the precautionary principle was considered during the risk analysis of notifications which received opinions supporting the authorization of these applications. Therefore it cannot be properly assessed whether and how risk managers apply the precautionary principle in their decisions. Transparency should therefore be increased here. Currently the public does not commonly assume that a precautionary approach is applied by regulating bodies. Increased transparency concerning the application of the precautionary principle could thus be valuable for demonstrating which considerations related to a precautionary approach were taken in the course of GMO evaluation.

This issue also underpins the importance of the interfaces between the different elements of the risk analysis process and the interconnections between e.g. risk assessment and risk management. Better explanations by decision-making bodies of their way of application of the precautionary principle could be important to improve risk communication and to provide the relevant feedback to the risk assessors, indicating how the prepared assessments are appraised during risk management. Furthermore, better explanations of the way the precautionary principle was applied during decision-making could aid in the assessment whether the principles for application of the precautionary principle on the EU level[1] which are outlined in the Communication were systematically applied.

On the other hand the considerations forming the basis of the conclusions of risk assessments need to be transparent for risk managers to facilitate the application of the precautionary principle.

4.2.2 Review of the application of the precautionary principle in the risk analysis process of GMOs

A review of the current application of the precautionary principle in the risk analysis process of GMOs should be undertaken to address the question whether the present implementation needs to be improved in specific ways. This review should assess whether guidance (e.g. for risk assessment) is adequately addressing issues which are important with regard to a precautionary approach, whether the general principles contained in the Communication have been observed and whether additional efforts could be taken to improve the application of a precautionary approach. For this general review results from case studies targeting the application of the precautionary principle for specific GMO applications should be used as supporting evidence (see chapter 4.2.3.).

[1] proportionality, consistency, non-discriminatory nature, examination of potential benefits and costs of action or inaction, review of the measures based on new scientific data, measures capable of assigning responsibility for producing the necessary scientific evidence

The review should assess whether

- the initial framing of the risk analysis is adequate (e.g. whether risk issues have been identified comprehensively, whether all plausible hypotheses are addressed and whether different receiving environments are adequately taken into account).
- uncertainties have been adequately analysed and taken into account in the course of risk assessments and whether considerations of prudence have been implemented (e.g. consideration of worst case scenarios, characterization of risks based on multiple lines of evidence, etc.).
- risk assessment opinions included all necessary information to facilitate the application of a precautionary approach (identification of uncertainties, identification of controversial interpretations of results, identification of "weight-of-evidence" approaches for drawing conclusions, …).
- issues were considered which were not covered by the scientific risk assessment (and how they were approached).
- open questions concerning specific risk issues could be investigated with specifically designed experiments at a relevant scale.

A recent analysis of risk assessment options by three non-food scientific committees shows that uncertainties were not addressed in a systematic and comparable way in the opinions they delivered (HARDY 2007). The results of this analysis show that a thorough review of the procedure and results of the risk analysis process for GMO applications is warranted.

The evaluation of (scientific) experience in the assessment of GMO applications constitutes a specific issue. It needs to be determined how the experience accumulated with the scientific investigation of GMOs could be used best to improve the ongoing assessment and reassessment of GMOs. The state of the art should be used as a reference point for the evaluation of the quality of available evidence. However, the scientific approach which is applied needs to be appropriate to address the specific assessment questions conclusively.

In this context an evidence-based approach could render possible the rating of available knowledge in a systematic, transparent and efficient way. Evidence-based approaches are successfully applied in fields like medicine and toxicology (SACKETT & ROSENBERG 1995, GUZELIAN et al. 2005). The US National Academy of Sciences recently advised the use of evidence-based methods for analyzing the strength of available scientific findings in toxicology, and the evaluation of data from different studies as an alternative to "weight-of-evidence" approaches based on the expertise of scientific committees (GUZELIAN 2008).

Furthermore, a precautionary analysis of the available science could be employed to identify how the analysis of potential errors and the power of the presented analysis is approached by the risk assessors (MCGARVEY 2005). Such an analysis could be valuable for the determination of the significance of the scientific findings used in GMO assessment.

Additionally, the assessment of previously reported evidence is an important issue which needs to be addressed. As pointed out in the interviews, some types of GMO crops were developed and authorised some years ago. This timeframe was regarded as adequate for gathering experiences in assessment and monitoring and to assess even long-term effects. Such information should be considered for the assessment of individual applications, dependent on an

evaluation whether the quality of data is meeting the quality standards applied to these assessments. Specifically the following requirements should be met for the applicability of such data:

- Results should be applicable for the conditions in question (e.g. similar GMOs grown under similar conditions in comparable environments)
- Results should be established according to given assessment standards (results established following comparable guidance, application of similar methods)
- Results should be of the level of detail which is deemed necessary, in the guidance for the assessment, to adequately address a question.

A review according to the above criteria may suggest changes in the process of the evaluation of GMOs which could improve among others the application of the precautionary principle. Examples of such specific changes could be

- the evaluation of the quality and the strength of the available evidence according to the principles of systematic review as employed in other fields (PETERS et al. 2006), to improve the current approach of relying on expert-oriented considerations to determine the weight of evidence.
- the in-depth evaluation of new types of GMOs which present generic developments and modifications, which result in the change of relevant characteristics (e.g. GMOs with changed nutritional characteristics, GMOs with enhanced tolerance against abiotic stress, such as draught resistance). These types of GMOs could present new challenges and should be evaluated in an elaborate way, including comparative analysis with alternative solutions and cost/benefit analysis.
- the introduction of an evaluation phase (to discuss the risk assessment procedure and the results of the risk assessment between risk assessors and risk managers, to identify the challenges for risk management and to assess risk management options).
- the involvement of a broader range of stakeholders for the framing of the evaluation process.
- the introduction of refined approaches and frameworks for the monitoring of GMO effects.

These aspects should be further addressed in the ongoing discussions between EFSA, the EFSA GMO panel, as well as national scientific advisory boards and authorities from Member States.

4.2.3 Case studies to evaluate the application of the precautionary principle

The use of specific examples and case studies conducted on different levels to illustrate current approaches and to exemplify specific shortcomings has been repeatedly suggested during expert consultations in the course of the project at hand.

Case studies should be undertaken to identify which approaches were implemented for the evaluation of specific applications of GMOs, and to highlight problems encountered with the application of the precautionary principle. Such case studies could be conducted on different levels, addressing on the one hand EU level assessments as well as, on the other hand, analyzing national

level assessments (e.g. for deliberate release notifications according to Part B of Directive 2001/18/EC). Such case studies can also address the question whether the current approaches to risk assessment of GMO applications by different risk assessment bodies are intrinsically precautionary. In such case studies risk assessments for specific GMOs should be investigated to analyse as to how the design of the specific risk assessments is influenced by judgments based on values and assumptions. It should be investigated whether the chosen design supports or does not support the application of the precautionary principle.

Such case studies should therefore analyse the different approaches of risk assessment bodies and identify the differences which have a potential impact on the application of the precautionary principle. Such an approach should involve institutions and Member States currently objecting to the conclusions put forward in risk assessments, e.g. the EFSA GMO panel, to substantiate the argument that the current risk assessments are considered insufficient. Such clarifications are specifically demanded by the GMO panel as an input for the discussions of the approach taken by the panel with regard to risk assessment.

The analysis of examples could furthermore illustrate approaches for applying the precautionary principle and demonstrate how a precautionary approach may be applied. This could very much support the general guidance given in the Communication.

Case studies should also be prepared to address specific issues e.g. cost/benefit analysis. An important issue which needs to be addressed is how the results of a cost/benefit analysis should be considered in the overall evaluation of GMO applications. Preliminary work on this aspect was e.g. published by ACRE (2007) in their analysis of wider issues raised by the Farm-Scale Evaluations of herbicide tolerant crops. ACRE suggested a comparative assessment of risks and benefits using a matrix based approach. The method essentially is an evidence-based approach for a multi-dimensional assessment of GMO applications as compared with current crops and practices. The approach proposed by ACRE should facilitate a comparative assessment of the sustainability of different agricultural production systems. Such work should be followed up on the EU level with the participation of Member States.

4.3 Broadening the scope of implementation of the precautionary principle

4.3.1 Implications of a precautionary approach regarding risk assessment and participation

The Communication states that the precautionary principle is particularly relevant to risk management. However, to essentially limit the implementation of the precautionary principle to risk management leads to an artificial separation of the steps of the risk analysis process. Such a separation is in conflict with the objectives of a precautionary approach as explored in this study and might be detrimental to the quality of the regulatory outcome. The Communication itself implies that considerations with regard to the precautionary principle are necessary at different steps of the risk analysis process. The current discussions in

the EU highlight controversies on the question which elements are required for risk assessment to facilitate the application of the precautionary principle in risk management. One of the shortcomings of the Communication is that it does not outline specifically how a precautionary approach can be achieved, but only stresses the functional differences between (technical) caution in risk assessment and the use of the precautionary principle for risk management.

The elements of such a precautionary approach which ensures that the precautionary principle can be meaningfully applied in risk management need to be elaborated further. The use of such a more comprehensive approach could also be a means to address some of the conflicts in the EU over GMO applications. Such an approach would encompass many of the suggestions which are listed in the above chapter in section 4.2.3. It should be based on a critical review of the framing of the risk analysis process and the involvement of stakeholders (FELT et al. 2007).

In analyzing the framing of the risk analysis process the importance of several elements should be specifically considered:

- Setting the desired level of protection by risk managers as a first step to informed risk assessment.
- Conducting risk assessment by identifying relevant risk issues and framing them by well-built meaningful questions as a start of risk assessment. The importance of such questions at the start of an assessment was recently highlighted (SCHLOSSER et al. 2006).
- Conducting a systematic and transparent review of the available knowledge to determine quality and weight of the scientific evidence. Furthermore conducting an analysis of knowledge gaps and uncertainties which are related to identified risks.
- Ensuring that conclusions of the risk assessment refer to elements which are required by risk managers to apply the precautionary principle (evaluation of evidence, interpretation of evidence, transparency of uncertainties, etc.).
- Communication between the bodies which are responsible for specific tasks at the different stages of risk analysis (risk assessors, risk managers and policy makers) to ensure that considerations taken at different steps support the objective of implementation of the precautionary principle in the overall process in the best possible way.

The suggestions outlined also take into account that risk analysis in reality is not a strict linear process (with risk assessment as an initial step, and risk management and risk communication as separate subsequent steps), but can be considered a circular exercise, whose results should provide a feedback on the design of the assessment process.

According to observations as summarized in Chapter 3, there are differences in interpretation concerning the precautionary principle even within EU institutions. A structured discussion process should address these differences and additionally review the concept of application of the precautionary principle as outlined in the Communication in the light of these discussions. The goal should be to avoid that conflicting interpretations prevail in EU institutions, which might translate into different approaches taken e.g. by the various EFSA scientific panels.

4.3.2 Considerations for a cost/benefit analysis of GM

The Communication advocates that an analysis of the potential benefits and costs of action or lack of action is conducted. This is regarded as an important aspect of the assessment of GMO applications, but the approaches necessary to conduct these analyses still have to be developed and implemented. The objective should be to implement the guidance given in the Communication and, accordingly, to address the issue in a broader sense, rather than focusing only on economic aspects. This approach, however, presents additional challenges for science as well as regulators. The general recommendation that cost/benefit analysis should be addressed in relation to the application of the precautionary principle as contained in the Communication therefore needs to be further elaborated and specified. In this context Life Cycle Assessment methodologies should be used for the assessment of GMOs (UMWELTBUNDESAMT 1999).

The objective to broaden the assessment of GMO impacts should include the application of cost/benefit analysis in a more general way. This approach may improve the results of the overall assessment of GMOs and facilitate a meaningful comparative assessment of GMO applications, which is demanded by various stakeholders. For the assessment of chemicals, biocides and pesticides such comparisons between different applications or technical approaches are possible (this approach is sometimes called alternative use assessment). Lessons learned from these approaches should initiate further steps in GMO regulation. The approaches taken in the assessment of developments in agriculture (IAASTD 2008) and ecosystems and biological diversity (TEEB 2008) can likewise be useful for the implementation of cost/benefit analysis in GMO regulation. The discussion is not exclusively connected to the precautionary principle. However, the results of a cost/benefit analysis could be helpful for taking decisions when faced with uncertainties related to risks identified during the risk assessment.

Since the current legislation on GMOs at the EU level does not explicitly demand cost/benefit analyses as suggested by the Communication, the difficulties concerning legal implementation need to be addressed. We suggest that concrete steps at the EU level should be taken to find out how to explore and implement cost/benefit analysis. However, a high-level decision (at the European Council) is needed to implement a strategy, on how this goal could be achieved. The conclusions adopted at the meeting of the Environment Council of the European Union on December 4th 2008 indicate that socio-economic considerations may be taken into account during risk management and that the socio-economic implications of the deliberate release and placing on the market of GMOs need to be assessed further (COUNCIL OF THE EUROPEAN UNION 2008).

4.3.3 Improved experience sharing between related regulatory fields

Since the sharing of experiences gained from the application of the precautionary principle is considered to be valuable for GMO regulation, efforts to actively transfer experience should be strengthened. Such efforts should include:

- Sharing of experiences gained from the application of the precautionary principle in other related fields (e.g. pesticide authorization, food/feed assessment, regulations on chemical substances and medicine, agriculture, etc.)

- Sharing of experiences of scientific advisory committees in related fields (exchange of best practice approaches to risk assessment)
- Analysis of case studies for application of the precautionary principle in different fields. An analysis of this kind was conducted by EEA (2001) to analyse the risk management decisions related to the effects e.g. by the use of certain chemicals, hormones and other technological applications. It was analysed how the available information was considered and how initial decisions resulted in costs or benefits. The objective of this analysis was to devise lessons on the application of the precautionary principle based on the examples investigated which are of general significance.
- Sharing of new approaches to the assessment of complex issues (e.g. climate change)

The objective of experience sharing should be to remain familiar with best practice approaches in related regulatory fields. This includes on the one hand the exchange of experience regarding regulatory approaches in different policy fields. One example which might be relevant for GMO regulation is a comparison with the regulatory approach to the authorization of pesticides in the EU. This approach couples an EU-wide authorization regime for active ingredients with the responsibility of Member States for establishing decisions on the use of pesticides according to the specific environmental conditions. On the other hand, experience with appropriate risk assessment approaches and assessment standards should be shared.

Efforts for such experience sharing should be strengthened, since considerable room for improvement is indicated. Specific attention should be given to the exchange between the advisory panels on GMOs in the EU and between EFSA panels performing risk assessment (pesticides, GMO, plant health-invasive organisms).

Approaches to analyses of how the precautionary principle was implicated in other fields are regarded very valuable and should be supported. Such methods e.g. used by the European Environment Agency (EEA 2001) for a detailed analysis of risk scenarios and approaches to risk assessment, can identify obstacles to learning within complex frameworks. Such an analysis can reveal whether application of the precautionary principle is a cost-effective measure. Furthermore recent approaches to the analysis of risks, benefits and measures (like applied in the Stern Review on the Economics of Climate Change 2006*)* should be analysed for applicability in GMO assessment.

4.3.4 Impact of a precautionary approach on the scientific development

The precautionary approach should also be reflected in the scientific strategies employed to assess potential risks. Specifically relevant in this context is the way potential errors which accompany the analysis of data are addressed and how the power of data analysis is taken into account. Examples from the assessment of environmental effects show that currently employed strategies in the scientific analysis of data may not be adequate for the assessment of environmental effects. These strategies (called hypothesis testing) tend to minimize errors leading to false positive results (Type I errors) over errors leading to false negative results (Type II errors). This may be appropriate for laboratory studies

in basic research, where studies are typically replicated and potential Type II errors have less significant impacts on the conclusions. On the contrary, in environmental studies, e.g. for determining potential environmental effects of GMOs, Type II errors should receive more attention since they may lead to a failure to detect significant effects. Other scientific approaches which focus on the analysis of specific, explicitly defined effects and include the "no effects" conclusion as alternative hypothesis, are considered superior for the investigation of environmental risks (McGARVEY 2007). Such approaches (also known as equivalence testing), which provide a more precautionary strategy without sacrificing scientific rigour, should therefore be used in the context of the precautionary approach.

In addition, a precautionary approach can identify research needs and open questions. It may furthermore indicate where methods need to be further developed for an adequate assessment. This is of particular importance for developing the basis for adequate monitoring. Specifically this analysis may indicate the need to conduct specific in-depth studies to address issues which are deemed to be relevant for the scientific evaluation and necessary to reduce uncertainties. The Farm Scale Evaluations (FSE) conducted in the UK to address questions on the effect of certain herbicide-tolerant GM crops on biodiversity (FIRBANK et al. 2003) are an example of such research. The impact of such studies is twofold: On the one hand open scientific issues concerning the effects of certain GM crops are addressed adequately, and on the other hand such research can highlight policy issues which need to be addressed further (see e.g. ACRE 2007 on implications of UK FSE trials, FIRBANK et al. 2005).

Based on the assessment of individual GMO applications, scientific advisory boards should identify issues which need to be addressed by specific research, e.g. complex and long term effects of GM crops and environmental effects, which are difficult to address experimentally. Risk assessors and risk managers should discuss whether a certain risk issue is worth being addressed experimentally and suggest a design for necessary experiments to be conducted at the national or EU level. Criteria for such decisions could be the potential magnitude of a risk for a certain hazard and the concerns which are voiced by stakeholders during the assessment of GMOs. For example the potential impacts on biodiversity due to the application of herbicide-tolerant crops were considered to be such a relevant research question in the UK and, in consequence, triggered the FSE trials. Such discussions could be part of the in-depth assessment of certain generic issues as suggested in Chapter 4.2.3. Authorities at the national and EU levels should then consider how these research programmes could be implemented and funded.

In this context it is relevant that questions with regard to funding of biosafety research and integration of research needs into public biosafety research are addressed. Thus cooperation needs to be strengthened with the authorities responsible for funding public research and specifically with the ones responsible for managing EU-level research programmes, like the EU Framework Programmes for Research and Technological Development.

One additional problem identified during expert interviews is that practical options for doing independent research are limited, due to the fact that for such investigations access to proprietary materials (like seed material of GM crops for further investigation) as well as confidential information on preceding tests is necessary. However, there is no requirement for developers to share these

materials and information with other scientists. Since some studies by applicants are considered to be confidential information few results are published in scientific journals. Risk assessment bodies thus mainly consider data submitted from applicants. However, the reassessment of individual GMOs (e.g. MOENS 2003a, b) shows that additional scientific results should be available to the risk assessment bodies and be taken into account for the assessments. Cooperation with the applicants is necessary to get access to the necessary materials and information to pursue additional research.

4.4 Summary of suggestions

The following summary highlights the most important suggestions from the preceding chapters.

Suggestions concerning policy considerations

1. The Commission Communication as an important general guidance for the application should be reviewed in the light of experience gathered with the application of the precautionary principle since publication.
   The process should involve current stakeholders at competent authorities, scientific advisory committees and institutions at the EU level (including EC and EFSA).
2. Key issues in the Communication which are currently not defined at a necessary level of specificity should be clarified and elaborated.

   Necessary specifications should be established by the EC in cooperation with Member States authorities and introduced e.g. by publishing a supplementary document to the Communication for the application of the precautionary principle and the precautionary approach in GMO regulation.

   Such guidance could be drafted in cooperation by risk assessors, risk managers and regulators.
3. The regulatory system should be developed further to better accommodate the relevance of regional differences in environmental conditions for the evaluation of GMO applications. This should be achieved by strengthening Member States' responsibilities in analogy with recent developments in pesticide regulation.

Suggestions concerning the review of current practices

1. The current evaluation of GMOs should be reviewed to assess whether elements of the risk assessment approach which are relevant for application of the precautionary approach are considered appropriately.

   We suggest the implementation of elements such as a precautionary scientific approach (using evidence-based methods, including uncertainties), an in-depth assessment of generic types of GMO applications, an evaluation phase for improved interaction between risk assessors and risk managers, improved stakeholder participation, and refined monitoring schemes.
2. Case studies should be conducted to evaluate and illustrate specific issues regarding the application of the precautionary principle in GMO regulations.

Such an analysis should assess whether the current approach to risk assessment supports the applicability of the precautionary principle.

The analysis should be conducted with the support from EU-level institutions which have relevant experience with work on case studies involving the precautionary principle, like the EEA.

3. The transparency concerning the application of the precautionary principle in individual decisions should be increased. Risk managers should specify better whether and how they apply the precautionary principle.

Suggestions to broaden the scope of application of the precautionary principle

1. All steps in the risk analysis process for GMO applications, and specifically the approach to risk assessment, need to be considered in the context of the precautionary approach.

   A critical review of the current framing of the risk assessment process and the involvement of stakeholders should provide the basis for such considerations.

2. A cost/benefit assessment comprising social, ethical and environmental aspects should be implemented for the assessment of measures based on the precautionary principle, and as an additional general element in GMO assessment.

   EU legislators should take steps to provide the legal basis for implementing such an approach.

3. Experience with the application of the precautionary principle in related regulatory fields should increasingly be taken into account. Comparison of legal frameworks for different fields regarding the application of the precautionary principle should be considered, as well as sharing experience of best practice approaches e.g. in risk assessment.

   Interdisciplinary approaches for a holistic assessment of complex issues developed in other fields (e.g. effects of climate change) should be applied.

4. Research needs and open questions concerning the evaluation of GMOs should be addressed by a precautionary approach, e.g. by implementing evidence-based methods to analyse the significance of scientific data. Additionally, specific research projects should be conducted to address important questions e.g. concerning long-term or complex environmental effects, in the framework of community research programmes. The governing bodies of EU framework research programmes should support the implementation of such biosafety research projects.

5 REFERENCES

AMMANN, D.; HILBECK, A.; LANZREIN, B.; HÜBNER, P.; OEHEN, B. (2007): Procedure for the Implementation of the Precautionary Principle in Biosafety Commissions. J. of Risk Research 10/4, 487–501.

BMGFJ (2006): The Role of Precaution in GMO Policy (Band 6-06), http://www.bmgfj.gv.at/cms/site/bestellservice.html?sort=datum&channel=CH0521&thema=CH0621

CAC – Codex Alimentarius Commission (2003): Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003.

COUNCIL OF THE EUROPEAN UNION (2006): Results of the 2740th Council Meeting, 10876/1/06 REV 1; http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/envir/90281.pdf

COUNCIL OF THE EUROPEAN UNION (2008): Genetically Modified Organisms (GMOs) – Council conclusions. Doc. 16882/08, AGRILEG 223, ENV 961.

EC (2000): Communication from the Commission on the precautionary principle, COM (2000) 1, Commission of the European Communities, Brussels.

EC (2006), Commission of the European Communities; Press release, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/498

EEA (European Environment Agency) (2001): Late lessons from early warnings: the precautionary principle 1896–2000. EEA, Copenhagen, 2001. http://reports.eea.europa.eu/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf

FELT, U.; WYNNE, B.; CALLON, M.; GONÇALVES, M.E.; JASANOFF, S.; JEPSEN, M.; JOLY, P.-B.; KONOPASEK, Z.; MAY, S.; NEUBAUER, C.; RIP, A.; SIUNE, K.; STIRLING, A.; TALLACCHINI, M. (2007): Taking European knowledge society seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission.

FIRBANK, L.G; HEARD, M.S.; WOIWOD, I.P.; HAWES, C.; HAUGHTON, A.J.; CHAMPION, G.T.; SCOTT, R.J.; HILL, M.O.; DEWAR, A.M.; SQUIRE, G.R.; MAY, M.J.; BROOKS, D.R.; BOHAN, D.A.; DANIELS, R.E.; OSBORNE, J.L.; ROY, D.B.; BLACK, H.I.J.; ROTHERY, P.; PERRY, J.N. (2003): An introduction to the farm-scale evaluations of genetically modified herbicide tolerant crops. J. Appl. Ecol. 40, 2–16.

FIRBANK, L.G; LONSDALE, M.; POPPY, G. (2005): Reassessing the environmental effects of GM crops. Nature Biotech. 23, 1475–1476.

GUZELIAN, P.S.; VICTOROFF, M.S.; HALMES, N.C.; JAMES, R.C.; GUZELIAN, C.P. (2005): Evidence-based toxicology: a comprehensive framework for causation. Human & Experimental Toxicology 24, 161–201.

GUZELIAN, P.S (2008): Growing acceptance of evidence-based toxicology (EBT) in regulatory decision making. Abstracts / Toxicology Letters 180S, S17–S18.

MCGARVEY, D.J. (2007): Merging Precaution with Sound Science under the Endangered Species Act. BioScience 57/1, 65–71.

HARDY, A.R. (2007): Comparative review of risk terminology. http://ec.europa.eu/health/ph_risk/documents/risk_rd01_en.pdf

IAASTD – International Assessment of Agricultural Knowledge, Science and Technology for Development (2008): Reports of the International Assessment of Agricultural Knowledge, Science and Technology for Development http://www.agassessment.org/index.cfm?Page=IAASTD%20Reports&ItemID=2713

MOENS, W. (2003a): Report on the molecular characterisation of the genetic map of event Bt11. Scientific Institute of Public Health, Service of Biosafety and Biotechnology; http://www.biosafety.be/gmcropff/EN/TP/MGC_reports/Report_Bt11.pdf

MOENS, W. (2003b): Report on the molecular characterisation of the genetic map of event Mon810. Scientific Institute of Public Health, Service of Biosafety and Biotechnology; http://www.biosafety.be/gmcropff/EN/TP/MGC_reports/Report_Mon810.pdf

PETERS, J.L.; SUTTON, A.J.; JONES, D.R.; RUSHTON, L.; ABRAMS, K.R (2006): A Systematic Review of Systematic Reviews and Meta-Analyses of Animal Experiments with Guidelines for Reporting. Journal of Environmental Science and Health Part B 41, 245–1258

SACKETT, D.S. & ROSENBERG, W.M.C. (1995): On the need for evidence-based medicine. Journal of Public Health Medicine 17/3, 330–334.

SCHLOSSER, R.W. & RAGHAVENDRA, P. (2006): Evidence-Based Practice in Augmentative and Alternative Communication. Augmentative and Alternative Communication, 20/1, 1–21.

Stern Review on the Economics of Climate Change (2006): http://www.hm-treasury.gov.uk/stern_review_report.htm

TEEB – The Economics of Ecosystems and Biodiversity (2008): Interim report "The Economics of Ecosystems and Biodiversity". http://www.ufz.de/index.php?en=16828

UMWELTBUNDESAMT (1999): Klöpffer, W.; Renner, I.; Tappeser, B.; Eckelkamp, C.; Dietrich, R.: Life Cycle Assessment gentechnisch veränderter Produkte als Basis für eine umfassende Beurteilung möglicher Umweltauswirkungen. Monographien, Bd. 111. Umweltbundesamt, Wien. S. 253.

UNDERWOOD, A.J. & CHAPMAN, M.G. (2003); Power, precaution, Type II error and sampling design in assessment of environmental impacts. Journal of Experimental Marine Biology and Ecology 296, 49–70.

WBGU (Wissenschaftlicher Beirat der Bundesregierung, Globale Umweltveränderungen) (1998): Welt im Wandel. Strategien zur Bewältigung globaler Umweltrisiken. Jahresbericht 1998.

6 ANNEXES

Annex 1: List of participants at 1st Workshop, 16.11.2007

List of participants at the Workshop "Implementation of the Precautionary Principle in GMO Policy" 16.11.2007, Umweltbundesamt, Vienna	
Participant	Country/Institution
Thomas Jakl	AT/Federal Ministry of Agriculture, Forestry, Environment and Water Management
Claudia Paoletti	IT/EFSA
Darja Stanic	SLO/Ministry of the Environment
Joel Tickner	USA/University of Massachusetts/Lowell
Les Levidow	UK/Open University
Angelika Hilbeck	CH/ETH Zürich, EcoStrat
David Quist	NOR/GenOK
Alan Raybould	UK/Syngenta
Anamarija Slabe	SLO/European Environment Bureau & Institute for Sustainable Development
Helge Torgersen	AT/Austrian Academy of Sciences
Helmut Gaugitsch	AT/Umweltbundesamt (Environment Agency Austria)
Andreas Heissenberger	AT/Umweltbundesamt (Environment Agency Austria)
Michael Eckerstorfer	AT/Umweltbundesamt (Environment Agency Austria)

Annex 2: Input paper distributed in preparation of 1st Workshop

Discussion input paper **Vienna, 9.11.2007**

Implementation of the Precautionary Principle in GMO Policy

The following paper gives an overview on the current situation of implementation of the Precautionary Principle in the regulatory framework for GMOs with specific regard to the situation in the EU. It summarises recent activities which have an impact on the discussions on further implementation steps primarily within the European Union. Furthermore international developments and discussions relevant for the debate are reviewed.

The paper additionally outlines the aim of the Workshop which will be held in Vienna at the 16th November 2007 and puts forward a number of guiding questions which are going to be discussed at the Workshop.

Introduction to current implementation of the Precautionary Principle in GMO regulation

The Precautionary Principle is an important element in various international, European and national biosafety regulations. At the European level the Precautionary Principle is of importance for regulations concerning deliberate release and placing on the market of GMOs as well as for regulations in other related fields, e.g. safety of chemicals and food-safety. Regarding GMOs the Precautionary Principle is one of the guiding principles of the European Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and the Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, which implements the Cartagena Protocol on Biosafety into the EU legal framework[2].

The Implementation of Directive 2001/18/EC into national law led to national biosafety frameworks in EU Member States, some of them embracing the Precautionary Principle.

At the international level the Precautionary Principle is one of the guiding principles for the Cartagena Protocol on Biosafety (CPB), one of the most important international agreements concerning GMOs. Like in other pieces of international agreements the application of the Precautionary Principle in the Cartagena Protocol on Biosafety is based upon Principle 15 of the Rio Declaration on Environment and Development (1992).

In accordance with recognition of the Precautionary Principle in a number of international agreements the Precautionary Principle is incorporated into many different pieces of national environmental regulations in Europe. The European Commission guided the implementation of the Precautionary Principle into European law with the "Communication from the Commission on the precautionary principle"[3] in the year 2000.

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[2] Regulation (EC) 1946/2003 of the European Parliament and the Council, Recital 2 and Art. 1 (Objectives) and Recital 22 (implementation).

[3] Commission of the European Communities: Communication from the Commission on the precautionary principle, COM (2000) 1, Brussels.

However based on current experience the practical implementation of the Precautionary Principle in GMO regulation is not a straightforward matter. A number of open questions and deficiencies in implementation of the Precautionary Principle are apparent at the EU-level as well as at the national and international levels. The difficulties in implementing the Precautionary Principle have been discussed during the Austrian EU-Presidency in the year 2006 at an international conference held in Vienna in April 2006. The results of this conference were discussed at the EU Environment Council in its meeting in June 2006 and the role of the Precautionary Principle was stressed in conclusions by the Presidency which were supported by many Member States.

The Role of Precaution in GMO Policy – Results from the Vienna conference, April 2006

On 18 and 19 April, in Vienna, more than 140 international experts discussed for the first time the importance of the precautionary principle in the assessment of genetically modified organisms. The conference was set up by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and the Federal Ministry of Health and Women. The Austrian Environment Agency was responsible for organising the EU Presidency conference. A panel of speakers from the European Commission, the EFSA GMO panel, national competent authorities, scientific community and other stakeholders (industry and NGOs) were addressing various aspects of the role of the Precautionary Principle in GMO regulation.

The conference offered participants the opportunity to discuss topical and controversial aspects of the legal, scientific and practical regulation of GMOs in the EU. The various international interpretations of the Precautionary Principle in the Risk Assessment of GMOs (e.g. in the context of the ongoing dispute at WTO level) were a major theme. The proceedings have been published.[4]

As part of a Presidency paper submitted to the EU Member States in preparation of the Council of Ministers for the Environment in June 2006 the results of the conference were summarised as follows:

- A broad consensus exists on recognition of the precautionary principle as an important principle in the European legislative framework for GMOs. It is seen as a useful means of achieving the required protection goals, even if there is still scientific uncertainty about the actual long-term effects of GMOs. In terms of its concrete application, however, further national and EU-wide discussion is needed if a better common understanding of how the precautionary principle should be implemented is to be achieved.
- The concrete application of the precautionary principle has an important role to play in relation to unresolved scientific questions concerning the risk assessment of GMOs. In the face of the criticism levelled at the EFSA and the EFSA's GMO panel, for instance, an improved, harmonised and generally comprehensible risk-assessment procedure should form the basis for a reliable system of GMO regulation both nationally and across the EU. The standard should be an unambiguous scientific data base, compiled using appropriate, robust methods, and not argument based on assumptions.

[4] BMGFJ (2006): The Role of Precaution in GMO Policy (Band 6-06), http://www.bmgfj.gv.at/cms/site/bestelliste.htm?channel=CH0295

- It was also emphasised that the precautionary principle can serve as an engine of scientific innovation. This relates to the scientific bases for risk assessment, but goes beyond that framework. With regard particularly to the desired broader application of the precautionary principle, this relates to the wide-ranging context in which decisions on the application of GMOs are taken. Here, the role of the social and economic sciences is as important as that of the natural sciences.
- There was a general demand for transparent implementation involving the stakeholders concerned, in order to ensure that decisions on GMOs were transparent, acceptable and proportionate. Along with the risk-assessment mechanism itself the communication of that process must also be improved so that the required principle of appropriate public participation can be satisfied. Here, progress must be achieved through dialogue between the European Commission, the European Food Safety Authority and the EU Member States.

Further developments at the EU-level with respect to implementation of the Precautionary Principle in GMO authorisation

The European Commission issued a statement in April 2006 on steps to be taken with regard to improvements in risk assessment practices and the scientific consistency and transparency of decision-making for authorisation procedures for GMOs[5]. This approach by the European Commission among others specifically included following actions:

- increase cooperation of EFSA and national scientific bodies to resolve diverging scientific opinions with Member States and to better address scientific comments and objections, and
- specify adequate guidance to address potential long-term effects and biodiversity issues more explicitly.

As stated in conclusions of the June 2006 Environment Council by the Austrian Presidency the EU Member States welcomed and supported the measures proposed by the European commission, which were aimed at improving the scientific consistency and transparency for decisions on GMOs by strengthening the liaison between the involved parties and in particular between EFSA and national scientific bodies.

In addition many delegations stressed during the discussions at the Environment Council that in particular further steps to improve the implementation of the Precautionary Principle in the framework of regulations for GMOs should be taken, e.g. by further implementation of the Precautionary Principle in the procedures related to authorisations and risk assessment of GMOs[6].

Due to an initiative of Italy the Environment Council on 30th October 2007 discussed the effects of the approach of the European Commission in the light of the events that have occurred since June 2006 and with a view to the opinions on notifications that have been issued by the EFSA in the meantime.

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[5] EC (2006), http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/498

[6] Council of the European Union (2006): Results of the 2740th Council Meeting, 10876/1/06 REV 1; http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/envir/90281.pdf

The Italian initiative stated that as regards the use of the Precautionary Principle the conflicting issues between the European Commission and the Member States were still unresolved, despite the commitments agreed on by Member States and shared by the European Commission in 2006.

A number of Member States supported the Italian initiative to strengthen the reform process with regard to Risk Assessment procedures for GMOs, e.g. by requiring high quality scientific data relevant to the national and regional conditions to conduct assessments. Further efforts to support the practical implementation of the Precautionary Principle and to increase transparency of decisions were requested.

This shows that further concrete efforts in line with the proposed actions need to be taken in the EU to address the identified problems:

- A need to pinpoint the underlying deficiencies in implementation of the Precautionary Principle in the framework of GMO regulation,
- The need to suggest concrete improvements in implementation of precautionary approaches in Risk Assessment and Management according to a common understanding,
- The necessity to harmonise the approaches of the European Commission, EFSA and EU Member States to implement the Precautionary Principle,
- to use experiences with application of the Precautionary Principle in related regulatory fields to inform any further implementation steps of the Precautionary Principle in GMO regulation as appropriate.

International constraints for implementation of the Precautionary Principle in European GMO regulation

As mentioned the Precautionary Principle is a guiding principle in a number of Multilateral Environment Agreements (MEAs), the Cartagena Protocol on Biosafety being the most prominent of these a with regard to GMO regulation. But the placing on the market of GMOs is also subject to Multilateral Trade Agreements (MTAs), like the WTO agreement. The agreed strategy is that both sets of international rules should be mutually supportive.

The current situation however raises some questions concerning the mutual supportiveness. Specifically the recent decision taken in the “EC: Biotech” case by a WTO Panel according to WTO dispute settlement procedures shows that different approaches towards the use of the Precautionary Principle seems to be taken in MTAs vs. MEAs. Additionally MTAs and MEAs are not necessarily shared by the same range of parties. The effects were seen in the outcome of the “EC: Biotech” case, as the Precautionary Principle was not agreed to be customary international law, that needs to be taken into account with regard to WTO decisions.

According to the ruling the precautionary approach with regard to GMOs at WTO is limited to measures consistent with the WTO framework itself.

Therefore additional initiatives for implementation of the Precautionary Principle at an international level are needed to ensure a consistent application of the European and international regulatory frameworks for GMOs.

Aims targeted in the Workshop

- Assessment of current implementation of the Precautionary Principle in GMO Policy, specifically with a view to the EU level (EC and MS).
- Identification and characterisation of deficits in implementation of the Precautionary Principle (EU-level, international level).
- Input to the identification of key issues for a stakeholder survey concerning the Precautionary Principle in GMO policy and input to definition of target group for the subsequent stakeholder survey.

Key questions

The following set of questions was drafted as a framework to structure the discussions on the topic at the forthcoming workshop and with a view to frame possible topics for the planned stakeholder survey, which is a subsequent activity in the project.

However the list of questions is not meant to be comprehensive and was not drafted to discourage discussions on further topics, which are considered relevant at the Workshop. Not all listed questions will necessarily be discussed at length at the Workshop.

A: Implementation of the Precautionary Principle in environmental regulation at EU-Level

1. Progress made since publication of the EC Communication on the Precautionary Principle
   - Specific progress of implementation in GMO policy?
   - Steps for implementation in comparable regulatory fields (Chemicals, Food Safety, …)?
   - Which authorities/actors involved in discussion?
   - Which additional stakeholders addressed the issue? Which effect?

2. Differences of approaches to implementation of the Precautionary Principle in GMO Policy at the EU-Level?
   - What are the key differences in approaches at EU-level? (Specifically EU institutions vs. MS?)
   - Is there a common understanding at different EU-Institutions? (Specifically EU institutions vs. MS?)
   - What are the obstacles to a common understanding at EU-Level?

3. Deficiencies in current implementation of the Precautionary Principle in GMO Policy at the EU-Level
   - What are the key deficiencies with regard to operationalising the Precautionary Principle at the EU-level? (Specifically EU institutions vs. MS?)
   - What are the obstacles to addressing the deficiencies and further specific implementation of the Precautionary Principle at EU-Level?
   - Which differences are apparent to the level of implementation of the Precautionary Principle in different regulatory fields?

B: International framework for the Precautionary Principle in GMO Policy

1. Which policy fora are relevant for the implementation of the Precautionary Principle at the international level? What are the obstacles to a common understanding towards the Precautionary Principle at the international level?
   - The Precautionary Principle in the framework of the Cartagena Protocol? Applicability?
   - Implementation of the Precautionary Principle on in trade related fora? (WTO, ... ?)
   - Which position is the EU taking on further implementation of the Precautionary Principle at the international level?
   - Concepts for shaping an applicable approach to implementation of the Precautionary Principle at the international level?

C: Implementation of Precautionary Principle in GMO Risk Assessment

1. Is there a common understanding of the Precautionary Principle within the Risk Assessment (RA) framework?
   - Applicability of the Precautionary Principle in RA vs. Risk Management?
   - Is current guidance on Risk Assessment reflecting the Precautionary Principle? (Guidance on necessary scientific data, methodologies?)
   - How should insufficiencies of scientific data and uncertainty be addressed with a view to implementation of the Precautionary Principle?
   - What are the different approaches in dealing with precautionary issues at EU-level, national level, notifier level?
2. The Precautionary Principle as an issue of scientific research
   - Perspectives for Precautionary Science concerning “new technologies”?
   - What research projects are addressing the Precautionary Principle with regard to GMOS? (other comparable regulatory fields?)
   - How is the diversity of scientific opinions being addressed?

D: Challenges in communication on improvements on implementation of the Precautionary Principle

1. Target groups to be addressed for questions regarding implementation of the Precautionary Principle
   - EU-level? National level?
   - How are issues related to the Precautionary Principle addressed in different policy debates?

Which stakeholders are not addressed in current discussions?

Annex 3: Summary record of discussions at the 1st Workshop

Summary record of the discussions at the expert workshop "Implementation of the Precautionary Principle in GMO Policy" (Vienna, November 16th 2007)

Vienna, January 2008

The discussions at the workshop progressed along the lines laid out by the prepared key questions supplied to the participants. A number of general issues were raised by workshop participants and discussed during the workshop.

The following text summarizes the discussion and includes conclusions in the summaries of the respective chapters.

1 Summary of discussions on general issues concerning the application of the Precautionary Principle in GMO policy

The following general issues were identified and discussed during the workshop. For some issues conclusions were suggested and are included in the summary:

1.1 Strategy of implementation of the Precautionary Principle:

Should the Precautionary Principle be viewed as a way of guidance for the (individual) assessment of individual GMOs – as means to get to specific decisions, or as a political principle for decision making – as the framework for decisions in general?

Both ways to implement the Precautionary Principle are possible and should be pursued. The current regulatory experience shows that the Precautionary Principle is rarely invoked as sole rationale for specific decisions.

1.2 Way of further implementation of the Precautionary Principle:

Two strategies to implementation of the Precautionary Principle were discussed:

- a top-down approach; i.e. by the definition of a clear policy, which is based upon further interpretation of the Precautionary Principle on an international or EU level, and
- a bottom-up approach; i.e. by developing a broader, multi-disciplinary scientific base for risk assessment and a standardization of this approach.

Since the mentioned options do not exclude each other, both should be pursued in a mutually supportive way.

1.3 Definition and wording of the Precautionary Principle:

From the experience with other emerging technologies like nanotechnology it is apparent that in certain fields precautionary approaches are discussed and implemented, while avoiding the term "Precautionary Principle".

Therefore terminology and further definition of the Precautionary Principle are important issues. The workshop participants discussed whether using a different term as "Precautionary Principle" could foster the international recognition of the substance of the principle. However participants did not arrive at a conclusion concerning this question.

As an example for initiatives to better define the Precautionary Principle the Lowell Statement on Science and the Precautionary Principle (2001) was mentioned[7].

1.4 General considerations for the debate:

In connection to the preceding issue the general need to be very specific with the terms and concepts used in discussions concerning the Precautionary Principle was highlighted.

This applies to the specific concept of the Precautionary Principle, as well as to terms like "progress" and "deficiency" in connection with the implementation of the Precautionary Principle.

It was stated that adequate transparency and specificity using these terms is a prerequisite for any meaningful discussion on the subject.

1.5 Aim of further developments of the Precautionary Principle:

It was discussed whether trying to achieve a common understanding of the Precautionary Principle at a specific political level is a feasible target and a prerequisite for any further implementation steps.

It was generally doubted that a common understanding on the relevant political levels (e.g. international or EU level) will be possible considering the divergent interests of stakeholders and countries. In case these differences cannot be overcome a different strategy for implementation of the Precautionary Principle is needed.

2 Discussion of key questions

Discussion issue A: Implementation of the Precautionary Principle in environmental regulation at EU-Level

1) Progress made since publication of the EC Communication on the Precautionary Principle?

Participants felt that it is necessary to indicate what is regarded as "progress" in the context of the discussion.

Concerning the EU level it was observed that the EC Communication on the Precautionary Principle follows the approach taken in the Codex Alimentarius and SPS documents with regard to GMO assessment. Evaluating the EC policy from the year 2000 onwards, it appeared that the EC was reluctant to proactively engage in discussions on the general approach as laid down in the document.

[7] Lowell Statement on Science and the Precautionary Principle. Available from: http://www.sustainableproduction.org//precaution/stat.html (as of January 2008).

Recently the EC appears to be more open to discuss the framework for application of the Precautionary Principle with other European stakeholders. This change can be regarded as progress and may lead to opportunities for further developments. It was also mentioned that respective discussions must take into account the different views on the application of the Precautionary Principle that exist in different Directorates General of the EU (e.g. DG Environment vs. DG Trade).

Concerning the practical application of the Precautionary Principle the EC recognizes that different scientific understandings and concepts prevail in different Member States and institutions. It can be observed that the EC shows increased readiness to address the implications of this situation.

It can be noted that awareness and recognition of the Precautionary Principle at the EU-level has increased during the last years. However, no common strategy towards application of the Precautionary Principle is apparent in the EU Member States and within the European Commission (EC). Thus without additional initiatives it is not likely that the official strategy as laid down in the EC Communication of 2000 will be revisited and adapted.

The different positions of EU institutions concerning the Precautionary Principle should be carefully analysed to devise a strategy for further implementation of the Precautionary Principle.

Concerning the international level it was observed that the EC is arguing in favour of precautionary language in Multilateral Trade Agreements (MTAs) referring to approaches in Multilateral Environment Agreements (MEAs), e.g. the Cartagena Protocol on Biosafety. The EC furthermore supported arguments of Member States put forward in defence of precautionary measures with regard to GMOs in the WTO “EC: Biotech” case.

Workshop participants stated that in this context certain drawbacks of the WTO/SPS approach to the application of the Precautionary Principle for GMO assessment need to be addressed, e.g. the implicit requirement to put forward a risk assessment to demonstrate that the scientific information available is insufficient to prepare a proper risk assessment.

Discussions on the “precautionary” character of the WTO/SPS agreement shall take into account that the application of technical caution in risk assessment of GMOs cannot be equated with the application of the Precautionary Principle.

It appears that the EU is more prepared to promote a discussion concerning the further implementation of the Precautionary Principle with regard to international GMO policy in the future. This can be regarded as a progress. With a view to the outcome of the WTO “EC: Biotech” case a need for initiatives for a better implementation of the Precautionary Principle, specifically for the WTO forum, was identified.

2) Differences of approaches to implementation of the Precautionary Principle in GMO Policy at the EU-Level?

Major differences in positions towards the Precautionary Principle in different EU institutions and Member States were identified. The opinions of different Member States and EU-institutions on GMO applications differ on issues that

are crucial for the risk assessment of GMOs. It was noted that these differences translate into different conclusions taken by involved Member States. Individual Member States generally were upholding their positions, limiting chances that the differences in positions will be resolved automatically over time.

Furthermore similar differences are also seen within Member States institutions and between institutions at the EU-level, adding further complexity.

These differences are – though not exclusively – due to different policies towards the application of the Precautionary Principle to the regulation of GMOs at the EU level.

Specifically differences were identified concerning the

- sufficiency of scientific information necessary for risk assessment of GMOs
- scientific uncertainties identified
- conclusions drawn from the available scientific information
- level of acceptable risk concerning applications of GMOs
- implementation of the Precautionary Principle as a risk assessment or as a risk management issue

The different positions are apparently shaped by different interests that drive decisions. For agricultural applications of GMOs in Europe many different interests have to be dealt with. Taking into account the diversity between Member States in the EU this is no surprise. Therefore the possibilities for the development of a common understanding in the near future are quite limited.

However it was concluded that the Precautionary Principle is a necessary tool or the basis in all steps of risk assessment. Nevertheless, there is a strong link to and an interaction with risk management issues.

There are limits for these issues to be resolved by science and scientific advancements. The identified differences are the expression of different national policies and need to be addressed at a political level. As a further step the transparency of decisions on GM applications could be improved by defining their basis (e.g. considerations concerning scope of assessment – which issues were addressed or not addressed and to what extent issues were assessed, as well as considerations with regard to uncertainties).

In the process of decision making and risk management it is also necessary to communicate uncertainties of the scientific assessment and to consider in a transparent way possible alternatives.

3) Deficiencies in current implementation of the Precautionary Principle in GMO Policy at the EU-Level

In line with one of the general issues mentioned above it was noted that any discussion of “deficiencies” should be accompanied by stating why the issue is recognised as deficiency. Additionally it was noted that the regulation of GMOs is a very specific matter compared with other regulatory issues and thus not ideally suited to draw conclusions with regard to implementation of the Precautionary Principle in a general way.

The following relevant deficiencies in the implementation of the Precautionary Principle with regard to GMO regulation were discussed:

- The concepts for a risk assessment framework for GMOs were devised following approaches taken with different types of applications (e.g. technical construction and building among others). The usefulness of such concepts with regard to GMO regulation was questioned.
- Specifically the system comprises no concept for alternatives' assessment or an assessment of the necessity for the applications of a certain GMOs during the authorisation procedure.
- The available guidance for risk assessments is not clear and comprehensive enough. Therefore the notifier predetermines which assessment is made and what endpoints are considered for certain important issues.
- The burden of proof for conclusions to be taken needs to be placed on actors in a fair and balanced way. The EC Communication on the Precautionary Principle (2000) laid the responsibility for assessments on the notifier. The notifier therefore has the obligation to present scientific evidence in a comprehensive assessment of product safety. Again this translates to a situation that the notifier is getting very influential in shaping the scope of the assessment and in determining which parameters are assessed.
- The concept for a risk assessment framework for GMOs in the EU was devised to achieve decisions which are valid in the whole community. This favours implementations of the Precautionary Principle based on a common interpretation and understanding in the EU. In this political context the possibilities for consideration of specific regional and political conditions in the implementation of the Precautionary Principle are limited.

Discussion issue B: International framework for the Precautionary Principle in GMO Policy

1) Which policy fora are relevant for the implementation of the Precautionary Principle at the international level? What are the obstacles to a common understanding towards the Precautionary Principle at the international level?

At an international level the differences in MEAs and MTAs were stressed with regard to the level of implementation of the Precautionary Principle. In general it appears that MEAs are regarded to encourage precautionary measures, and MTAs are opposing a broader application of the Precautionary Principle. The analysis of the recent decision of the WTO panel in the "EC: Biotech" case was regarded as supporting this view.

Countries supporting the application of WTO rules for emerging technologies and specifically the concept of scientific risk assessment followed in WTO agreements are generally critical to further implementation of the Precautionary Principle. This is specifically the case for the approaches in GMO regulation taken by these countries.

However this relationship is not without exceptions. For example the US, which are specifically critical to an application of the Precautionary Principle in GMO regulation, are more open to precautionary policies for other emerging technologies like nanotechnology, while avoiding the term "Precautionary Principle".

As a possible reason the pending economic consequences of liability were identified.

However experience from liability judgments in the US in chemical policy shows that the applicability of liability does not automatically guarantee that precautionary action is taken. This is specifically the case, when any liability is restricted to causal relationships, which are scientifically understood and can be easily addressed by established scientific methodology.

Governments, which are not supporting further application of the Precautionary Principle tend to follow a similar approach to draft regulations that frame the scientific risk assessment for technologies like GM.

The following obstacles to further implementation of the Precautionary Principle at the international level were identified:

- MEAs and MTAs are both relevant for GMO regulation at an international level. However their impact on specific decisions taken by Parties is different, since MTAs like the WTO may imply economic consequences for non-compliance according to deliberations by an own arbitration mechanism.
- To build a coherent framework these MEAs and MTAs are intended to be mutually supportive. In reality this is not the case.
- The scope for risk assessment and they way scientific evidence is interpreted is highly relevant at the international level e.g. for differences on the regulation of technologies like nanotechnology and GM. Therefore risk assessments in different countries for similar products might arrive at different conclusions. Among other reasons this can be caused by different ways of implementation of the Precautionary Principle in different countries.
- The name but not necessarily the concept of the Precautionary Principle is being avoided in some countries, like the US. Therefore a change of terminology may foster implementation of the concept of the Precautionary Principle.

Discourses at the EU- and international level are not fully analogous and adequate suggestions have to be devised which are specific for each level of discussion.

Discussion issue C: Implementation of Precautionary Principle in GMO Risk Assessment

1) Is there a common understanding of the Precautionary Principle within the Risk Assessment (RA) framework?

The following results can be summarised from the discussions at the workshop:

- The Precautionary Principle was identified as an important tool for both risk assessment and risk management.
- With regard to risk assessment the Precautionary Principle needs to be implemented at all steps of the process.
  The science applied in risk assessment needs to be open about uncertainties and scientific ignorance and explicit about the limitations of the models which are applied.

- With regard to data requirements the following suggestion was discussed. Well tested hypotheses which do not require further testing for conclusions to be drawn (making up a specific category of “assumptions”) need to be differentiated from “assertions”, which are not backed by data and need to be further scrutinised.
- The requirements for scientific data for risk assessment have to be transparent. However these requirements for data need to be based on a reasonable level of safety.
  Participants suggested in addition that the availability of alternatives could be used to gauge the power of evidence required for concluding an assessment.
- The current controversy in the EU on potential precautionary decisions on GM applications which are supported by a positive risk assessment opinion from EFSA highlights the interconnectedness of risk-assessment and risk management issues in GMO regulation.

Generally the responsibilities of decision makers at the political level should not be transferred to experts and expert institutions.

2) The Precautionary Principle as an issue of scientific research

The application of the Precautionary Principle should strengthen the multidisciplinary approach to identify issues which are relevant for decision-making. However participants were sceptical whether the Precautionary Principle can act as a major driving force for scientific research.

Participants also noted that the timeframes of relevant interacting processes are different and not compatible:

- day-to-day interventions at policy making,
- average duration of funding-cycles for science,
- duration of product life cycles relevant for the assessment of technology effects.

Recommendations for scientific funding bodies should further address questions relevant to application of the Precautionary Principle. Relevant research needs have to be submitted by Member States and institutions involved in risk assessment and management.

The implementation of the Precautionary Principle is not limited to public regulation and publicly funded research. As an example the application of the Precautionary Principle by private companies on directing their research and development processes was mentioned.

Discussion issue D: Challenges in communication on improvements on implementation of the Precautionary Principle

1) Target groups to be addressed for questions regarding implementation of the Precautionary Principle

A big challenge for the planned survey is to address in an adequate way all the various stakeholders which are involved in the implementation of the Precautionary Principle. Participants noted that the instrument of a common questionnaire for all stakeholders should be reviewed critically. Other tools like stakeholder interviews should also be considered.

- The survey should be targeted specifically to the different target groups. Different sets of questions for different subsets of participants (target groups) could be an option.
- For devising questions for the survey the list of key questions should be revisited to ensure that relevant information can be easily retrieved from an analysis of the answers.
- It was recognised by participants that a broadly distributed questionnaire will be an instrument to raise awareness of recipients on the topic. The contents of a questionnaire should be drafted in a way to support this additional task.
- According to suggestions from the participants the overall purpose of the survey could be achieved by a combination of methods.

Annex 4: List of participants in stakeholder interviews

List of participants in Stakeholder Interviews on the Implementation of the Precautionary Principle in GMO Policy September – October 2008	
Participant	**Country/Institution**
Harry Kuiper	NL/EFSA GMO Panel
Jeremy Sweet	UK/EFSA GMO Panel
Inge Anneborg Myhr	NOR/University of Tromsö, GenOK
Gabor Lövei	DK/University of Aarhus
Brian Wynne	UK/University of Lancaster
Daniel Ammann	CH/Schweizerische Arbeitsgruppe Gentechnologie (SAG)
Christopher Pollock	UK/ACRE
Les Firbank	UK/IGER/North Wyke
Ulrike Felt	AT/University of Vienna
Piet van der Meer	BE/Horizons sprl
Sarah Hugo	UK/Central Science Laboratory (CSL)
Beatrix Tappeser	DE/Bundesamt für Naturschutz (BfN)
Hans Bergmans	NL/RIVM
Bruno Ferreira	FR/Office of the Prime Minister
Katalin Rodics	HU/Ministry of the Environment
Willy De Greef	BE/EuropaBio

Annex 5: Questionnaire for stakeholder interviews

Preparatory questions for expert interviews on the implementation of the precautionary principle in GMO policy

In response to policy developments at the international level and to discussions on the use of the precautionary principle in the EU the European Commission in 2000 published a Communication on the precautionary principle (COM (2000)1). The Communication of the EC is a general document and thus also an important guidance document for the application of the precautionary principle in GMO regulation. The following questions address some specific issues contained in the Communication, which are relevant for GMO regulation.

Regarding the goals of the Communication

A) The aim of Communication of the EC on the use of the precautionary principle is to describe for all parties (Eur. Council, Eur. Parliament, Member States) the framework of application of the precautionary principle for actions taken by the Eur. Commission and to provide input for discussion.

1. Is the framework as outlined in the Communication suitable and sufficient for GMO regulation?
2. Which amendments would be needed with regard to GMO regulation?
3. Do you think that the relevant authorities and institutions are following the approach outlined in the Communication?
4. In your opinion did the Communication stimulate discussion on application of the precautionary principle? Which specific needs for further discussion prevail?

B) The Communication should establish a common understanding of application of the precautionary principle and its place in decision making and establish guidelines for application.

Currently such a common understanding seems to be lacking with regard to application of the precautionary principle in GMO regulation.

1. If the Communication did not succeed to establish a common understanding, why did it fail?
2. Which specific aspects of GMO regulation are not compatible with the approach of the Communication?
3. What initiatives are necessary in response to the current situation?
4. Is the concept of the precautionary principle reflected in the Communication consistent with policy changes concerning GMO regulation?

Regarding the application of the precautionary principle

C) The precautionary principle can be implemented with respect to various elements of the decision making process in GMO regulation (Risk assessment, risk management, risk communication). The Communication mainly assigns a role for the precautionary principle in risk management.
A broader interpretation of the precautionary principle (e.g. according to PEG results) calls for the consideration of the precautionary principle in risk assessment to shape the risk assessment framework and identify uncertainty and ignorance about potential risks.

1. How can the interconnectedness of risk assessment and risk management in GMO regulation be addressed?
2. How need unsolved controversies regarding risk assessment of GMOs be addressed?

D) The Communication calls for an objective scientific evaluation of risks as complete as possible preceding the potential application of the precautionary principle.

1. Is this principle applied to GMO regulation in a satisfying way?
2. Are the degrees of scientific uncertainties of the analysis identified as proposed?
3. Are uncertainties of the assessment of GMOs accounted by factors of prudence as exemplified in the Communication for chemical substances in the Communication (p.15)?
4. Did the above mentioned concept outlined in the Communication foster the development of science necessary for the assessment of GMOs?
5. Could guidance for a broader consideration of the precautionary principle support the development of relevant science for the risk assessment?

E) The Communication states that the precautionary principle may be triggered when potentially dangerous effects (e.g. of application of GMOs) are identified and the risks cannot be determined with sufficient scientific certainty.

1. Is this concept for triggering the precautionary principle suitable with regard to GMO regulation?
2. Could reasonable suspicion based on scientific findings and undesirable effects be accommodated by an amended concept?
3. Can inadequate evidence of safety also trigger the application of the precautionary principle?

F) Regarding measures to be taken the Communication calls to assess the consequences of inaction and action based on an examination of costs and benefits and observing other general principles (proportionality, non-discrimination, consistency, reexamination according scientific developments).

1. Is such an approach feasible with regard to GMO applications?
2. How could the examination of alternative solutions be accommodated?

G) The Communication indicates that according to the precautionary principle the burden of proof (responsibility of producing scientific evidence) is shifted from demonstrating risk to demonstrating safety and thus on the applicants of technology.

1. In your opinion is this concept working out for GMO regulation? How can the question of the burden of evidence for identifying uncertainties which trigger the precautionary principle be accommodated?

H) The Communication refers to the experience with application of the precautionary principle in various fields of environmental regulation (measures for protecting the ozone layer or concerning climate change).

1. How can experience from other fields inform the implementation of the precautionary principle in GMO regulation?

<u>Regarding international implications</u>

I) Concerning the international framework of implementation of the precautionary principle the approach of the Communication is considering that the precautionary principle has been progressively consolidated in international law

1. Must this concept be updated with a view to the recent WTO decisions?
2. Which initiatives need to be taken to foster the international recognition of the precautionary principle as an important pillar of the EU GMO regulations?
3. How can the apparent differences in concepts for application of the precautionary principle in Multilateral Trade Agreements, Multilateral Environment Agreements and the EU guidelines be addressed?

Annex 6: List of participants at 2nd Workshop, 20.11.2008

List of participants at the Workshop "Implementation of the Precautionary Principle in GMO Policy" 20.11.2008, Ministry of Agriculture, Forestry, Environment and Water Management, Vienna

Participant	Country/Institution
Thomas Jakl	AT/Federal Ministry of Agriculture, Forestry, Environment and Water Management
Michael Wittmann	AT/Federal Ministry of Agriculture, Forestry, Environment and Water Management
Michel Haas	AT/Federal Ministry of Health, Family and Youth
Gabor Lövei	DK/University of Aarhus
Les Levidow	UK/Open University
David Gee	DK/European Environment Agency (EEA)
Ulrike Felt	AT/University of Vienna
David Quist	NOR/University of Tromsö, GenOK
Hans Bergmans	NL/RIVM
Andreas Krug	DE/Bundesamt für Naturschutz (BfN)
Hans Hosbach	CH/Bundesamt für Umwelt (BAFU)
Helmut Gaugitsch	AT/Umweltbundesamt (Environment Agency Austria)
Michael Eckerstorfer	AT/Umweltbundesamt (Environment Agency Austria)

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The report at hand addresses the application of the precautionary principle in GMO policy at EU level. Wherever possible, relevant experience in related regulatory fields in the EU is considered. Further actions are recommended to implement a comprehensive precautionary approach in EU GMO regulation. A review of the current risk assessment and risk management processes, by way of case studies, is suggested and specific guidance for applying the precautionary principle in GMO policy should be elaborated to complement the relevant Communication of the European Commission, published in 2000. Based on a critical analysis of the current system, measures for implementing a broader precautionary approach are suggested, including regulatory changes to strengthen the Member States' responsibilities for the protection of regional environments.

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