Genetically Modified Organisms and Precaution in Norway

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The precautionary principle has, together with requirements concerning sustainable development and usefulness to the society, been core elements in the regulation of deliberate release of genetically modified organisms (hereafter GMOs) in Norway. The Norwegian legislation on GMOs was adopted in 1993 (the Act relating to the Production and Use of Genetically Modified Organisms, no. 38 of 1993, hereafter the GMO Act), and has essentially remained unchanged since it was adopted. However, the link established in 1992 between Norway and the European Union (hereafter the EU) through the Agreement on the European Economic Area (hereafter the EEA Agreement) means that the framework within which the legislation has been applied to a large extent has been dominated by issues concerning the relationship between the criteria set out in the law and legislation adopted by the EU.

Despite the close relationship between Norway and the EU through the EEA Agreement, which inter alia means that Norway is part of the internal market for trade in goods, Norwegian authorities have so far pursued a policy on marketing of GMOs that differs significantly from that of the EU. Given the fact that Norway is depending on the political will of the EU in order to continue its cooperation with the EU through the EEA Agreement, which gives Norway, Iceland and Liechtenstein a unique possibility to participate in political processes within the EU, it is remarkable that Norway has been willing to deviate from the policy of the EU on such a politically important issue as the marketing of GMOs. This indicates the extent to which Norwegian politicians have considered GMOs to be a major political issue.

This article will not address all aspects of GMOs. It will focus on deliberate release of GMOs into the environment. In addition to use of GMOs for agricultural or aquacultural purposes, it will cover use of living GMOs for food and feed. Issues concerning use of GMOs in processed food or feed, contained use of GMOs and transborder movement of GMOs from Norway to other countries will not be specifically addressed.[1]

In the following, we shall first address the international legal framework within which Norwegian authorities are making decisions concerning marketing and labeling of GMOs. Thereafter follows an overview of the status for GMOs in Norway and the framework for decision-making (sections 2-5). The latter part of this article (sections 6-11) will address the way in which the precautionary principle has been and may be applied in individual cases.

1 The international framework for the Norwegian legislation

Norway is party to a number of treaties of relevance to decisions concerning release of GMOs. First, there are environmental treaties, in particular the Cartagena Protocol on Biosafety (2001, hereafter the Cartagena Protocol) and the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (1998, hereafter the Aarhus Convention). While the Cartagena Protocol is primarily of relevance to decisions concerning export of GMOs, it is also of relevance as a justification of domestic policies in view of obligations under international trade law. In particular, the Cartagena Protocol is of relevance to the use of the precautionary principle when making decisions on marketing and labeling of GMOs and when determining the burden of providing information and evidence concerning the impacts of GMOs on human, animal or plant health and the environment.

The Aarhus Convention is primarily of relevance when setting out rules concerning the decision making procedure to be applied when determining whether to allow marketing of GMOs. In particular, the Aarhus Convention is relevant for public access to information on the properties of GMOs and their effects on health and the environment, and for participation in decision-making and access to justice in cases concerning decisions on deliberate release of GMOs.[2] In relation to Norway, the Aarhus Convention has been important for the establishment of separate procedures for impact assessment of GMOs.

Except from the points noted above, the above mentioned treaties have been insignificant for the design and application of the Norwegian legislation on GMOs. Their main role has so far been to justify maintenance of current regulation of GMOs in view of challenges it may face with a view to facilitate international trade and internal marketing of GMOs. Against this background, there will not be any separate analysis of the relationship between the Norwegian regulation of GMOs and the treaties in the following.

Secondly, there are treaties of relevance that aim at reducing trade barriers. This is particularly the case for the following treaties under the Agreement Establishing the World Trade Organization; the General Agreement on Tariffs and Trade (hereafter the GATT), the Agreement on Technical Barriers to Trade (hereafter the TBT Agreement), and the Agreement on the Application of Sanitary and Phytosanitary Measures (hereafter the SPS Agreement). These Agreements set out rules that have the potential to be of great significance to the design and application of measures to prevent negative health and environmental effects from the release of GMOs. Nevertheless, they were not considered when Norwegian authorities designed the basic system for regulation of GMOs. One did not point to any potential problem in relation to the GATT, and the system was designed before the TBT and SPS Agreements were adopted. Moreover, the relationship to the GMO legislation was not considered when Norway ratified the WTO Agreements.[3] Finally, in relation to the application of the legislation in individual cases, issues concerning the relationship to the trade agreements have not been part of the formal justification for the decisions taken, and do not seem to have been any main concern in relation to the design and application of measures to GMOs.[4] Against this background, I do not intend to carry out any independent analysis of the WTO rules in this article.

Thirdly, there are international regimes aiming at international harmonization of the use of measures related to the contained use and deliberate release of GMOs. Such regimes can be found in the form of development of international standards under international institutions, such as under the International Plant Protection Convention (1997), in the form of obligations to base measures on international standards, such as in the SPS Agreement, and in the form of rules setting out a more or less closely defined framework for decision making, such as in the legislation adopted by the EU. As the first two forms of regimes have had limited effect on the design and use of Norwegian regulation, this will not be addressed in the following.

Of the international framework in the area of GMOs, it is thus the legislation of the EU that has had significant impact on Norwegian measures. The EU legislation of primary interest in the context of this article are Directive 90/220/EC on the deliberate release into the environment of genetically modified organisms (hereafter the 90/220 Directive), which has subsequently been replaced by Directive 2001/18/EEC on the deliberate release into the environment of genetically modified organisms (hereafter the 2001/18 Directive). Norway has actively participated in the preparation of the 2001/18 Directive, but this Directive has not yet been included in the EEA Agreement.[5] The 90/220 Directive, which is still the only instrument on GMOs applicable under the EEA Agreement, has in general not been significant for the design of the GMO Act, but it has played an essential role for the way in which the Act has been applied through adoption of regulations and through decisions in individual cases. Moreover, Norwegian participation in the development of Directive 2001/18 and other new secondary legislation on GMOs in the EU has been of importance to the design of Norwegian policy in the area of GMOs. For these reasons, and also because the way in which the 90/220 Directive has been applied in Norway differs from the way in which the Directive has been applied in the EU, this Directive will be an essential part of the analysis to be carried out in the following. Directive 2001/18 will be referred to wherever it may be of relevance.

2 Status for GMOs in Norway

There is some biotechnological research in Norway, and some of this research aims at producing GMOs that may at a later stage be subject to deliberate release. Examples often cited are the production of a genetically modified winter-flowering begonia (“juleglede”), tobacco and aspen (“osp”).[6] However, so far none of this research has resulted in the application for deliberate release of any product based on GMOs, and Norwegian biotechnological industry is in general insignificant.

So far only one application for deliberate release of genetically modified tobacco and three applications for deliberate release of carnation have been approved by Norwegian authorities. Norway is requested to make decisions concerning marketing of all GMOs for which there are applications for marketing within the EU.[7] A number of these applications are under consideration in the Norwegian decision making bodies. Norway has refused marketing of eight GMOs that have been accepted by the EU, namely two

applications for marketing of vaccines, five applications for plants and one application for microorganisms.[8]

In the following, it will be of interest to analyse why Norway has rejected applications for marketing of these products and the role that the precautionary principle has played in this context, in view of the fact that Norway has allowed other GMOs to be marketed. Moreover, the status of the application processes for those GMOs that have not yet been subject to any decision does also need to be addressed in order to identify the role of the precautionary principle for the procedures followed during the application process. But before addressing these issues, we need to take a closer look at the general conceptual and regulatory framework for the decision-making procedure.

3 General conceptual framework

It may be useful to distinguish between three general approaches that are essential to the design of decision-making procedures. One approach, which is generally regarded as the approach to be used unless there are specific and convincing arguments for other approaches, is to take decisions on the basis of cost benefit analyses. Here, the task of decision-makers is to identify relevant costs and benefits of alternative decisions, and to make the decision that gives the highest net benefit. This is generally the approach to be chosen where decision-makers have a broad margin of appreciation.

A second approach, which is most common where decision-makers' margin of appreciation is significantly limited through legislation, is to base the decision on cost effectiveness. Here, the legislator has limited the options available and the factors that can be taken into account when making the decision, and a main task for decision-makers is to design the decision in such a way that costs of the decision are kept to a minimum. There is no clear distinction between decision-making based on cost benefit analyses and on cost effectiveness. Both approaches may be of relevance in the context of a given decision.

A third approach is to base decisions on precaution. Such an approach is of relevance in cases where the available information on the effects of decisions is such that it is not possible to make a decision based on a cost benefit analysis. Such cases occur primarily where there is uncertainty related to the costs of the decision. Hence, there is a fundamental difference between decisions based on a cost benefit analysis and decisions based on a precautionary approach, as a cost benefit approach will per definition not be available in cases where a precautionary approach is called for. Nevertheless, a decision-maker will in many cases be expected to take into account cost effectiveness when designing decisions based on a precautionary approach.[9] Moreover, it can be argued that a cost benefit analysis could be replaced by a proportionality test in cases where the precautionary principle is applicable.[10] In the opinion of this author, it cannot in this context be distinguished between a proportionality test and an approach based on ensuring cost effectiveness.

4 General legislative framework

It can be argued that the environmental clause in Section 110 b of the Norwegian Constitution[11] is a general starting point for the application of the precautionary principle in the Norwegian legal system in the sense that it implicitly presupposes its existence. However, the provision does neither explicitly refer to the principle, nor address issues concerning decision-making in cases of uncertainty. There is thus no reason to emphasize Section 110 b when addressing the use of the precautionary principle in relation to GMOs.

Decisions concerning deliberate release of GMOs in Norway are regulated in Section 10 of the GMO Act (no. 38 of 1993):

"1. Deliberate release of genetically modified organisms may only occur subject to approval by the [Government]. … A product may not be approved for placing on the market until it has been satisfactorily tested in natural environments that will be affected by the intended use. …
2. Deliberate release of genetically modified organisms may only be approved when there is no risk of harmful effects on health or the environment. Moreover, when deciding whether or not to grant the application significant emphasis shall be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.
…
6. Approval is not required for the placing on the market of a product that is approved for placing on the market in another EEA country pursuant to the rules laid down in Annex XX, Entry 25, of the EEA Agreement (Council Directive 90/220/EEC). The authorities responsible under the present Act, however, may still prohibit or limit such placing on the market if in their opinion it involves a risk to health or the environment or if the placing on the market is otherwise in conflict with the purpose of this Act."

Since almost all GMOs for which approval is sought in Norway have been approved for placing on the market in a Member of the EU, Section 10(6) is by far the most important provision in practice. According to Section 1 of the Act, its purpose:

"… is to ensure that the production and use of genetically modified organisms … takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment."

One difference between Section 10(2) and Section 1 is that the latter does not refer to the criterion "benefit to the community". However, it can be asked whether this difference is of any practical importance. An assessment of usefulness to society would necessarily be included in an evaluation of the extent to which a GMO contributes to sustainable development. The main difference is thus whether benefit to the society should be regarded as an individual requirement or whether it should be regarded as part of an overall evaluation of relevant factors.

When analyzing the criteria listed in the legislation, we may distinguish between those criteria that generally can be regarded as part of a cost benefit analysis and those that point in the direction of a precautionary approach. In general, we may place benefit to the society and contribution to sustainable development as part of a benefit cost analysis. The requirement with respect to benefit to the society means that there must be a net benefit to the society from the release of the GMOs. The requirement that release of GMOs contribute to sustainable development means that there must be net benefits both to present and future generations, and that release of GMOs must contribute to equitable sharing of benefits between those living today.

On the other hand, the requirement that there be no risk of harmful effects to health or the environment is a criterion that is closely related to a precautionary approach. We should, however, note the difference between cases where an applicant submits the application to Norwegian authorities and where there is a strict requirement concerning risks to health and the environment, cf. Section 10(2), and cases where the applicant submits the application to a country of the EU and where Norwegian authorities have a far broader margin of appreciation when determining whether a certain risk to health or the environment is acceptable, since the authorities simply "may" still prohibit GMOs if they pose a risk to health of the environment, cf. Section 10(6). This difference between the two provisions indicates that one may face situations in which an applicant may argue that discriminatory treatment in violation of Article 11 of the EEA Agreement.[12]

Our focus in the following will be how a precautionary approach is reflected in the decision-making procedures and practice of Norwegian administrative authorities,[13] with a main emphasis on how the issue of health and environmental effects has been addressed. But before addressing these issues, it is of interest to take a closer look at how the Norwegian legislation is linked to EU's decision making system.

5 Norway, the EEA Agreement and the EU

As noted above, for the time being, the Directive in force for Norway under the EEA Agreement is the 90/220 Directive.[14] There are two main issues that need to be solved in the context of updating the EEA Agreement with the new secondary legislation in this area, in particular the 2001/18 Directive, namely the modalities for the decision making procedures, and whether the EFTA States shall be allowed adaptations to the text of the legislation.

As to the first issue, the question is whether a decision made by one party to the EEA Agreement on allowing release of GMOs shall be binding for all parties to the EEA Agreement, or whether there shall be an opening for a separate decision making procedure for each party to the EEA Agreement. Following the logic of the establishment of an internal market, there is little room for accepting that each party to the Agreement shall have the right to maintain separate decision-making procedures for products. However, for some products that are regarded as sensitive due to their potential harmful effects, a need for separate decision making by national authorities has been acknowledged. Such separate decision making can either be carried out in the form of invoking narrow and provisional exceptions under the secondary legislation ("safeguard

measures"), such as in the case of the 90/220 and 2001/18 Directives, or in the form of opening for separate decision making in each country, such as under Directive 98/8/EC concerning the placing of biocidal products on the market.

As the secondary legislation on GMOs has opted for the use of safeguard measures, a question that remains is whether the EU can accept a decision allowing the marketing of a GMO by an EFTA State as binding for the whole of EU. In the case of biocidal products under Directive 98/8/EC, the final decisions are made by the EU, and these final decisions will be binding also for the EFTA States unless they can invoke the safeguard clause.[15] A similar approach has been adopted in relation to other sensitive products, such as medicines. Against this background, it seems unrealistic to expect the EU to accept separate decision-making in the EFTA countries that may be given legal effects for the EU.

This leads us to the second issue, namely the need for adjustments to the text of Directive 2001/18. Under Directive 90/220, the EFTA countries enjoy the following adaptation to Article 16:

"(b) Article 16 shall be replaced by the following:
'1. Where a Contracting Party has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the other Contracting Parties through the EEA Joint Committee of such action and give reasons for its decision.
2. If a Contracting Party so requires, consultations on the appropriateness of the measures taken shall take place in the EEA Joint Committee. Part VII of the Agreement shall apply.'"

Moreover, the EFTA countries have been given an additional opportunity to apply their domestic legislation through inclusion of the following clause:

"(c) The Contracting Parties agree that the Directive only covers aspects relating to the potential risks to humans, plants, animals and the environment. The EFTA States therefore reserve the right to apply their national legislation in this area in relation to other concerns than health and environment, in so far as it is compatible with this Agreement."

Of these two elements, it is the adaptation to Article 16 of the 90/220 Directive (litra (b) above) that is of primary relevance to the precautionary principle. As indicated above, the possibility of refusing release of GMOs on the basis of the criteria "benefit to the society" and "contribution to sustainable development" are primarily part of a cost benefit analysis.

If we compare the wording of the adaptation to Article 16 of the 90/220 Directive with the safeguard clause under Article 23 of the 2001/18 Directive, we can conclude that there are the following main differences:

- Article 23 has detailed and strict conditions for invoking the safeguards clause,[16] while the adaptation text merely requires ”justifiable reasons”.
- Article 23 provides for a detailed procedure with strict deadlines for dealing with cases where a country has made use of the safeguard clause, while the adaptation text merely indicates that “consultations on the appropriateness of the measures taken shall take place in the EEA Joint Committee”, and refers to Part VII of the EEA Agreement which contains procedural rules in Article 113 and indicates a possibility of taking measures to remedy “imbalance” caused by safeguard measures in Article 114.
- Article 23 opens only for provisional exemptions that may be overturned by decisions by EU institutions, while the adaptation text indicates that the safeguard measure will be permanent unless it is voluntarily given up by the country that adopted it.

The above shows that EFTA countries currently enjoy a broad margin of appreciation when determining the extent to which a precautionary approach should be taken in relation to deliberate release of GMOs. The question that is getting increasingly urgent is to what extent EFTA States will have to accept restrictions on this flexibility when including the 2001/18 in the EEA Agreement. According to Article 102 of the EEA Agreement, there is an obligation to:

“… take a decision concerning an amendment of an Annex to this Agreement as closely as possible to the adoption by the Community of the corresponding new Community legislation with a view to permitting a simultaneous application of the latter as well as of the amendments of the Annexes to the Agreement.”

Hence, there is an increasing pressure on the EFTA States to accept the new secondary legislation from the EU concerning GMOs. Moreover, if no such decision is taken within a given time limit, the affected part of the relevant Annex to the EEA Agreement “is regarded as provisionally suspended, subject to a decision to the contrary by the EEA Joint Committee”, cf. Article 102(5). Hence, the EFTA countries risk being excluded from cooperation with the EU on the regulation of GMOs, in particular participation in expert committees if they cannot agree to make the 2001/18 Directive part of the EEA Agreement in the near future. This shows that three alternative outcomes are possible in relation to the 2001/18 Directive: (1) EFTA States may accept to make the Directive part of the EEA Agreement without adaptations, an alternative that to a large extent will block their opportunity to follow a precautionary approach in the future, (2) EFTA States may achieve adaptations to the text of the safeguards clause of the Directive, and thus maintain a certain freedom to pursue a precautionary approach depending on the wording of the adaptation text, or (3) EFTA States may refuse to allow the Directive into the EEA Agreement, and thus face the possible retaliation from the EU that their participation in development of the EU policy in the field of GMOs will be suspended.[17] The outcome of the political process is highly uncertain. However, it can be mentioned that the current Norwegian Government has expressed a willingness to make use of the possibility to refuse to make new EU legislation on the internal market part of the EEA Agreement.[18]

6 Measures to reduce uncertainty

Several measures that aim at or may have the effect of reducing uncertainty have been taken by Norway in the context of GMOs. In the following, I will address four such measures, and discuss some specific issues of particular interest in the context of the precautionary principle. The first measure is the requirement that an environmental and health impact assessment be carried out by the party applying for a permit to release the GMO. A separate Regulation on impact assessments has been adopted in accordance with Section 11 of the GMO Act.[19] According to Section 2-4 of the Regulation, the authorities dealing with the application has full freedom to ask for supplementary information and to put the application on hold until such additional information has been supplemented if they find that the information provided is not sufficient to make a decision. Sections 4-1 to 4-5 contain detailed rules on the content of the impact assessment. The impact assessment procedure gives the authorities a broad margin of appreciation and a broad opportunity to make use of a precautionary approach, in particular by postponing decisions until they have received such information that they deem necessary to determine the extent of risk to the environment or human health. Moreover, it should be noted that the burden of providing the information and carrying out the research needed rests with the applicant. This approach is in line with the "polluter pays principle" and the approach provided for under the Cartagena Protocol, cf. Article 15, but may be at odds with the rules of the WTO which indicate that the burden of demonstrating the need for trade restricting measures rests with the State, cf. for example Article 2(2) of the SPS Agreement. It should also be noted that Norwegian authorities have made extensive use of this opportunity to ask for additional information, and that such requests in many cases in practice resulted in applications being put on hold for an indefinite period of time. Whether this is due to the requests for additional information being too burdensome, or to applicants not being particularly interested in placing their products on the Norwegian market, is hard to determine.[20] Most likely the current situation is due to a combination of the two.

The second measure used to reduce uncertainty is public hearings. According to Section 13 of the GMO Act, all cases concerning deliberate release of GMOs shall be subject to a public hearing. The public shall have access to relevant information and they shall have a real opportunity to present their opinions and comments. In this way, public hearings may serve to generate additional information concerning potential consequences of releasing the GMO, and thus to reduce uncertainty. On the other hand, a public hearing may contribute to discovering new potential effects from releasing the GMO, and thus be a generator for awareness concerning existing uncertainty. Such new awareness may become a basis for precautionary action.

This leads us to a third measure used to reduce uncertainty, namely the establishment of a Biotechnology Advisory Board ("Bioteknologinemnda"). This Board, which is an independent advisory institution appointed by the Government, was established in 1991, and it has subsequently been regulated in Section 26 of the GMO Act. The members of the board serve in their personal capacity, and they represent a broad range of knowledge and interests. They serve as an essential contributor in the public hearing process, partly

through their own input to the hearings, and partly as an "information clearing house" and active participant in the public debate. Their statements are multidisciplinary, in general unanimous, in general focused on pointing out areas in need of further clarification, and in some cases recommending a specific result.[21] Hence, in addition to generating information that may reduce uncertainty, the Board also serves as an important source for new awareness concerning existing uncertainty. Their input in the decision making process may thus be an essential element for precautionary action.

Finally, there are the rules on access to information. Such rules are set out partly in Section 12 of the GMO Act, and partly in the Act concerning Access to Environmental Information (no. 30 of 2003). In some cases, the private party may argue that the information in question represents a business secret and thus must be kept confidential. However, such arguments are not available in all cases. According to Section 12 of the GMO Act, information regarding, inter alia, the purpose of use of the GMO, the place in which it shall be used, methods and plans for surveillance, and assessment of potential effects of releasing the GMO shall be public regardless of whether they may be considered business secrets. Moreover, according to Section 11 of the Environmental Information Act, the burden of proof rests to a large extent with the private party invoking a confidentiality clause. In addition, this Act gives the public access not only to environmental information held by public authorities, but also to such information directly from undertakings, cf. Chapter 4 of the Act. Against this background, it can be concluded that the rules on access to information ensures a flow of information between interested parties, and thus contributes to the process of reducing uncertainty. Moreover, the increased access to information may also contribute to new awareness concerning existing uncertainties, and thus contribute to establishing a basis for precautionary action.

Against this background, we may conclude that there are at least four main measures that may contribute to reduce uncertainty, and thus reduce the need for precautionary measures. On the other hand, it has also been indicated that these measures may contribute to increased awareness concerning existing uncertainties, and thus increase the likelihood that precautionary action will actually be taken.

7 Level of protection

In the following, it may be useful to distinguish between defining a level of protection and the taking of measures to achieve the level of protection. While the acceptable level of protection is generally considered to be mainly a political issue, measures taken to attain the prescribed level of protection ("risk management") are considered a more technical issue for which a precautionary approach may be appropriate in order to be sure that the chosen level of risk is achieved. However, this distinction is not always clear-cut. One general decision may in some instances both constitute a definition of a level of protection and constitute the measure to achieve that level of protection. This will for example be the case when the measure is a complete prohibition of the production of a substance. Here, the measure shows that the level of protection is set at "zero risk tolerated". Hence, there is no need to define a level of protection. Moreover, it should be recognized that in most cases, countries do not in practice first explicitly define a level of

acceptable protection and subsequently proceed to design the measures needed to achieve that level.

Against this background, the distinction between level of protection and the measures taken to achieve the level of protection may be criticized for being too theoretical. Nevertheless, the distinction is of importance for analytical purposes, it has been introduced as a basic distinction in the WTO SPS Agreement, cf. in particular Article 5, and there may possibly be a development in the direction of increasingly designing relevant decision making procedures according to the distinction. The main reasons why one has not in a more systematic way defined levels of protection prior to adopting measures seem to be that such issues to a large extent are depending on cultural and social traditions, such as differences in risk perception, and that there is a basic lack of knowledge about risks.

If we take a look at the Norwegian GMO Act, we can observe that there is no independent statement defining in general the acceptable level of protection. On the other hand, it can be argued that there is no need to define the acceptable level of protection separately, as long as the conditions for allowing marketing of GMOs set out in the law indicate that there shall be "zero risk", cf. the phrase "may only be approved when there is no risk of detrimental effects on health or the environment" in Section 10(2) of the GMO Act. However, the wording of Section 10(6), as well as statements in the preparatory works, in administrative decisions and in subsequent documents from relevant institutions, indicate that Section 10(2) cannot be read so strictly as to require a "zero risk" approach.[22] This is particularly so in cases where decisions are made on the basis of Section 10(6) of the Act, since this provision does not oblige the authorities to prohibit deliberate release of GMOs if they will have harmful environmental or health effects.

In the case of antibiotics resistance, there is an absolute prohibition against allowing deliberate release. In this case, there have been clear statements by both the Parliament and the Government that there shall be a "zero risk" approach.[23] This has been expressly reflected in legislation only in relation to GMOs used for food.[24] Nevertheless, it has in practice been strictly adhered to also in other cases concerning deliberate release of GMOs.[25]

As to the relationship between level of protection and the precautionary principle, some will argue that one may apply the precautionary principle both when defining the level of protection and when determining the measures to be taken to achieve the level of protection. This understanding of the precautionary principle is based on a broad definition of the principle, being applicable in the context of highly political decisions. Others will argue in favor of a more narrow understanding of the precautionary principle. Such an understanding of the principle will relate it more closely to the process of risk assessment and subsequent decisions concerning measures to be applied in individual cases. This understanding of the principle is based on a more technical and administrative approach.

If we take a broad approach to the precautionary principle, we may conclude that the Norwegian policy when setting a "zero risk" approach in relation to antibiotics resistance is based on a precautionary approach. However, as Norway has not defined an appropriate level of protection in other contexts, we will have to discuss the precautionary principle only in relation to the actual measures taken for the rest of the cases of deliberate release of GMOs.

8 Burden of proof

According to Section 10(2) of the GMO Act, the starting point is that the party applying for release of a GMO has the responsibility of demonstrating that the conditions for releasing the GMO are fulfilled. However, the Act does not clearly allocate the burden of proof in cases where the GMO in question has been allowed to be released within the EU, cf. Section 10(6) of the GMO Act. According to this provision, one could argue that since the Act states that the authorities "may" prohibit the marketing of GMOs, it must be up to the authorities to demonstrate that the GMOs pose unacceptable risks or do not constitute a sufficient benefit to the society or contribution to sustainable development. Such an approach would also be in line with the adaptation text to Article 16 of the 90/220 Directive, which states that:

"Where a Contracting Party has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may restrict or prohibit the use and/or sale of that product on its territory."

On the other hand, it can be argued that the GMO Act contains additional conditions that do not fall within the scope of the decision making procedure of the EU, and that at least in relation to these conditions, there must be an obligation for the applicant to provide relevant information to demonstrate that the conditions are fulfilled. Such an approach would be in accordance with the following text related to incorporation of the 90/220 Directive into the EEA Agreement:

"The Contracting Parties agree that the Directive only covers aspects relating to the potential risks to humans, plants, animals and the environment. The EFTA States therefore reserve the right to apply their national legislation in this area in relation to other concerns than health and environment, in so far as it is compatible with this Agreement."

Hence, according to this provision Norway clearly has the freedom to place the burden of proof on the applicant, at least in relation to information necessary to demonstrate benefits to the society and contribution to sustainable development. There is an important overlap between information concerning health and environmental effects and information to demonstrate net benefit to society and contribution to sustainable development.

In addition, it can be argued that Norway, at least in the past, has adopted a stricter level of protection than the EU in relation to genes coding for antibiotics resistance, and thus

that applicants should carry the burden of proving that releasing the GMOs will not violate the level of protection in Norway. One question that arises is whether Norway is allowed under the EEA Agreement to maintain a higher level of protection in relation to antibiotics resistance. The wording of the adaptation text indicates that there is some freedom for Norway to set a level of protection that is stricter than that adopted by the EU as long as there is "justifiable reasons to consider that … [such GMOs constitute] a risk to human health or the environment". If we assume that Norway can bring forward such reasons, it seems justifiable for Norwegian authorities to place the burden of proof that the GMO in question does not constitute such a risk on the applicant.

Finally, we are left with the question whether Norway is allowed to place the burden of proof on the applicant in cases where Norway has not defined a higher level of protection than the EU. As a starting point, one could argue that pursuant to the wording of the adaptation provision, Norway should not be allowed to place the burden of proof on the applicant in these cases. On the other hand, Norway could in practice in most cases argue that a decision would have to be based on an overall assessment of the potential benefits on the one hand and risks of harmful effects of a GMO on the other, and that as long as the applicant has not provided sufficient information concerning potential harms, the GMO cannot be approved. Such an approach has been widely applied by Norwegian authorities when considering individual applications. In a number of cases, the authorities have made requests for further documentation, and when the information provided has failed to convince the authorities that potential harms are insignificant or limited, the authorities have in general denied permissions to release the GMOs.

Placing the burden of proof on the applicant can generally be regarded as a precautionary measure. However, it can also easily be misused in the form of a measure that unreasonably distorts international trade. The discussion above shows that Norway under the EEA rules has at least some freedom to take a precautionary approach when allocating the burden of proof. Moreover, there seems to be a limit to the extent to which such an approach can be used, but it is quite unclear where this limit shall be drawn. Finally, it is clear that Norway will not be able to continue the precautionary approach if the 2001/18 Directive is included in the EEA Agreement without an adaptation text similar to the current text. However, the need for an adaptation text will depend on the extent to which a precautionary approach will be followed in practice under the 2001/18 Directive.[26]

One long term problem of placing the burden of proof on the applicant is that research on effects of GMOs to a large extent will be left to those having an interest in ensuring that the GMOs get access to markets on as favorable terms as possible. Hence, there is a need for authorities to secure a certain amount of independent research into the effects of GMOs in order to be able to check the quality of the information provided by applicants.

9 Risk assessment*

Issues discussed above, such as burden of proof and measures taken to reduce uncertainty, can be regarded as elements of the risk assessment process. In particular, the rules on impact assessment are at the core of the risk assessment process in the context of

deliberate release of GMOs. These rules serve to indicate which risks must be assessed, including which potential harmful effects to take into account.

The rules on impact assessment do not restrict the authorities' possibilities of requesting information should they consider it necessary in order to show that the GMO is sufficiently safe. In Section 4-2 of the Regulation on impact assessment,[18] there is only a non-exhaustive and illustrative list of information that must be presented with respect to effects on health and the environment. According to Sections 4-4 and 4-5 of the Regulation, the applicant has also a duty to present information on possible health or environmental effects from measures to be taken to avoid or remedy harmful effects of the GMO, and from non-conventional or erroneous use of the GMO. All these rules give the authorities broad discretion when defining the scope and quality of information to be presented in individual cases.

In many of the cases where a product has been approved for release within the EU, Norwegian authorities have not been satisfied with the information that had been presented by the applicant to the EU, and requested additional information. Such requests must be understood in light of the requirement of Section 10(1) of the GMO Act that a "product may not be approved for placing on the market until it has been satisfactorily tested in natural environments that will be affected by the intended use." A main reason why some of the applications were rejected by Norway was that the applicant failed to provide the additional information requested. In their overall assessment, Norwegian authorities concluded that due to uncertainty regarding the harmful effects, they could not allow release of the GMOs.

In other cases, the authorities stated that they considered the risks posed by the presence of genes coding for antibiotics resistance differently from the EU. The difference in opinion between Norway and the EU was mainly related to the likelihood that such genes could be transferred to other organisms.

The margin of appreciation enjoyed by Norwegian authorities through the GMO Act and related Regulations means that they are free to ask the applicant to make an assessment that is of specific relevance to the Norwegian environment, that possible indirect and long term effects of releasing the GMO be assessed, and even that possible effects outside of Norway be assessed. Moreover, Norwegian authorities have broad discretion when determining the quality of the information to be presented, and they thus have an extensive possibility of taking a precautionary approach in the context of the risk assessment procedure. Practice demonstrates that they have made use of this possibility.

So far, international standards have not been of importance in the context of this part of the decision making procedure. Once such standards are developed and must be applied, Norway will have to reassess its policy of giving broad discretionary power to public authorities.

10 Risk management

The basic option in the context of risk management is the possibility of denying release of GMOs in Norway. Such a measure is obviously a precautionary measure. However, there remains the problem of unlawful release of GMOs. A prohibition against release of a GMO in Norway may thus turn out to be of limited effect in practice if it is not followed by a sufficiently strong control regime. It has not been possible to carry out any examination of the Norwegian control regime for the purpose of this article.[20] Given the broad possibility of denying release of GMOs, Norwegian authorities have an extensive opportunity to pursue a precautionary approach in the context of risk management measures.

The next question is which options Norwegian authorities have to take precautionary measures in cases where they permit the release of GMOs. Here, the question is what kind of conditions they may attach to the permit. Section 15 of the GMO Act sets no limit to the conditions that may be used. It merely lists examples of possible conditions, including:

"the best technical procedure and other means of production from the point of view of health and the environment, a duty to take out insurance or provide security for liability … or measures for preventing and limiting possible detrimental effects."

Moreover, Section 15 indicates that the approval may be time limited, and according to Section 5-1 of the Regulation on impact assessment the authorities may set as condition that the applicant reports on the results of the release and undertakes additional examinations of effects of the release to be carried out at a later stage. It can be observed that all these conditions may apply to the applicant, and thus that the applicant may be regarded as responsible for fulfillment of the conditions.

There is no general restriction in the 90/220 Directive on the conditions that may be set when approving release of a GMO.[21] However, the adaptation text to Article 16 restricts the conditions available in cases where a GMO has been approved by the EU. But, as has been noted above, Norwegian authorities enjoy broad discretion under the adaptation text of Article 16.

In sum, Norwegian authorities have a broad possibility of taking a precautionary approach in the context of setting conditions for approvals to release GMOs. This discretion will be substantially limited in cases where GMOs have been approved by the EU if the adaptation text of Article 16 is discontinued when the 2001/18 Directive is included in the EEA Agreement.

11 Responsibility and liability

Any person who intentionally or negligently contravenes the provisions of the GMO act or conditions set in permits under the act may be liable to imprisonment for up to one year, and four years if there are especially aggravating circumstances, cf. Section 25 of the GMO Act. Hence, a person who sells or uses a GMO in violation of conditions set in the decision allowing the marketing of the GMO may be subjected to penal sanctions as a

consequence of the violation.[22] There is also the possibility of imposing a coercive fine in accordance with Section 24 of the GMO Act.

There are separate rules on compensation in cases of damages in Section 23 of the GMO Act. There is strict liability, i.e. liability to pay compensation regardless of fault. Liability may occur if the release causes "damage, inconvenience or loss". There is thus a low threshold for liability. One may as well become liable in cases where one has complied with all conditions set out in the approval. However, in these cases it can be argued that a higher threshold for liability should apply, requiring that the harmful effects were "unreasonable or unnecessary", cf. Section 56 of the Pollution Control Act (Act no. 6/1981).

Section 23 of the GMO Act indicates that one may become liable for a broad range of both pecuniary and non-pecuniary losses. This is particularly indicated by the use of the word "inconvenience" ("ulempe"). It should be recalled that a duty to take out insurance or provide security may be set as a condition for the approval, cf. Section 15 of the GMO Act. Finally, the liability would apply to any "person responsible for an activity pursuant to" the GMO Act. This must be read as including any person carrying out activities relating to production and use of GMOs.

Against this background, we can conclude that the rules on responsibility and liability reinforce the precautionary approach of the GMO Act, in the sense that they give applicants strong incentives to minimize harmful and even inconvenient effects from GMOs. It can also be argued that these rules as such constitute precautionary measures.

12 Concluding remarks

As a first impression, the Norwegian GMO Act seems to instruct public authorities to adopt a very restrictive practice in relation to approval of GMOs, cf. Section 10(2). However, at closer scrutiny we see that the rule in practical terms is not particularly strict, and that it allows public authorities a broad margin of appreciation in relation to both the decision-making process and the content of decisions, cf. Section 10(6). The extent to which a precautionary approach is pursued by Norway is thus to a large extent depending on the political priorities of the Government.

Norwegian authorities have broad opportunities to adopt a precautionary approach in relation to GMOs under the current rules of the EEA Agreement. The authorities have made active use of these opportunities and adopted a more precautionary approach than the EU in several cases. This approach has partly consisted in setting a higher level of protection than the EU, i.e. in the case of genes coding for antibiotics resistance, and partly consisted in adopting a strict approach to the burden of proof. The precautionary approach has been closely related to an overall assessment of whether the GMOs constitute benefits to the society and contribute to sustainable development.

The rules on GMOs under the EEA Agreement will most likely have to be updated in the near future, and it is unlikely that Norwegian authorities will be able to maintain the degree of discretion that they currently enjoy. Moreover, the authorities have so far not

explicitly addressed the issue of compatibility of their GMO measures with international trade law. These factors indicate that Norwegian authorities are under heavy pressure to change their policy on GMOs. To predict the speed at which, the areas in which, or the extent to which Norwegian policy will change, will only be speculative.

End notes

(1) This distinction is basic in the sense that the former group of GMOs has the ability to reproduce (unless they have been made infertile), while the latter group has no such ability. However, this distinction is generally not reflected in the rules that have been set out to regulate the use of and trade in GMOs, cf. inter alia Section 9(f) of the GMO Act.

(2) See in particular Decision I/4 adopting Guidelines on Access to Information, Public Participation and Access to Justice with respect to Genetically Modified Organisms (MP.PP/2002/7) and Decision II/1 on Genetically Modified Organisms of the Meeting of the Parties to the Aarhus Convention. The latter decision introduced more specific rules on GMOs into the convention.

(3) See Stortingsproposisjon nr. 65 (1993-94) [proposition from the Government concerning ratification of the Agreement Establishing the World Trade Organization], in particular at *105-*106 and *110.

(4) Those decisions where Norwegian authorities have refused approval of GMOs that have been approved in the EU can be found on http://odin.dep.no/md/norsk/tema/biomangfold/aktuelt/022031-990074/dok-bn.html (in Norwegian, last visited 13/11-05). For more details, see Elisabeth Lier Haugseth: Utsetting av genmodifiserte organismer, Institutt for offentlig retts skriftserie, No. 2/2001, Chapter 5 and Jens Plahte: Regulering og forvaltning av ustetting av genmodifiserte organismer i Norge 1993-2000, in Retfærd no. 96 (2002) at 76-92.

(5) Directives and other secondary legislation adopted by the EU are included in the EEA Agreement through references in Annexes to the Agreement. Directive 90/220 has been included through a reference in Section IV of Annex XX to the Agreement (See entry no. 25. The Annexes can be accessed on http://secretariat.efta.int/Web/EuropeanEconomicArea/EEAAgreement/annexes, last visited 8/12-05).

(6) See Jens Plahte: Regulering og forvaltning av ustetting av genmodifiserte organismer i Norge 1993-2000, in Retfærd no. 96 (2002) at 84-87.

(7) The reasons why Norway has to make decisions in relation to all these applications are partly that many of the applications are for marketing in the whole area covered by the EEA Agreement, and partly that the EEA Agreement makes Norway part of the internal market of the EU, and hence that a product that is allowed marketed in the EU can be marketed in Norway unless a decision to the contrary has been made. For an overview of the status of applications for release of GMOs in Norway, see http://www.dirnat.no/archive/attachments/02/80/GMOli042.pdf (in Norwegian, last visited 8/12-05).

(8) See http://odin.dep.no/md/norsk/tema/biomangfold/aktuelt/022031-990074/dok-bn.html (in Norwegian, last visited 8/12-05).

(9) In the reference to the precautionary approach in Principle 15 of the Rio Declaration, it is stated that: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing *cost-effective* measures to prevent environmental degradation" (emphasis added).

(10) On the issue of the precautionary principle, cost benefit analysis and proportionality, see the article by Nicolas de Sadeleer above.

(11) The wording of the relevant part of Section 110 b of the Norwegian Constitution is as follows: "Every person has a right to an environment that is conducive to health and to natural surroundings whose productivity and diversity are preserved. Natural resources should be made use of on the basis of comprehensive long-term considerations whereby this right will be safeguarded for future generations as well."

(12) Article 11 of the EEA Agreement corresponds to Article 28 of the Treaty Establishing the European Community.

(13) No case concerning GMO has so far been brought before a Norwegian court.

(14) Cf. Section IV of Annex XX to the Agreement (See entry no. 25. The Annexes can be accessed on http://secretariat.efta.int/Web/EuropeanEconomicArea/EEAAgreement/annexes, last visited 8/12-05).

(15) See forskrift no. 1848 of 18 December 2003 om godkjenning av biocider og biocidprodukter (biocidforskriften).

(16) "Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment …"

(17) For a discussion of possible consequences of not making a Directive part of the EEA Agreement, see Trond A Eriksen: Norges muligheter til å reservere seg mot nytt EØS-regelverk – direktivene om tilsetningsstoffer i næringsmidler, IUSEF no. 41 (2003).

(18) See Politisk plattform for en flertallsregjering, adopted at Soria Moria on 13 October 2005 (the Soria Moria Declaration), p. 8, which states that: "If other means do not succeed, the Government will consider making use of its right of reservation under the EEA Agreement if essential Norwegian interests are threatened as a consequence of EU legislation to be considered included in the EEA Agreement." (translation of the author).

(19) Forskrift no. 816 of 20 August 1993 om konsekvensutredning etter genteknologiloven.

(20) On these issues, see also the article by Teofanis Christoforou above.

(21) The statements of the Biotechnology Advisory Board can be accessed on http://www.bion.no/uttalelser.shtml (in Norwegian only, last visited 8/12-05).

(22) See Elisabeth Lier Haugseth: Utsetting av genmodifiserte organismer, Institutt for offentlig retts skriftserie, No. 2/2001, in particular at 44-51. See also the article by Teofanis Christoforou above, in which he concludes that the level of protection provided for under the 2001/18 Directive is a "level of no risk". He bases this conclusion on an analysis of several provisions and preambular statements in the Directive, and not on an explicit political statement identifying the acceptable level of risk.

(23) See in particular Innst. S. no. 272 (1996-1997).

(24) Forskrift no. 257 of 4/3 2000 om forbud mot visse genmodifiserte næringsmidler og næringsmiddelingredienser.

(25) The content of genes coding for resistance to antibiotics was a main reason for not allowing release of GMOs in at least six cases. In one case, the authorities stated that permission to market the product may be given provided that the gene coding for antibiotics resistance is removed. Norwegian authorities have allowed use of such genes in one case which did not concern deliberate release. See Jens Plahte: Regulering og forvaltning av utsetting av genmodifiserte organismer i Norge 1993-2000, in Retfærd no. 96 (2002) at 89-90.

(26) The 2001/18 Directive does as a starting point place the burden of proof on the applicant, and it can be argued that it provides for a zero risk level of protection, cf. the article by Teofanis Christoforou above. However, there is a margin of discretion under the Directive, and there is clearly a possibility that a GMO that may be regarded as acceptable under the Directive may subsequently be regarded as unacceptable by Norwegian authorities.

(18) Forskrift no. 816 of 20/8 1993 om konsekvensutredning etter genteknologiloven.

(19) For cases where final decisions have been made by Norwegian authorities, see http://odin.dep.no/md/norsk/tema/biomangfold/aktuelt/022031-990074/dok-bn.html (in Norwegian, last visited 13/11-05).

(20) The Norwegian Food Safety Authority (Mattilsynet) has the main responsibility for control issues.

(21) We may note that there is no restriction on the use of conditions in Directive 2001/18, cf. in particular Article 19.3(c).

(22) In this context, it is remarkable that decisions to allow release of GMOs are made in the form of individual decisions that are not subject to the procedural requirements that apply to regulations, including requirements concerning publishing.