Precautionary Expertise for GM Crops

National Report – Denmark

Co-existence Bypassing Risk Issues

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List of abbreviations

DAC    Danish Agricultural Council
DARCOF Danish Research Centre for Organic Farming
DCC    Danish Consumer Council
DFNA   Danish Forest and Nature Agency
        Skov-og Naturstyrelsen
DPD    Danish Plant Directorate
IFVR   Institute for Food and Veterinary Research
NERI   National Environmental Research Institute
NUOF   National Union of Organic Farmers
NSCN   National Society for the Conservation of Nature
SICE   Special Interministerial Committee for the Environment
Abstract

In Denmark, three different accounts of precaution or a precautionary approach can be identified in relation to the risk issues of GM crops, where a key issue is uncertainty. These accounts correspond in general with stakeholders’ view on GM crops. Industry views precaution as a general requirement for a product category to undergo a prior authorisation procedure based on science that is perceived as being value-free and beyond discussion. The authorities consider precaution in relation to risk management: even if no clear evidence of potential risks is documented, uncertainty means that extra market-stage controls could be imposed, for example to monitor or prevent a potential risk. For NGOs, precaution means more acknowledgement of, and a focus on, scientific uncertainty and lack of knowledge, in an iterative process that entails both risk assessment and risk management.

The framing of the different accounts of precaution by stakeholders also defines the contending accounts of the same issue, for example GM crops as un/sustainable agriculture, GM material as ‘contamination’ or as ‘adventitious presence’, co-existence as impossible.

Despite a new Liberal-led Government in November 2002, the Danish restrictive GM policy has continued because what could be called a ‘GMO-cautious majority’ has emerged in Parliament. The Danish GM policy has included several measures that could be seen as precautionary, for example: the moratorium (allowing time to develop more restrictive measures), traceability (uncertainty is acknowledged and managed), labelling (allowing choice in cases where consumers regard the safety of GM products as uncertain), co-existence (limiting dispersal of GMOs in the environment), and liability (imposing accountability for dispersal of GMOs in the environment).

In risk regulation there has been a greater emphasis on separating scientific expertise and decision making. In May 2000 responsibility for the environmental risk assessment of GM crops was transferred from the Danish Forest and Nature Agency to the National Environmental Research Institute (NERI), a step that could be regarded also as a broadening of the expertise involved in environmental risk assessment. For food safety, the same separation took place in 2004, when the Institute for Food and Veterinary Research was created by combining two smaller research institutions with responsibilities for risk assessment.

The relation between risk research, risk assessment and risk management has changed from being mainly sequential (risk research informs risk assessment, which in turn is the basis for risk management judgements) to being more interactive. Risk management, especially post-release monitoring, has emerged as a way of dealing with the remaining uncertainty and thus becomes risk research. But this development has further complicated the political effort to separate risk assessment and risk management, given that value judgements implicitly also enter risk assessment.

Despite these institutional changes, advisory practice has continued largely as before. In its assessment of product files for the marketing of GM crops, NERI has made close links between risk assessment and risk management. It has addressed not only the potential risks and uncertainty but also measures to reduce this risk, for example by risk management.

This precautionary approach has emerged in efforts to investigate and clarify uncertain risks before regulatory decisions on GM crops. In the case of GM fodder beet, research identified a dilemma for farm management practices. Early spraying meant killing all weeds and thus harming biodiversity, but it also meant less herbicide was used and thus less impact on groundwater; late spraying meant more weeds and thus benefited biodiversity but also meant more herbicide was used and thus more impact on groundwater. In proposals for extra market-stage controls, for example for Bt maize, the authorities have demanded specific monitoring and buffer zones, even for risks for which there is no clear evidence.
Main findings

Main questions for the study

The precautionary principle (PP) has been acknowledged as a basis for decision making about genetically modified crops. Nevertheless, the precautionary principle has only been loosely defined in policy and thus there exist many perspectives on its interpretation and how it should be invoked in practice. For GM crops and their food uses, this project analyses how current European practices – regulatory measures, expert judgements and stakeholder roles – compare with different accounts of the precautionary principle/precautionary approach/precaution. This report elaborates on the use of precaution in Denmark, mainly from 1998 to 2004 (March 2004).

Diverse approaches to precaution

The precautionary principle/precaution is understood and interpreted by key stakeholders in diverse ways but precaution is mainly regarded as a general approach rather than as a specific principle, at least in relation to GM crops. In these different understandings, central issues are the source and significance of uncertain risks, judgements on how to deal with this scientific uncertainty, the normative baseline for risk comparison, the role of scientific expertise and public participation, and models for future agri-environmental systems.

In Denmark three different implicit and explicit accounts of a precautionary approach can be identified in relation to the risk issues of GM crops. These accounts correspond in general with the views of the main groups of stakeholders on GM crops:

Industry, and to some extent DAC (Danish Agricultural Council):

GM crops represent a positive future for agriculture because they could be used to solve the problems of industrialized agriculture by offering opportunities for more sustainable practices. Precaution is viewed as the general requirement for GM products to undergo a prior authorisation procedure (case-by-case, step-by-step) based on science that is perceived as being value-free and beyond discussion. Risk assessments of product files so far have shown that any risks are negligible. No further precautions, such as monitoring, are needed except in special cases where the risk assessment has documented evidence of risks with adverse effects. Assumptions about uncertainty are not a valid basis for requiring further precautions.

DFNA (Danish Forest and Nature Agency), NERI (National Environmental Research Institute) and DPD (Danish Plant Directorate) and to some extent DAC:

GM crops are regarded in the same way as any other, conventional, crop. Harm is defined to include ‘undesirable effects’ (not just ‘damaging effects’). In risk assessment, conventional non-GM crops have been chosen as the normative comparator for judging the effects of a GM crop. Only those scientific criteria included within the prescribed risk assessment in the Deliberate Release Directive should be taken into account in the decision. Risk management should mainly be based on evidence of risk and uncertainty in order to investigate and clarify uncertain risks before final regulatory decisions are taken on GM crops. If no clear evidence of potential risks is documented, then extra market-stage controls, e.g. to monitor or prevent a potential risk, could be imposed. Precaution is only considered in risk management.

Environmental NGOs, NUOF (National Union of Organic Farmers) and to some extent DCC (Danish Consumer Council):
GM crops represent a threat to sustainable agriculture, including organic agriculture, as they impose unpredictable hazards. Furthermore, GM crops would lead to an intensification of agriculture, thus accelerating the loss of biodiversity. The basic framework for risk regulation is inadequate. Risks should be seen more broadly, in a framing that includes socio-economic effects and the potential consequence for the development of society, for example by considering farming systems. In risk assessment, scientific ignorance and uncertainty are poorly handled; value judgements by experts are made in non-transparent ways, with little opportunity for public participation in these judgements. In risk assessment the choice of comparator should be the less-intensive agricultural farming systems, including organic farming methods, as alternatives and these alternatives to the GM strategy should be evaluated alongside the GM strategy. Precaution means acknowledgement of, and much more focus on, the questions of scientific uncertainty and lack of knowledge. Precaution should be considered at all stages of approval and not only in risk management. Precaution is also linked to liability for environmental harm and harm to non-GM farmers, which would mean changing the burden of proof and allowing an assessment of the economic risk involved.

These different accounts of precaution have not been voiced explicitly by the different stakeholders, as the terms PP or precaution have rarely been used. The debate on risk regulation, scientific expertise and stakeholder roles has not (or has rarely) been framed by stakeholders with reference to the PP or precaution. Nevertheless, the framing of the different accounts of precaution by stakeholders also informs the contending accounts they give of the same issue, e.g. GM crops as either unsustainable or sustainable agriculture, GM material as either ‘contamination’ or ‘adventitious presence’, co-existence as either possible or impossible. Furthermore, the different practices in risk research, risk assessment and risk management seem also to be informed by these different accounts of precaution.

Policy context and conflicts

When GM food products reached the commercial stage in the mid-1990s, the public debate became more intense. Citizens, NGOs and members of Parliament focussed their concern on risk in a broader sense, including questions of social and environmental values and scientific uncertainties, especially the potential agronomic-environmental effects, including the question of whether growing GM crops could lead to a more sustainable agriculture. In fact the debate became more and more polarized – between NGOs and most people on one side, and industrial and agricultural decision makers on the other.

In response to this polarization, the Social Democratic Minister for the Environment took an explicitly precautionary initiative, beyond the regulatory process, and reached a voluntary agreement with industrial and agricultural decision-makers that no GM crops would be marketed in Denmark in 1999. Another part of the agreement involved an agreement that herbicide-tolerant GM fodder beet could result in ‘a real benefit for the environment’, but this part was not published with the press release or sent to Parliament, probably because of its controversial content.

This line was followed in the EU, where Denmark was among the five member states behind the so-called de facto moratorium. These five member states made up a blocking minority in the Council of Environmental Ministers. Taking their lead from France, four other member states – Denmark, Italy, Greece and Luxembourg – issued a declaration in June 1999 that they would effectively block new GMO approvals until the European Commission proposed legislation for traceability and labelling of GMOs and products derived from them.

Such a policy could implicitly be regarded as a precautionary approach. The moratorium provided a pause that allowed time to set up regulatory restrictions that would have been impossible under previous regulatory practice. In this way the moratorium could be said to have an implicit link to precaution. As one purpose of traceability is to enable the monitoring of any adverse effects from a specific product,
this could be seen as having an explicit link to precaution, since it means that uncertainty is acknowledged and managed. As the purpose of labelling is to allow informed consumer choice, this could implicitly be linked to precaution if consumers regard the safety of GM products as uncertain and use labelling information in their social judgements of the products.

Following the adoption by the European Parliament in February 2001 of the revised Deliberate Release Directive (Directive 2001/18/EC, repealing Directive 90/220/EEC), the same five member states again declared that they would not lift the moratorium until the issue of traceability and labelling had been resolved. In fact, the revised Deliberate Release Directive included several measures in line with Denmark's restrictive policy, for example a broader risk assessment, time-limited market authorisation for GM crops, a requirement for post-release monitoring linked to the risk assessment, and the phasing-out of at least some antibiotic-resistance marker genes.

The election in Denmark in November 2002 resulted in a new Liberal-led Government that with the support of the Danish Peoples’ Party (a populist and ultra-right wing party) could govern alone, without support from the centre parties (which had been the basis for the former social democratic governments). This change in Government meant that large cuts were made in the environmental administration (1 in 7 posts were cut), and 18 environmental board and councils were closed down or their funding withdrawn.

After the November 2002 election, there were expectations that GMO policy would become less stringent, in line with the Liberal-led Government’s ‘Lomborgist’ anti-environmentalism. However, this has not been the case, because a new ‘GMO-cautious’ majority in Parliament has emerged. The Danish People’s Party, which in general forms the basis of the Liberal-led Government, has joined the oppositions’ more restrictive line on GMO issues including GM crops. The Danish People’s Party, which is a populist party, probably adopted this stance because public surveys have found that citizens in Denmark are very sceptical/suspicious of GM crops.

This GMO-cautious majority in Parliament has forced the Liberal-led Government to continue the restrictive Danish GMO policy against its own will. Hence, the Liberal-led Government was forced to take another initiative beyond the regulatory space by introducing a Danish co-existence strategy for GM and non-GM crops. At the same time it had to work at the EU level for common rules on co-existence and for liability rules to cover harm from GMOs on the environment and on non-GM farmers. Thus Denmark has continued a restrictive policy on the development of GM crops at the national and EU level that could be termed precautionary.

The Liberal-led Government has continued to provide scope for consultation of stakeholders, from industry to NGOs, and public participation and consultation on GMO issues. But several NGOs do not see how such involvement can address their main overall concerns, for example whether the present course of agro-food development is sustainable since it is dependent on pesticides, the issue of intensification versus sustainability, and their view that alternatives to the GM strategy should be evaluated alongside the GM strategy.

For these overall concerns there exists no forum for debate in Denmark. The Danish Board of Technology does not fulfill such a role. Almost no independent environmental advisory board that could have dealt with such concerns exists any longer, since the Liberal-led Government has closed them down and replaced them with the Environmental Assessment Institute, with the purpose of ‘getting the most environment for the money’. The so-called bioethics initiative of the Government has not fulfilled such a role either.

The result has been a growing polarization between industry and NGOs, both using websites as an important means for promoting their view. Both have formed alliances to strengthen support for their view. Major transnational agricultural biotechnology companies, such as Bayer CropScience, Dupont, Monsanto, Plant Science Sweden, Swalöf Weibul, and Syngenta in association with DLF Trifolium, have produced an internet website together.
NGOs have formed a rapidly growing coalition between several environmental NGOs, consumer NGOs, organic farmers, some conventional small farmers, and trade unions. These are groups which prefer to discuss overall questions of risks in a broader sense, including questions about social and environmental values and uncertainty, the potential agronomic-environmental effects including a debate on whether growing GM crops can be regarded as leading to a sustainable agriculture, the fundamental rights of farmers and citizens to grow and eat GM-free products, the socio-economic effects, and the liability issue, before a debate on whether/how and under what conditions the growing of GM crops should be allowed.

**Framing of uncertainty/precaution in policy and expert judgements**

The GM controversy over the development of GM crops, especially herbicide-tolerant but also Bt crops, has been framed in the context of a wider and intense public debate over the last 20 years on pesticide use as a result of continuing agricultural intensification. This debate has raised major concerns in relation to the effects on human health, on groundwater quality and on farmland diversity.

This debate has meant that successive governments, together with Parliament, have signed up to the first Pesticide Action Plan, adopted in 1986 with the objective of tightening up the approval procedure and reducing the total use of pesticides by 50% within a period of ten years. Because the knowledge about pesticides was fragmented, the action plan was supported by research activities, dissemination activities, education programmes for all people involved in spraying, and taxes on pesticides. The research programmes were initiated to find ways of minimising the need for pesticides, including an examination of the potential for using reduced dosages.

When routine monitoring of groundwater for pesticides and their metabolites revealed that the contamination of wells and groundwater reservoirs by pesticides was still increasing throughout the 1990s, a national strategy on groundwater was adopted by Parliament in 1994. Its purpose was to reduce groundwater contamination (including that from pesticides) in order to protect this important source of drinking water. Any pesticides threatening groundwater quality were to be completely banned.

When glyphosate, and in particular its metabolite AMPA, was found in groundwater in 2002 as a result of its method of use in agriculture, the Liberal Minister for the Environment decided not to ban glyphosate as such but to ban its use in autumn, when leaching is extensive because of heavy rain. This resulted in a strong reaction from stakeholders, who were all aware of its implications for glyphosate-tolerant GM crops. The manufacturers of glyphosate, in a joint statement, questioned the findings, arguing that water at a depth of one metre should not be classed as groundwater. They thus condemned the Minister’s move as unacceptable to them and to Danish farmers. DAC criticised the Minister’s move as extending the PP to its limit, while NGOs used the PP to advocate a general ban.

As pesticide use was still at the forefront of the public agenda in 1997, the Minister of the Environment decided to set up the Bichel Committee to assess the overall consequences of reducing or totally phasing out the use of pesticides in Denmark, as well as to investigate the consequences of a switch to organic farming, as a basis for Pesticide Action Plan II. The Bichel Committee presented an economic analysis showing that the use of pesticides could be reduced by 30-40% over a period of 5 to 10 years without significant loss of yield and without any change in crop rotation. But it would require alternative control methods to be incorporated and farmers would have to adopt all available information on how to reduce pesticide inputs. Along with such a reduction, the Bichel Committee recommended that the exposure to pesticides of non-agricultural biotopes adjacent to farmland should be reduced by the introduction of 10-12 m no-spray buffer zones along waterways and lakes, and that conversion to organic farming should be supported.
This agro-environmental debate on pesticides has framed the debate about, and regulatory development of, GM crops in Denmark. It is generally regarded as precautionary as it encompasses a broad range of plausible effects relevant to crop protection methods in the risk assessment criteria. From the beginning in the 1980s, NGOs have made explicit links between the development of herbicide-tolerant crops and the potential for increased use of herbicides, which would thus contradict the Danish environmental policy to minimize pesticide usage.

The public debate led to the first Danish Gene Technology Act in 1986 and framed the way that the regulatory system assessed the risks of GM crops. All GM crops had to undergo a prior authorisation procedure. Any effects resulting from the agricultural management of the GM crop (e.g. secondary effects of herbicide usage) were regarded as caused by the crop and thus part of the risk assessment (whereas at the EU-level, secondary effects were not included in the risk assessment until the revised Deliberate Release Directive came into force in 2002). The assessment was combined with a public consultation procedure and consultation of Parliament. Thus Danish policy incorporated precaution in several senses – as a political norm, as a general framework, and as an approach to uncertain risks – rather than as a special case to be invoked under specific circumstances. The EC communication on the PP was seen to be in line with the Danish approach.

This precautionary approach could be seen, for example, in the efforts to investigate and clarify uncertain risks before regulatory decisions on GM crops, and in proposals for extra market-stage controls for managing uncertain risks (for the latter, see the section on product files). Such measures could be seen in responses to the marketing application for a Danish glyphosate-tolerant GM fodder beet. In this case NERI proposed and conducted research, with the support of Monsanto, focussing on the effects on biodiversity of growing GM fodder beet compared with conventional fodder beet. The research showed that the most important factor affecting biodiversity was farm management practice, i.e. spraying with glyphosate. Early spraying meant that all weeds were killed, thus harming farmland biodiversity, while later spraying meant more weeds, thus benefiting farmland biodiversity.

The findings from this research posed a dilemma for policy makers in relation to the Pesticide Action Plan, which recommends reducing the use of pesticide as much as possible. According to this policy, early spraying is best because less herbicide is used. Thus early spraying would benefit groundwater quality, but would disadvantage farmland biodiversity. No solution to this dilemma has yet been found. To date (June 2004), the product file for marketing glyphosate-tolerant GM fodder beet is still pending in the Danish regulatory system.

NERI stated that the farmers’ readiness to accept weeds below the economic threshold for a longer period would be ‘decisive for the positive effect on biodiversity during early summer’. Whether this is a realistic claim has been questioned by the Bichel Committee, which found that it has been difficult to convince farmers to accept a lower level of control. Although farmers generally act in a rational economic way, they still tend to use preventive spraying, partly due to difficulties in determining the exact risk of crop loss. NGOs have been very sceptical about whether farmers in practice would follow a recommendation to spray later for environmental reasons, while DAC claimed that farmers would be able to manage the eventual problems in the same way as they do for conventional crops.

Product files requesting commercial use

In assessing product files, it has always been the Danish stance that the agri-environmental uncertainties of a GM crop should be included in the risk assessment. This approach has been extended to product files under the revised Deliberate Release Directive, where Denmark has given reasoned objections to the first six product files for marketing.

In addition, Denmark has even commented on 25 of 75 applications for field trials in the EU, with an emphasis on conditions or experimental data that could be relevant for a later marketing release. In this way Denmark lets Member States know at an
early stage that a Danish objection could be possible if some element of risk, or suggestions to reduce risk, were to be ignored. This indicates a change in the relation between risk research and risk assessment, from being mainly sequential, to being more interactive.

This analysis concentrates on the product files for a glyphosate-tolerant rapeseed for import, three Bt and glufosinate-tolerant maize varieties (two for growing and one for import and processing), and a glyphosate-tolerant fodder beet for growing. For all these notifications for marketing authorisation, the companies claimed that any risk is effectively zero or negligible. These claims were based on their view that the potential effects are not considered to be environmental harm, on the proposed management measures to prevent such effects, or on research that found no evidence of risk. Companies used such claims to argue that case-specific monitoring is unwarranted.

In the Danish consultation of stakeholders on these product files, only the Danish Food Industry supported these claims. Scientific expert bodies, DFNA, environmental and consumer NGOs, and organic farmers opposed the claims, from different perspectives. In Denmark stakeholders are given an opportunity to express their view several times during the consultation process, as well as to comment on the Danish expert advice on any additional material received by the authorities. Any scientific advice from expert bodies is open to stakeholders by request, although only the essential part is quoted directly in the minutes of the DFNA. DFNA has consistently followed all the scientific advice from NERI and DPD.

In the environmental risk assessment, harm is understood by NERI to include ‘undesirable effects’, not just ‘dangerous effects’ as in the Commission Communication. In its environmental risk assessment NERI had identified some uncertainties that it considered warranted more rigorous science or the use of specific management safeguards. NERI thus assumed that any negative impacts picked up by the extra market-stage controls (monitoring) could be reversed. But the basis for this judgement has not been transparent; NERI did not explain how it came to that conclusion. Furthermore, although NERI generally states in its risk assessments that there are no reasons to expect that a particular product will pose a risk to the environment or human health, it rarely answers the question of whether there are adequate grounds to expect no harm.

Such advice concerning uncertainty could be viewed as an expression of a precautionary approach in a scientific sense – the demand for specific monitoring, and the establishment of buffer zones, on the basis of insufficient knowledge. Yet precaution has never been used in their terminology. This may be because DFNA holds that the PP/precaution has always been the general basis for implementing the Danish Gene Technology Act.

NERI has taken an even more rigorous approach to environmental risk assessment and risk management. It has recommended the imposition of extra market-stage controls, even in the case of grain imports, for example to monitor or prevent potential risks for which there is no clear evidence in the risk assessment. This approach could be regarded as precautionary, especially as NERI disagrees with the view that ‘lack of indications of undesirable effects at a certain level in the risk assessment is a valid reason to exclude or limit monitoring’.

DPD too has followed that approach as they recommended ‘care’ in connection with the transport of the GM rapeseed, for example conditions to prevent unintended dispersal of GM seeds, in order to ensure segregation from non-GM products and thus make the co-existence of GM crops and non-GM crops possible in future.

As a consequence of the Danish objections, Denmark received additional information via the Commission. This information was assessed by NERI and DPD but only in one case did they reach a favourable opinion as a result. In all the other cases, they found the additional material unacceptable (simply a claim that no environmental risk can be demonstrated) or insufficient (regarding geographical dissemination, butterfly habitats, and the fact that no Danish or European butterfly was included in the risk assessment). Thus, the additional information from the Commission did not resolve the uncertainty and the scientific disagreements.
The Danish Food Industry has consistently been in favour of all the product files and has found no ‘valid’ arguments to make reasoned objections. Thus, it has ignored any speculations about uncertainty not identified in the risk assessment. The Danish Food Industry has rejected any objections based on such grounds.

DAC have expressed different opinions on the product files. As DAC only favour GM crops used with ‘care’ they have supported the Danish objections in some cases and not in others – they have even shifted their argument during the consultation process from a straight yes to support for the objections from DFNA. Thus, DAC seems at least to accept uncertainty as a basis for an objection if the authorities mention uncertainty in their risk assessment.

NUOF views GM crops as a threat to organic agriculture and farmers. This resistance is based on uncertainty about the long-term effects on the environment and animal and human health.

Environmental NGOs, in particular, have attempted to undermine safety claims made for GM products by focussing on uncertainties in the risk assessments in relation to biodiversity. Greenpeace states that the biodiversity issue is so uncertain that ‘any marketing should be banned for precautionary reasons’. Both Greenpeace and DCC use the consultation process to express fundamental objections, for example to argue that herbicide resistance is the wrong strategy, and to emphasise that liability regulation is lacking.

Unlike before, the Parliamentary Subcommittee on the Environment has not made any comments or raised any questions about any of the recent applications for market release. The reasons for this could be many. The chair of the committee is now in the hands of the Liberal-led Government; its members have changed since the last election; its focus has been more on the overall initiatives relating to GM crops, such as traceability, labelling and co-existence; many of the applications have been sent for comments at short notice; and several NGOs have given up commenting on all the marketing applications because they feel they are never listened to anyway. That change could be important because committee members formerly used at least some of those comments as a basis for raising questions, in co-operation with NGOs.

**Co-existence strategies**

In Denmark, there is considerable political awareness of organic farming methods as one of the means to reduce pesticide use and to protect groundwater quality. This is the reason why the organic sector has been supported by successive governments over the last 10 years or so. Support has been given to convert farmland to organic farming, to increase the market share of organic products, and to establish the Danish Research Centre for Organic Farming (DARCOF) in 1995 as a so-called ‘centre without walls’, where research is performed in interdisciplinary collaboration between the participating research groups.

In organic farming, the use of GM crops is banned but the existing risk assessment of GM crops did not cover problems in relation to organic farming. In 1999, DARCOF decided to study the potential risks of growing GM crops for organic farming and to suggest concrete measures to avoid or to minimize the risk of GM-contamination from GM crops. The report was published in May 2002.

Co-existence became a major issue in the parliamentary debate on the implementation of the revised Deliberate Release Directive in spring 2002. The result of this debate was that the GMO-cautious majority in Parliament forced the Liberal-led Government to prepare an official Danish strategy for co-existence between GM, conventional and organic crops as part of the revised Danish Gene Technology Act. In this way the GMO-cautious majority in Parliament treated co-existence as an environmental issue linked to precaution, since it involved limiting the dispersal of GMOs in the environment. Another implicit consequence of the proposed strategy for co-existence was a recognition that GMOs were here to stay: the question now was how GM crops should be introduced and under what circumstances, not whether GM crops should be grown at all.
The Liberal-led Government saw a possibility to bypass the fundamental questions of the risks of GM crops and instead to focus on the management of GM crops in economic terms. Co-existence is regarded as solely a management issue, where solutions to any problems can be found. The Liberal-led Government was proud that Denmark was the first country to publish a major study on co-existence problems and possible solutions, including attempts to devise cultivation protocols for segregation. Denmark hosted the first Europe-wide conference on co-existence in November 2003.

The basic idea behind co-existence is that two or three production systems can be managed independently of each other at the same time. But the management of co-existence is not an easy task. It opens up a whole range of complicated issues such as separation distances and buffer zones, labelling and traceability, thresholds and liability. Thus the re-framing of GM policy around the idea of co-existence broadened the boundaries of politically-relevant uncertainties.

NGOs argued that the whole idea of co-existence between GM crops and non-GM crops is unrealistic. In their view gene-transfer from GM fields to non-GM fields (both conventional and organic) is inevitable. This raises a fundamental question of acceptable thresholds for GM presence in non-GM products. Industry and agriculture would like to establish a feasible threshold. By contrast, the NGO coalition holds that ‘GM-free’ should mean 100% GM-free seeds and a free choice between food produced with or without any GMOs. Despite criticising the basic idea of co-existence, the NGOs invited to join the group of stakeholders contacted to discuss the co-existence work decided to participate in order to influence the work.

The NGOs demanded rules concerning liability for any environmental harm to biodiversity originating from GM crops, and for any economic loss suffered by growers of non-GM crops, since no such liability rules existed at national or EU level. This stance was subsequently adopted by the GMO-cautious majority in Parliament, which forced the Liberal-led Government to advocate that the EC’s draft Liability Directive (which, when finalised, became 2004/35/CE) should be extended to cover harm from the GM grower, and any harm to the environment, not only to ‘protected areas’.

After Denmark was outvoted on this issue at EU level, in June 2003, the GM-cautious majority forced the Liberal-led Government to uphold the de facto moratorium until the Commission has proposed or implemented a motion to change the liability regulation to cover compensation and liability from GMO production, including harm to the environment. Thus the GMO-cautious majority again made an implicit link between co-existence and precaution, since strict liability regulation would involve strict measures to limit the dispersal of GMOs in the environment.

As a result of these demands, and because the European Commission’s guidelines of July 2003 devolved responsibility for the issue of liability to the national level, the Liberal-led Government was forced to incorporate the liability issue into the Danish strategy for co-existence, which is still being negotiated in March 2004.

Restructuring expertise

The main development in the risk regulation system in Denmark has been the increased emphasis on a separation between scientific expertise and decision making, as recommended by the EU. Thus several efforts have been made to separate risk assessment from risk management.

In May 2000, responsibility for the environmental risk assessment of GM crops was transferred from the Danish Forest and Nature Agency (DFNA) to the National Environmental Research Institute (NERI), an independent research institution under the Danish Ministry of Environment, as a consequence of the EU recommendations. This step could be regarded as broadening the expertise for the environmental risk assessment, as the NERI staff come from a broad range of different scientific disciplines such as agriculture, ecology, and social science.
It has been more difficult to make the same separation for food safety issues, including toxicological issues. Several efforts have been made with the help of different stakeholders but, until 2003, without much success. The Minister for Food and DCC preferred the existing so-called ‘integrated model’, where research is closely connected to the political and administrative system and thus facilitates quick reactions and decision making.

But when forces outside this forum – the Liberal-led Government – decided to make research by the research institutions more cost-effective, the Institute for Food and Veterinary Research was created by combining two smaller research institutions. At the same time it was decided to separate risk assessment and risk management, which meant that the Institute for Food and Veterinary Research will be responsible for risk assessment and the Danish Food Directorate for risk management and control.

No institutional changes were made in relation to agricultural scientific advice. The Danish Plant Directorate (DPD) is a directorate under the Danish Ministry for Food and thus part of the political/administrative system. No changes have been made, despite the fact that the scientific advice from DPD to DFNA is sent through the Ministry for Food, thus opening up an opportunity for political influence on the advice.

Despite the institutional changes, advisory practice has continued largely as before. Theory is one thing and practice is another. In the assessment of product files for market release of GM crops, NERI and sometimes DPD have made close links between risk assessment and risk management. The scientific advice has addressed not only the potential risks and uncertainty but also measures to reduce risk, i.e. risk management (see section on product files).

There are several reasons for this linkage. It is difficult to make a clear distinction between risk assessment and risk management for post-release monitoring of GM crops; such a separation in specific product files would limit the relevance of the advice. Another reason might be that the scientific advice might comment on possible options for monitoring according to the Deliberate Release Directive, which states that monitoring should be linked with the risk assessment. It would in any case be up to DFNA whether or not to follow the recommendation.

Stakeholders, especially NGOs, have demanded greater openness and transparency in decision making as a precautionary approach. They argue that transparency in the decision making in the risk assessment, including the judgements on how uncertainty and evidence is evaluated, should be the norm. Otherwise, these social judgements are hidden in the scientific advice.

The relation between risk research, risk assessment and risk management has changed from being mainly sequential (risk informs risk assessment, which in turn is the basis for risk management judgements) to being more interactive. Risk management, especially post-release monitoring, has emerged to deal with the remaining uncertainty and thus becomes risk research. But this development further complicates the political effort to separate risk assessment and risk management, since value judgements frequently also enter risk assessment, although without being called such.

The Liberal-led Government has closed 18 environmental boards and councils. Among those closed was the (Danish) Nature Council, which played a relative large role in setting the national agenda for the sustainable development of wildlife, the environment and landscape by focussing on a cautious, broad and far-sighted context (including GMOs). It thus was often seen as challenging Government analyses and proposals, which was the main reason that its funding ceased.

Denmark has opposed the centralizing of responsibility for risk assessment in the negotiations about the establishment of the European Food Safety Authority (EFSA) and in the negotiations about GM food and feed regulation. Denmark doubted that EFSA would have sufficient competence to cover the ecological and environmental differences of the regions of EU, unlike the national CAs. So far, Denmark has been out-voted at the EU level. From the public debate in Denmark it is apparent that
citizens generally do not trust decisions taken by an EU expert body. The Liberal-led Government finds it a prerequisite for the public acceptance of GM products that their risks must be assessed on the basis of knowledge about national environmental conditions.
1 Introduction

Denmark has a long tradition of developing policy by consensus, by involving the main interested parties in negotiations until a solution is reached that is acceptable to most of them. This approach expresses democratic aspects of Danish political culture, where policy-making has been less confronting than in many other EU member states. One reason for this consensus-seeking is that no political party has had an absolute majority in Parliament in fact since 1909. A majority has to be built only through open negotiations among several parties.

Danish environmental policy has traditionally been based on a combination of a consensus-seeking policy style, negotiating overall guidelines and standards with representatives from peak business and environmental or consumer interest organisations. With coalition minority Governments and rather frequent elections (13 in the last 31 years) political stability has often been sought by political compromises and settlements.

This tradition has been changed after the election in November 2002 where a new Liberal-led Government could govern alone with the support from the ultra right wing party Danish People’s Party without support from the so-called middle parties.

In the late 1990ties GMOs has been an key issue for a public debate. The continuing pressure from this debate, the environmental NGO's and many questions raised in Parliament together with the rapid development in biotechnology, product development and international trade in this area has forced the Minister of Environment to enter into an voluntary agreement with the Agricultural Council of Denmark, the Confederation of Danish Industries and the seed companies DLF Trifolium and Danisco in November 1998. The agreement sometimes called a moratorium stated that no GM crops would be marketed in Denmark in 1999 and that only large-scale demonstrations plot of GM fodder beet would be sown in Denmark.

As a follow up on this agreement, NOAH, Greenpeace and the Danish Society for Nature Conservation advocated for a three year moratorium for all deliberate releases of GMOs, sale and import of all GM products in EU because of the documented risk with deliberated releases of GMOs for the environment and human health and an openly inadequate regulation in EU.

The Social Democratic-led Government also worked on the EU level to tighten up the regulation on GMOs – the Minister for Environment on the environmental regulation and the Minister for Food on the labelling issues.

The Social Democratic Minister of Environment followed the line from the national scene as Denmark was among the 5 member states behind the so called de facto moratorium – these 5 member states made up a blocking minority in the Council for Environmental Ministers. By the lead of France, 4 other member states Denmark, Italy, Greece and Luxembourg issued a declaration in June 1999 that they would effectively block new GMO approvals until the European Commission proposed legislation for traceability and labelling of GMOs and products derived therefrom.

The Social Democratic Minister for Environment also were in favour of tighten up the Deliberate Release Directive as it included measure in good line with the Danish restrictive policy (e.g. broader risk assessment, time-limited market authorisations for GM crops, a requirement for post release monitoring linked to the risk assessment and the phase-out of at least some antibiotic resistance marker genes).

Following the revision of the Deliberate Release Directive regulating the release of GMOs into the environment (Directive 2001/18/EC repealing Directive 90/220/EEC, adopted by the European Parliament in February 2001), these five countries, again declared that they would not lift the moratorium until the issue of traceability and labelling has been resolved.

The Social Democratic Minister for Food were in favour of better labelling of GM crops (processed based rated than product based) and favoured even meat and milk
from animals fed up on GM materiel to be labelled. Traceability were also seen as a way to tighten up the regulation, also from an environmental point of view.

After the election in November 2002 a new the Liberal-led Government came into power and supported by Danish People's Party has made large cuts in spending on environmental policy making in order to find extra money for improvements in hospitals and elderly care and new tax breaks for business. Funding for 18 environmental boards and councils has been closed down including the Danish Nature Council. In the public debate many of these boards and councils has played a relative large role in their field of interest. They have often been seen as less prejudiced than the ministries and have therefore often been used to challenge the Governments analysis and proposals.

The environmental administration has been particularly hard hit as one in seven has been cut wiping out 420 jobs. The Danish EPA has been cut one in 5. At the same time the Liberal Minister for Environment has established the Environmental Assessment Institute with the purpose to ‘get the most environment for the money’. And the Government has appointed the widely criticised Danish statistician Bjørn Lomborg as Director. Lomborg is author of the much criticised tome ‘The Sceptical Environmentalist’ which claims that many of society’s concerns about the environment are ‘phantom problems’ created and perpetuated by the environmental movement for its own ends. In the book, Lomborg claims that ‘the precautionary principle is actually all about making worse decisions than we need to (Lomborg, 2002).

This development have had an impact on the GMO issue in general. On the other hand, a new what could be called GMO-cautious majority in Parliament has emerged as the Danish People’s Party, which in general form the basis for the Liberal-led Government, has joined the oppositions more restrictive line on GMO issues including GM crops. The GMO-cautious majority has forced the Liberal-led Government to act against it owns will in several cases and thus Denmark has continued a restrictive development of GM crops on the national and EU level. The GMO-cautious majority for instance forced the Liberal-led Government to introduce a Danish co-existence strategy between GM and non-GM crops and to demand stricter liability regulations in EU.
2 Use of the precautionary principle

The term precautionary principle (PP) has been used several times in national debates on for instance environmental issues, questions of food safety and questions of the safety of chemicals. The term has been used in various ways dependent on the subject. In some cases as a special case of demonstrated scientific uncertainty and in others as considerations beyond science. Denmark has also used the principle on the EU level on the same questions and pushed for its wider use in EU regulation. But the PP as such has only been loosely defined in these debates and has been used in different manners depending on the matter in question.

Thus, on May 29, 1998, the Danish Environmental Protection Agency arranged a conference with focus on the meaning and application of the PP: How much care is needed if scientific uncertainty arises about an action which could have a detrimental effect on the environment? The question is addressed from 4 different angles: administrative, technical and economical, and social. The objective of the conference was to encourage a technical debate on how we apply the PP to the environment.

The Danish EPA concluded, that the conference provided no clear answers and no easy solutions; the issue is too complex for this. However, in general there was broad agreement amongst the presenters and during the debates that the PP must be regarded as a political norm for both legislation and administration, and that application of the PP demands a great deal of openness (Danish EPA, 1998).

But on the conference a disagreement showed up between the Danish EPA by its director Erik Lindegaard and the Institute for Food Safety and Toxicology by its director Ib Knudsen. Mr Knudsen emphasised that the PP is definitely an instrument to be used in risk management and it is inextricably bound to those tasks: 'The precautionary principle can be used when, in a given situation, we do not have a quantitative risk assessment, when we are unsure of the scientific data, and when science still can not offer a certain answer that can shed light on what has been called into question based on the current methods' (Knudsen, 1998). Mr Lindegaard emphasised on the other hand that the PP also could be used in the more specific use of scientific uncertainty in risk assessment (Danish EPA, 1998). However, this disagreement was not mentioned in the conclusion from the conference.

There has only been a little awareness among stakeholders on the precautionary principle. Many stakeholders makes no clear distinction between the precautionary principle and a precautionary approach. The debate on risk regulation has only been framed by a few stakeholders with reference to the PP/precautionary approach.

2.1 Government and the precautionary principle

In general, the precautionary principle (PP) is not referred to directly in Danish environmental law, but the line of thought is often detectable. For example in the Environmental Protection Act – which refers to probable effects – and in the Chemical Substances and Products Act – which refers to substances and products that are presumed to be hazardous to health or harmful to the environment. This means that there is no legal specification of the use of the PP and that one of the reasons why the PP have been contested. Thus, the concrete application of the PP remain dependent to the matter in question and in the end the value judgments of the responsible authorities.

The Danish EPA distinguish between risk assessment, that is used when there is a scientific foundation for calculating the probable number of deaths resulting from a particular activity over a 10,000-year period and risk control when there is a deliberate modification of activities so that the calculated number of deaths during the same period becomes acceptable. The precautionary principle can be applied in situations where such calculations cannot be made. Thus even if one cannot justify application of the principle on the basis of calculations, one can still identify some central elements of the precautionary principle.
According to the Danish EPA the six most important elements of the principle are as follows (Lindegaard, 1999):

1. It requires positive action. The logic of technological and economic development entails that we are continually being brought into an increasing number of potentially problematic situations. An example is the legislation on genetecology passed in the 1986.

2. When there is scientific uncertainty pertaining in a specific situation – an uncertainty which can be greater or lesser, but which nevertheless makes someone consider whether action needs to be taken before a possible problem is fully elucidated. The crux of the matter here is that scientific uncertainty is not sufficient grounds for refraining from action. An example is the depletion of the ozone layer.

3. How great is the damage risked if we do not act? Here the question of reversibility plays a central role. Is the damage involved of a type that we can rectify, or are the effects of a type that will permanently affect our nature?

4. Voluntary or not – have we subjected ourselves to a potentially hazardous situation voluntarily? For example, we have a completely different attitude to what risks we are willing to run when the decision is our own such as with respect to smoking and travelling by car than when we open the tap to take a glass of water.

5. When should the principle be applied? If the price of using it in a specific situation is very high, one should consider whether it is worthwhile. In this sense the principle can be compared with an insurance policy. When one applies the principle it is exactly in order to prevent the accident from occurring in the first place.

6. Openness is decisive. Scientists, authorities, enterprises, organizations and politicians will have to openly acknowledge how much they know and how much they do not know.

Finally the central point is, that the precautionary principle is a political principle, involving attitudes and ethics, and it is a principle that it is difficult to avoid using because whatever happens, decisions have to be made – also when the experts are unable to provide us with clear answers.

The Commission have attempted to standardize criteria for the PP in the Commission Communication on the Precautionary principle. Measures based on the precautionary principle should be, *inter alia* (CEC, 2000):

- proportional to the chosen level of protection,
- non-discriminatory in their application,
- consistent with similar measures already taken,
- based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- subject to review, in the light of new scientific data, and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

These criteria seems to be in line with the interpretation from the Danish EPA. The Danish EPA did not made any comment on the communication and have never made any guidelines for use by government departments on the use of the principle. The only thing they did was to send a copy of the Communication to the Danish Parliament which neither made any comments.

In relation to risk and PP in GMO regulation, the Ministry of Environment states in 1999: ‘In risk assessment the PP should be leading in each case. A risk assessment is made in each case covering the effects on nature, environment and human health.'
If it is a crop an assessment of whether use of the crop could have a negative agricultural impact should also be made. What is meant with the PP is not defined. It is only stated that 'the precautionary principle is a central point in the regulation of the application of modern biotechnology. The main rule must still be that any application requires prior authorisation' (Danish Nature and Environment Policy, 1999).

The Danish Forest and Nature Agency (DFNA in Danish Skov- og Naturstyrelsen), that have the overall responsibility for the regulation and act as the Danish Competent Authority finds that precaution has always been the basis for the administration of the gene technology act (DFNA, 2002) as in general with the whole environmental legislation (MPU, L 131 – bilag 14, 23/2002). Although the precautionary principle has not directly been mentioned in the old Danish genetecnology act DFNA has acted with precaution in the assessments of applications. So for the agency, mentioning the PP in the revised genetecnology act would not change the administration of the act. The agency have consulted the Danish EPA, which is responsible for the administration of the PP in general environmental policy.

In 2002 the Institute of Food Safety and Nutrition (formerly Institute for Food Safety and Toxicology) again stated that the PP is especially relevant for risk management (as in 1998, see above). The PP is part of the political assessment on whether a crop should be approved (under certain conditions) or not on the basis of the risk assessment from the scientists especially in relation to the uncertainty that exist from a scientific point of view. The problem with the use of the PP is that a risk assessment 'always will contain uncertainty and that it is very seldom that this uncertainty could be quantified' (Pedersen, 2002).

2.2 Industry and the PP

Generally, industry rely on the regulatory system and have an ongoing dialogue with regulators. If regulators want more information on a special subject in connection with their risk assessment of a certain product then these information is provided.

Danisco together with the Confederation of Danish Industries was part of the national voluntary agreement concerning growing of GM crops in Denmark in 1998. Although they did not agree readily they could see a favour in being seen as acting responsibly toward GM crops. On the other hand they feared that the agreement might be perceived as a moratorium that would be difficult to reverse (ENDS Daily, 30 November 1998).

As the de facto moratorium later also was decided at the EU level in 1999 this exactly were what happened. Especially Danisco has been trying to reverse the moratorium by announcing that they would be ending all its operations in plant biotechnology (Nature Biotechnology, Vol. 18 p. 139, February 2000). This announcement was repeated in spring 2002 when Danisco stated, that it have lost faith in the future of GM crops in Denmark. Thus, Danisco has given up its scientific research into genetically modified sugar beets as they do not wish to market a product that would be unacceptable for the food market. But at the same time they together with Monsanto and DLF Trifolium maintained their application to the European Commission for approval of European use of the GM fodder beet as this product is targeted at the feed market.

DLF Trifolium has chosen another strategy than Danisco in the hope that things would change. They decided to conduct extensive field releases of GM fodder beets during 1999 and 2000 in order to gain knowledge about agricultural practices and to assess its environmental impact compared to conventional fodder beet. The latter was conducted by NERI who investigated the effects of growing fodder beets on biodiversity, especially on weed flora and arthropod fauna. These trial were partly funded by Monsanto. DLF Trifolium has also decided that before marketing the GM fodder beet on the European market that would carry through an economic analysis in order to find out whether there would be money to earn from marketing the GM fodder beet (Danish newspaper Børsen, May 26. 2003).
For Danisco precaution is already in place in the regulatory process for GM crops. The PP is viewed as a requirement for GM crops to undergo a prior authorisation procedure (case by case assessment and step by step) and has the full support from Danisco. But Danisco would like to see a common set of clear criteria for its use in all EU Member States. Thus, in practice it would be up to the regulatory authorities to consider the precautionary principle.

Concerning the fodder beet Danisco holds that an adequate risk assessment has already taken place and that there is no need for further actions based on the precautionary principle (Danisco, 2002). The reason for this is that no evidence of harmful effects exist of the marketing of GM crops and that the growing of GM fodder beet might be better for the environment (biodiversity) than conventional fodder beets. The director for DLF Trifolium has stated: ‘It is difficult to see that it would be possible to approve anything if the GM fodder beet could not be approved’ (Danish Newspaper Information, August 10, 1999).

This is in line with the position of Danisco and the Danish Association of Biotechnology Industries that they see no need for the proposal for monitoring in 7 years during commercial use, as this only increases the risk that the biotechnology industry takes without at the same time contribute to an improvement for the human health and of the environment (Danisco, 1998).

Both Danisco and DLF-Trifolium argued in the marketing application for GM fodder beet that no specific measures had to be anticipated as there is no risk. ‘Cultivated *B. vulgaris* varieties are not invasive, are weakly competitive outside cultivated areas, and possess few weedy characteristics. Furthermore, volunteers of bolting beet plants are readily managed using current agricultural practices including herbicides (other than glyphosate), hand weeding, and cultivation’. Thus, ‘as no specific adverse effects or uncertainties – which should require case-specific monitoring – were identified, the objective of the monitoring plan should be general surveillance which seek to identify and record any indirect, delayed and/or cumulative adverse effects which have not been anticipated in the risk assessment (SNIF, RR fodder beet derived from Line A5/15. January 15, 2003).

### 2.3 Farming organisations and the PP

Organisations representing farmers in Denmark has since the very start had different approach to GM crops and thus precaution:

- **Danish Agriculture** (who represents the major part of all Danish farmers and affiliated to COPA, where the national president is also the president for COPA) regards GM crops as fundamentally desirable and valuable as a supplement to the traditional methods for breeding plants and has as a consequence always been in favour of commercialisation of GM crops. Precaution means that GM crops had to undergo thorough risk evaluations before they are marketed.

- **The organic farmers organisation, the National Union of Organic Farmers (NUOF)**, regards GM crops as a threat to organic agriculture as there exist a substantial doubt about the risks and has as a consequence always been against any commercialisation of GM crops. The main reason for this stance is that NUOF would like to design new systems on the basis of visions about new social and cultural systems, and in such systems real precaution means that organic agriculture is the only existing alternative.

These different approaches to GM crops is seen in the approaches to coexistence of different types of agriculture: Danish Agriculture have called for decisions as to separation distances, monitoring programmes, documentation and labelling in connection with marketing approvals for GM crops (Landbrugsrådet, 2000a). NUOF claim that they have a right not to be contaminated with for instance GM pollen with reference to the ‘polluter pays principle’. Thus it is the grower of GM crops that had to pay if any problems occur from neighbouring fields.
In fact, NUOF is a member of Danish Agriculture, where they traditionally only have worked with issues related to organic production, for instance on the position of Danish Agriculture to organic farming (NUOF, 2002): Danish Agriculture recognize, that organic production makes a major contribution to the variety of agricultural produce and that organic production is one of the factors that give consumers alternatives. Besides, organic production is absolutely in keeping with the aim of the entire agricultural sector of environmentally sustainable agricultural and horticultural production. Danish Agriculture finds furthermore that in future organic production should rest on the demand of consumers and not depend on political regulation.

Today, 175,000 hectares are farmed organically on 3,800 organic farms, corresponding to 7 percent of the total Danish farmland. Denmark is one of the top-five countries in Europe as regards the organic share of the total cultivated area. In organic agriculture genetically modified organisms (GMO) are forbidden in animal feedstuffs and in connection with plant production and processing. The reason for this ban is the position of NUOF (NUOF, 2002).

For Danish Agriculture precaution is seen as a requirement for GM crops to undergo thorough risk evaluations before they are released into the environment and before they are marketed. This is to ensure, for instance, that GM crops do not spread unwanted properties to weeds and wild relatives and do not affect the health and welfare of human beings. In the regulatory process it is the regulatory authorities that have the responsibility that no GMOs are marketed with such undesirable effects. When GM crops has been approved, farmers will be able to manage GM crops with precaution if necessary (DAC, 2002).

From this perspective Danish Agricultural Council of Denmark (DAC, a joint committee for the Danish farmers’ associations, Federation of Danish cooperatives and professional organisations representing the cooperatively owned part of the food industry, as well as part of the privately owned food industry) was part of the voluntary agreement reached with the Minister of Environment and Energy Svend Auken in 1998 (Miljøministeriet, 1998a). According to DAC, this agreement contained elements of precaution and management: Monitoring of agricultural effects of agricultural practices in large-scale demonstrations plots and development of a codex for Good Agricultural Practice by growing GM crops in Danish agriculture (DAC, 2002).

The Codex for Good Agricultural Practices is a set of voluntary guidelines for what a farmer should consider before growing GM crops. These guidelines is a set of measures the farmer should take in order to avoid or minimize that growing of GM crops causes problems to other farmers or in his own rotation of crops, for instance registration of variety name in the growing journal, physical separation between GM-crops and non-GM crops, clear labelling of seeds, contact to neighbours growing for instance organic crops or other special crops in order to discuss for instance spread of pollen, to fight volunteers in succeeding crops, careful treatment of GM crops in order to maintain the fauna as much as possible – for instance a delay in spraying with herbicide as much as possible (Landbrugsrådet, 1998a).

Specific in relation to PP DAC has welcomed the new guidelines from the Commission (CEC, 2000) as it have the right balance between precaution and action. In their comments DAC have focussed on the PP in relation to food: DAC specially pointed out that the PP should only be used in cases where the scientific based risk assessment does not identify a reasonable hazard for the safety for consumers. Finally, DAC were also satisfied with the fact that the actions to be taken should be seen together with the ‘real’ risk for the consumer – the principle of proportionality (Landbrugsrådet, 2000b).

Furthermore, DAC have been working in order to get IFAP – the International Federation of Agricultural Producers – to adopt a common position for the use of the precautionary principle, but it has been very difficult to get support for this from farmers outside Europe.

For NUOF, precaution or the PP is regarded as a set of values to be taken into consideration in the case of GM crops in contradiction to so-called pure science. The
attitude in NUOF is that if there exists any doubt about negative effects of a given product, then one must dare to say no. NUOF believe that there exist a risk with GM crops, that one shouldn’t take as for instance unforeseen consequences to the environment and human health (NUOF, 2002).

Moreover, use of GM technology is incompatible with the fundamental principles and values of organic farming: In organic farming the interaction between Nature and Man is an important ingredient of the philosophy. ‘The precautionary principle in organic farming can therefore be justified as recognition of our limited understanding of Nature and the risk that we damage something of which we are ourselves a part. Thus, environmental problems are not only solved through the acquisition of more knowledge and technology, but also through an increased recognition of the ignorance associated with technology, the avoidance of risky technologies (characterised by their unpredictability, which means that the knowledge on which they are based carries with it a considerable amount of non-knowledge or ignorance), and the continued use of production systems that experience has shown to function well’ (DARCOF, 2000).

Thus the future for NUOF is mainly about how to avoid dispersal of GM crops to different fields or being mixed with organic crops (NUOF, 2002). In fact, the rapid development of GM crops was the reason why NUOF in 1999 decided to take more active part in the public debate on GMOs. Organic farmers also see themselves as part of the society and not only as farmers. As organic farmers have the same type of objections as the environmental NGOs and the consumer organizations it was natural for them in order to find allies in the polarized debate on GM crops.

NUOF is on the other hand also pragmatic in their stance. The prefer to use the term ‘produced without GMOs’ instead of the term ‘do not contain GMOs’ as this term indicate, that the (organic) producer has prevented to use GMOs in the production. In order to fulfil this demand, the NUOF took the initiative to set up a voluntary action plan (signed by the Agricultural Council, NUOF and other representatives form the organic sector and all the 7 feed companies selling organic feed to farmers) in order to secure GM-free fodder for the organic farmers by preventing any GMO in the fodder:

From December 1, 2001 the feed companies agreed to introduce an effective control of raw material from all imported lots of soya, maize and rapeseed and to introduce their own control programme in order to prevent any contamination from the handling of feed for the organic farmers. In order to test the reliability of the companies own control the Danish Plant Directorate will make spot test on the feed (Økologiens hus, 2001). In EU, Denmark is the only country with organic production that is subject to State inspection.

2.4 NGOs and the PP

In general, NGOs regard precaution as an approach and not just a special decision to be triggered. This could be seen by the fact that NGOs rarely use the term precautionary principle at the same time as themes in the debate on environmental risk relates to a precautionary approach although this is not always the wording that is actually used in practice.

In fact, only one NGO has directly taken a stance to the guidelines from the Commission (CEC, 2000). This stance is based on regulations of chemical substances, which for several years have been in focus in the Danish environmental debate, a debate where also the precautionary principle has been in focus. For the Ecological Council, the precautionary principle means 1) early action on the basis of reasonable suspicion of harm, even if a scientific uncertainty exist, 2) that reversal of the burden of proof – this does not mean that the producer have to prove that a certain product is without harm, but that they should be able to reject a positive and reasonable doubt, that has been raised about a certain product, 3) that all information and decisions should be transparent for the public and 4) assessments of alternatives should be made in order to give a real opportunity to choose the less harmful decision (Nielsen, 2001).
This stance is dealt by several NGOs and thus it could be seen that NGOs interpret the PP/precautionary approach in much broader terms than for instance the Danish EPA, industry and DAC. On the other hand NGOs understand the PP/precautionary approach in different and even sometimes conflicting ways.

NGOs have been critical to the existing framework for regulation of risks from GMOs. NGOs criticise the regulatory focus on risk and the approach to risk in risk research, risk assessment and risk management. Different NGOs have been concerned with issues like the safety of GM crops, the lack of independent risk research, the lack of focus on uncertainties in the scientific risk assessment, the lack of openness and transparency in decision making, the lack of recognition of broader societal concerns (including the socio-economic costs and benefits) in the consultation process and the lack of ways to consider the alternatives to GM crops in the existing framework.

The Danish Consumer Council (DCC) wants a paradigm shift, a move from having risk assessment and the application of the precautionary principle based solely on the rationale of natural science to having it based on interdisciplinary science as the public has lost faith in assessments based purely on so-called Sound Scientific Evidence. DCC has called for new models, models using a wider perspective on risk assessment and models which place science within a larger social setting and which give the public the opportunity to voice their opinions on risk assessment (Nedergaard, 1998).

Public assessment of risk includes social justice, ethics, potential consequences to the development of society and indirect effects on the environment and wildlife, just as it includes an overall assessment of the balance between risk and potential advantages in a wider social sense. It is also crucial that stronger public participation become an element of risk assessment (Nedergaard, 1998).

The DCC has even called for the inclusion of legitimate factors other than science to be included in the process of risk assessment, for instance the usefulness of a given GM product. The DCC finds that the order of priority of research in GM crops should be changed in order to improve the interdisciplinary research, research where the consumer aspects are dealt with and research in a more concrete use of the PP (DCC, 2002).

Several NGOs links precaution with liability as this would change the burden of proof from the authorities to the applicant (see for instance Greenpeace, 1999). Introduction of liability would mean that all the economic costs in a worst case scenario should be paid by the applicant according to the polluter pays principle. Furthermore, liability would also mean an assessment of the economic risk in a given project (www.gendebat.dk).

Most NGOs link precaution directly with uncertainty. Important uncertainties mentioned is science itself and the environmental effects like effects on biodiversity in farmland and nature and change in pesticide use as a consequence of the GM in-built pesticide resistance strategy (herbicide tolerance and the development of insect-resistant GM crops). This uncertainty together with socio-economic effects on the future farming systems and on the effects on the organic farming system means that some NGOs like NOAH and Greenpeace finds that marketing of GM crops should be stopped immediately on precautionary reasons while other NGOs like DCC find these uncertainties (or part of them) preliminary and thus to be solved by further research.

In fact, all NGOs opposed the GM pesticide resistance strategy (including both herbicide tolerance and insect tolerance) as a wrong strategy with major environmental impact. DCC oppose as no independent demonstration exist on the benefits for the environment whereas NSCN, Greenpeace and NOAH oppose as they see it an agricultural intensification as a wrong strategy for the future sustainable agricultural system as it continues to be dependent on chemical treatment of weed and the following risk to make crops resistant to broad spectrum herbicides (Greenpeace, 2002 and globalegener.dk).

Some NGOs like Greenpeace find the risk from GM crops unpredictable (e.g. the possibility of transfer of pollen to other related varieties and loss of diversity in the
fields), and precaution thus means prevention and elimination of contaminants at source. Zero input levels for substances suspect to harm the environment should be a firm objective (Greenpeace International, 1996). Thus no GM crops should not be released into the environment as precaution emphasise the little-known impacts of GMO releases on the environment and the unpredictable and inexplicable risk of GMOs (Greenpeace, 1998).

Other NGOs like the National Society for the Conservation of Nature (NSCN) have called for more stringent requirements for safety testing as ‘a real precautionary approach’ to regulation of GM crops. For instance, the uncertainty with dispersal of pollen is too big at the moment to approve any GM crop where such dispersal could take place. For the NSCN, even a minimal risk for dispersal of pollen from the fodder beet to the sea beet should be basis enough not to approve it with clear reference to precaution. Bt crops are not even under discussion as the uncertainty is too big now and in the long run. Furthermore, resistance to Bt could destroy the use of Bt by organic farmers (NSCN, 2002).

Furthermore, NSCN finds that the precautionary principle should be used strictly. That means that a risk exists as long the opposite is not dealt with in a convincing way. The reason for this view is that with genetechnology one deals with a fundamental ‘technology jump’ where the barriers between species is crossed, barriers that could not be crossed beforehand. That means that new genes escape in new environments and that they could not be recalled (irreversible). Thus, risk assessments are uncertain and precaution are needed (NSCN, 2002).

In practice, risk assessments should reflect realistic scenarios (for instance growing of big areas of HR crops) and not only ‘case by case assessments’. The effects of releases on neighbouring grown fields and related derived growing problems should be part of the risk assessment together with the effects on the natural ecosystems (NSCN, 2002).

For several NGOs a precautionary approach also mean transparency and openness in decision making and the need to emphasise alternatives to the GM solution. NOAH has consistently advocated for more openness and transparency on uncertainty and decision making in the risk regulation as part of an precautionary approach. NOAH has also been involved with several initiatives to inform the public about the development in the GM fields as the authorities did not give any information about field releases in Denmark.

Thus, NOAH together with other NGO’s decided to open a special internet portal www.gendebat.dk in the spring 2000. This site made it for the first time possible for citizens to get information on whether they were living near places where field releases took place (all field releases were placed on a map) and if, to find further information on the actual field trials. Also information on the different GMO marketing applications and GMO food applications were traced at the site in order to give the public an overview over the current development and on the conflicting views on these.

In this way it was disclosed, that the general the amount of field releases in Denmark has declined substantial since 1999. In 1999 field releases of 5 GM crops took place at 39 plots in Denmark: fodder beet (20), sugar beet (14), rape seed (2), potatoes (2) and maize (1). In 2000, field releases of 4 GM crops took place at 19 plots: fodder beet (10), sugar beet (1), rape seed (6) potatoes (1) and maize (1). In 2001, field releases of 2 GM crops took place at 7 plots: fodder beet (6) and sugar beet (1). In 2002 and 2003, field releases of only 1 GM crop took place at 1 plot: fodder beet (after www.gendebat.dk).
3 Three institutional practices

3.1 Regulatory measures

In the regulatory procedure in Denmark the Ministry for Environment has drawn mainly on in-house expertise combined with a public consultation process for making safety judgements on GMO releases. But in the year 2000 the responsibility for performing ecological risk assessments were transferred to NERI an independent research institute under the Danish Ministry of Environment. Since then NERI has had an key role in environmental risk research, environmental risk assessment and risk management.

Together with the implementation of the revised Deliberate Release Directive with its demand for data for a broader risk assessment and eventually plans for post release monitoring this meant that the relation between risk research, risk assessment and risk management has been changed. Formerly the relation could be described as more sequential that interactive, e.g. that risk research informs risk assessment which again are the basis for a risk management judgement, and in line with the step-by-step procedure of the old Directive where one step had to be evaluated as safe before the next step could be taken. But interactive in some cases as the authorities demanded more research and broader risk assessment before regulatory decisions on herbicide tolerant GM rapeseed (Toft, 2000).

This relation between risk research, risk assessment and risk management has changed to be more interactive than sequential. In performing risk assessment the expert body use knowledge from risk research, but could also create a demand for more research to be conducted to answer questions that has not been answered in a sufficient way and this is a value judgement. Risk management especially the post release monitoring has emerged in one way to deal with remaining risk and uncertainty and in this way risk management becomes risk research. In this way the political effort to separate risk assessment (science) and risk management (value judgement) are not separated in the real world as value judgements frequently also enter risk assessment although without being termed as such.

This new relation between risk research, risk assessment and risk management could be seen in the assessment of product files for field trials in other member states. NERI receive SNIFs from all field trials in EU through DNFA. In their comments, NERI focus on conditions that could be relevant for a later marketing release. In this way the member state where the product notification would be filed already would know at an early stage that a Danish objections could be made if some elements of risk had not been dealt with in a sufficient way or if suggestions in order to reduce risk has been overlooked. The comments relates to environmental aspects in Denmark of an release in other member states and eventually later of growing in Denmark. In fact NERI made specific comments on 25 of the 75 files for fields trials in 2003 (Kjellsson, 2003).

In this way NERI reinterpret the original step-by-step principle where a positive evaluation of the earlier step indicates that the next step can be taken. NERI now evaluates the different steps prospectively.

The new relation between risk research, risk assessment and risk management could also be seen in the development of the glyphosate-tolerant fodder beet. In this case NERI was invited as research institution to conduct what they found would be relevant research on the effects of biodiversity by growing the glyphosate-tolerant GM fodder beet compared to conventional fodder beet.

NERI is at the same time scientific expert body to DNFA in the ecological risk assessment on the marketing application of the glyphosate-tolerant fodder beet, where they perform a risk assessment and eventual proposals to risk management. In this case NERI has had an opportunity to conduct what they found relevant risk research before they were performing the risk assessment in relation to the
application for the marketing release. Presumably this research has created a demand for more research to be conducted before the final risk assessment could be performed as the marketing approval has been delayed by many month and is still waiting for approval in march 2004.

3.1.1 Risk research
The voluntary agreement between the Minister for Environment and industry and seed companies in November 1998 was announced as a precautionary measure in order to gain a breathing space in the rapid development (Toft, 2000). The time gained was announced to be used to procure some answers to the issues which has engaged citizens, farmers and politicians like What happens when you cultivate genetically modified crops in Danish fields on a larger scale? Does it influence flora and fauna more or less than the cultivation of conventional crops? Can it lead to a cut back in the use of pesticides and thereby reduce the environmental impact of agriculture?

In a not published annex to the voluntary agreement it is stated: ‘It is a common assessment of the herbicide-tolerant fodder beet that it could result in a real benefit for the environment as traditional praxis for the growing of fodder beets include spraying with several different herbicides but whereas the new treatment only imply spraying with one herbicide’ (Miljøministeriet, 1998b). But this annex were never send to the Parliament nor published together with the press releases probably because of its controversial content.

As a follow up on this agreement, NOAH, Greenpeace and the Danish Society for Nature Conservation advocated in a common letter to the Minister for environment for a three year moratorium for all deliberate releases of GMOs, sale and import of all GM products in EU. The idea behind such a moratorium was not an ‘extreme interpretation of the precautionary principle’ but born out of real, serious and documented risk with deliberated releases of GMOs for the environment and human health and an openly inadequate regulation in EU (Greenpeace, 1999).

Additionally, the 3 NGOs advocated for the following issue to be dealt with in the new directive:

- the precautionary principle to be implement ed directly in the goal of the directive
- introduction of an obligatory insurance (liability) – an economic precautionary principle
- the need for society should be taken into consideration along with an ethical assessment of its use
- a call to set up categories of traits, that is seen as unacceptable, for instance resistance against antibiotics, herbicides and insects
- a call for set up of realistic risk scenarios, including the actual and future risk
- a call for independent systematic risk assessments
- better information to citizens about the actual development
- more public involvement in the assessment of GMOs including the ethical aspects
- use of ‘Best Available Technology’ in the overall assessment
- more transparency
- a call for definition of ‘reasoned objections’ as reasonable uncertainties

Anyway, one result of the agreement was, that Monsanto, DLF-Trifolium and Danisco Seed ran demonstration trials with glyphosate tolerant fodder beets in Denmark in 1999-2001 in collaboration with The Danish Agricultural Advisory Centre, and NERI. Another result was, that NERI took the opportunity to conduct research on herbicide-
tolerant GM fodder beets as this research was partly funded by Monsanto. In this way the work on herbicide-tolerant crops, that has been undertaken in several years, were continued.

**Herbicide resistance and farmland biodiversity**

The lack of knowledge of the possible environmental effects of herbicide-tolerant crops has been in one of the key concerns expressed in the early 1990s by NOAH. Thus NOAH has argued for extreme precaution before any deliberate release of GM crops takes place (Toft, 1996). Because of these concerns the Danish EPA linked commercialization to precaution by promoting risk assessment research to clarify the plausibility of potential environmental effects. Thus the Danish EPA funded in the mid1990s some studies on herbicide-tolerant crops (especially oilseed rape but also beets) with the aim of investigating the consequences for herbicide use by using computer simulations (Madsen et al, 1994).

The result on oilseed rape showed different tendencies: The use measured in active substance has not been reduced compared to conventional growing with non-GM oilseed rape, but the frequency for treatment were substantial lower (Madsen KH and Streibig JC, 1999). NGOs like NOAH have criticised this research as being too narrow in scope and would have preferred a much broader view on the possible environmental effects and organic agriculture as another comparator (Toft, 1996 and Toft, 2000).

As a result of the voluntary Agreement between the Minister for Environment and industry and seed companies in 1998, the Danish EPA invited representatives from the Danish Agricultural Council, the Confederation of Danish Industries, the Danish Society for the Conservation of Nature, Greenpeace and the Danish Consumer Council to discuss the possible growing of GM crops in 1999. In 2000 another meeting was held as the last meeting to discuss the result of the first NERI study.

At these meetings, DLF Trifolium and Monsanto invited NERI to conduct relevant research on GM fodder beets. NERI suggested research focussing on the growing of herbicide-tolerant GM fodder beet and the effects on biodiversity (wildlife in or near fields) compared to conventional fodder beets. The aim of the study was to evaluate the hypothesis that the introduction of glyphosate tolerant beets might benefit the flora and fauna in beet fields without a reduction of the yield by comparison of the weed flora and arthropod fauna in conventional and glyphosate-tolerant fodder beet fields (Elmegaard and Bruus Pedersen, 2001). In this way NERI linked the design of their risk research with their interpretation for relevance to uncertainty and risk assessment. At these meetings no stakeholder made any link between risk and precaution (Miljøministeriet, 1999).

The study aimed at a comparison of the effects of conventional and glyphosate fodder beet management strategies on biodiversity. The results revealed that the implementation of glyphosate-tolerant fodder beets may increase biodiversity in beet fields in the early summer period. This improvement was indicated to rely on a delayed weed control. However in some fields the second treatment with Roundup Ready was delayed so long that yield was lost (Elmegaard and Bruus Pedersen, 2001).

The aim of the second study was to look at the relationship between the timing of the herbicide application (whether conventional beet herbicides or Roundup Ready) and biodiversity further and during the entire growing season. The results showed that the Roundup Ready treatments may result in significant improvements of weed flora and arthropod fauna during June and early July compared to conventionally treated plots but only if the first application of Roundup Ready is delayed relative to the application of conventional beet herbicides (Strandberg and Bruus Pedersen, 2002).

Late treatment also meant that as weeds are available in the field for a much longer period, a significant weed biomass built up for the benefit of the fauna in the field. The long period with weeds in the field did not result in any yield reduction the present year, but ‘the farmers’ readiness to accept weeds below the economic threshold for a
longer period will be decisive for the positive effect on biodiversity during early summer’ (Strandberg and Bruus Pedersen, 2002).

However, this benefit for the fauna in the field were lost after a second treatment with Roundup, in fact the weed density were even lower than in conventional beet fields. Moreover, GM crops might disturb the balance of weed species in fields, killing many in late summer before they can produce seeds. In this way weeds may not be as bountiful if glyphosate is sprayed year after year. The use of GM beet might favour weeds such as dwarf nettles, which are harder for glyphosate to kill, over weeds such as meadowgrass, which succumb quickly. This could have unpredictable effects on farmland biodiversity, and to conclude about the long-term such consequences of transgenic herbicide tolerant crops on arable land biodiversity it will be necessary to study the effects over several seasons in relevant crop rotations (Strandberg and Bruus Pedersen, 2002, Beate Strandberg, to Biotik.dk March 20. 2003).

NGOs has been sceptical to whether farmers in the real world would follow a commendation to spray later because of environmental concerns. NSCN sees farmers as very bound to tradition and thus it would be difficult to make them do things in another way than the already known way. So if farmers had to spray later with herbicides than traditionally to improve the biodiversity who will be able to guarantee, that the farmer in a rainy spring would not use the opportunity when it is there -- too early? Thus a code for good agricultural practices for GM crops has no value if it isn’t followed! In theory environmental benefits could exist but because farmers do not act optimal seen from an environmental angle they could not be trusted in practice (NSCN, 2002).

Some NGOs like NOAH has used the result from the UK Farm Scale Evaluations to state that it now has been shown that growing of GM crops have major effects on wild plants, insects and birds. It is very doubtful whether it will be possible to avoid ‘GMO contamination’ if GM rapeseed and GM beets is released on Danish fields. NOAH urged the Minister for Food to rewrite the Danish co-existence strategy (NOAH, press release, October 16, 2003).

Some experiences with field trials of GM herbicide-tolerant crops has also been collected. The field trials has included sugar and fodder beets, spring and winter varieties of oilseed rape and maize, which have been resistant to either glyphosate or glufosinate. In these field trials, the primary focus has been on 3 undesirable potential effects of growing herbicide-tolerant crops: increased problems with weed as a result from resistant weeds, increased use of pesticides and replacement of plants in the natural ecosystem through competition and to some degree on pollen transfer. Results from the trials show that these crops are similar to traditional varieties with respect to other traits than weed control. Herbicide-tolerant crops offer the potential for a more broad spectrum herbicide effect on both grass and broadleaf weeds and more flexibility with respect to timing of the application (Madsen et al, 2001).

The Danish Institute of Agricultural Sciences and Danish Agricultural Advisory Centre took part in the FACTT project FROM 1995-1999 (To promote Familiarisation and Acceptance of Crops Incorporating Transgenic Technology in Modern Agriculture) together with partners from France, Belgium, Germany, UK and Sweden (Madsen et al, 2001). One of the major aims of the FACTT project was to investigate the effectiveness of herbicide tolerance and the impact on herbicide management in oilseed rape production. Thus, growing of conventional and GM glufosinate-tolerant spring and winter varieties of oilseed rape were compared and the result 'confirm that there is no reason to believe that transgenic varieties will behave any differently than non-transgenic varieties' (FACTT, 2000). The results showed that transgenic spring or winter rape varieties performed equal to or better than non-transgenic varieties.

In Denmark some of these field trials were open for the public to see the experiments as on of the general objectives were to demonstrate and communicate agronomic practices for transgenic crops to direct-interest groups.
The herbicide link to groundwater protection

Pure drinking water has been a key issue in Danish environmental policy for many years as a consequence of an intense public debate that still goes on. In Denmark as one of the only countries it is possible to drink the tap water without any purification. For several years it had been a Danish policy that any pesticide found in the groundwater should be banned. In order to achieve this goal Danish environmental policy has sought to achieve substantial reductions in herbicide usage, partly so that groundwater still could be used directly as drinking water.

Thus, monitoring for pesticides and their metabolites has been conducted in the national ground water monitoring programme since 1990 in order to follow the development. In the beginning only a few substances were analysed for, but the number of substances has gradually increased and with that also the number of detections. In the last couple of years the counties have reported an increasing number of detections of glyphosate and in particular its metabolite AMPA. This substance has also been detected in the 'Pesticide warning' project (GEUS, 2002).

New data from 2002 now shows that glyphosate and in particular its metabolite AMPA has been found groundwater, although concentrations in drinking water did not exceed permissible limits, a presence due to its method of use in agriculture, where glyphosate is widely used. These new data forced the Minister for Environment to act in some way. After consultation with companies, that manufacture or sell glyphosate on the Danish market (Cheminova, Syngenta and Monsanto) he announced restrictions on the further use of glyphosate. From 15 September, autumn spraying of glyphosates will be banned on sites ‘where leaching is extensive because of heavy rain’. There are a number of exceptions to the new restrictions, which should be subject to revision after an interim consultation period.

Such restrictions could have a severe impact on the future of the herbicide glyphosate in Denmark in the first place but also world-wide as many countries look upon Denmark as a frontrunner in regulation on pesticides. Restrictions could also have a severe impact on the glyphosate tolerant GM crops as many of them could be worthless if the use of glyphosate is restricted in any way. This fact could be seen in the reaction from the manufacturers of glyphosate and from NGOs.

In a joint response, Cheminova, Syngenta and Monsanto, which manufacture or sell glyphosate in Denmark, deeply regretted the Minister of Environment’s decision to restrict the use of glyphosate in the autumn. Glyphosate could only be identified as a threat by ignoring ‘scientific findings and knowledge’, they stated. According to the firms, the restrictions appeared to be based on finding of glyphosate at one metre’s depth in the soil. This ‘can hardly – and only with the most narrow political intentions – be regarded as groundwater, and certainly not as drinking water’, they complained (Joint Press release Cheminova, Syngenta and Monsanto Jun 3, 2003).

Danish Agriculture characterised the Minister of Environment’s restriction of the use of glyphosate as an expression of the PP being used as far as one can (Danish Agriculture, press release June 4., 2003).

NGOs on the other hand has called for more restrictions on the use of glyphosate. Greenpeace for instance had advocated for a general ban with reference to the PP and a responsible protection of the groundwater (Greenpeace, press release June 6, 2003).

The Parliament is also considering the case and a majority of Parliament seems to decide against the Government further restrictions on the use of glyphosate. The Parliament are also debating a new action plan to reduce the use of pesticides as the old action plans expire in 2003.

General risk research

In the later years the Danish EPA or later the DFNA has not funded any substantial environmental risk research projects. Thus it has been up to the research institutions to look for funding by other sources on the national level and on the European level.
Since the beginning of the 1990’s the plant and insect ecology group in NERI has carried out research and advisory tasks concerning environmental and ecological risk assessment of genetically modified plants. The research deals with insect-resistant crops and includes population dynamics, food chain effects and possible consequences for non-target organisms in agricultural as well as non-agricultural ecosystems. Use of different models is an integrated part of the research.

NERI used such modelling when they conducted a literature review on insect-GM crops funded by DFNA. The study focussed on two questions: Whether the GM crops as the insecticide unintended affects the food chains in the field by affecting the predatory insects in the field and by reducing the basis for the food for birds? On the basis of the chosen model it is possible that insect-resistant GM crops (with Bt toxin) could have unintended effects on the predatory insects in the field. This could cause that other harmful insects would be increased or that the harmful insects faster would be more resistant against the toxin (Kjær et al, 2000). By funding this literature review the DFNA linked commercialization to precaution by investigating the unintended effects of the insect-resistant crops.

The risk research at NERI has links to risk management especially post release monitoring as NERI also has been an active partner in the Danish co-existence strategy. Although the purpose of this forms of monitoring is different, some overlap exist as for instance dispersal of pollen, that could be used in the environmental risk research also.

The experiences on risk assessment from the researchers at NERI has been published in a couple of book, which compile relevant test methods for the study of ecological consequences of genetically modified plants: Competition, establishment and ecosystem effects and Pollination, gene-transfer, and population impacts (Kjellsson,1997, Ammann, 2001). In a book from 2001, co-financed by the Danish Ministry of Environment, the author gives an overview of the environmental concerns and provide measures for analysis of possible effects when GM higher plants are cultivated in large scale (Kjellsson, 2001).

NERI and DIAS (Danish Institute of Agricultural Sciences) participates together with 7 other European countries in the project ECOGEN, Soil ecological and economic evaluation of genetically modified crops. ECOGEN looks at the need for in-depth investigations of ecological and economical consequences by combining simple lab tests, multi-species model ecosystems and field studies to acquire mechanistic and realistic knowledge. Economic trade-offs is assessed and related to ecological effects (www.ecogen.dk).

**Wider context = alternatives?**

Several NGOs NGO’s looks upon research as part of precaution but at the same time they are also sceptical to the actual research agenda – NGOs have for instance called for more risk research and research for alternative approaches to GM. Such research is considered to be nearly missing but nevertheless an important element in a precautionary approach. Many NGOs has also called for research on organic practices as an alternative comparator than conventional practices and as an alternative option for future agriculture. But again, research on alternative approaches to GM crops is very under funded although some research is conducted.

More specific, several NGOs has expressed concerns over the use of herbicide-tolerant crops in a broader context, as for instance of whether the use of herbicide-tolerant GM crops would be the right step on the way to sustainable agriculture. Use of GM crops will drive the conventional agriculture in the wrong direction and not in the direction of sustainability that maintains biological and cultural diversity without undermining future cultivation of the soil. So the real agenda is a debate on the values behind the future of agriculture. In this way NGOs view precaution as an element of sustainability.

Thus GM crops should be seen within a wider context than just an isolated crop to be approved. Some NGOs are afraid of a future agriculture with only 3 or 4 different
crops and with GM crops that will displace the wild fauna through competition (Johnsen, Lone, 2000).

Organic agriculture is an alternative, not only in the retail shops but also as an example that shows that development in agriculture can be made different in the real world (Serensen, KE, 2000). On the other hand, the Agricultural Council is not worried about GM crops at all. It’s the responsibility of the authorities that no marketing take place of GM crops with unacceptable affects. Thus they foresee a mosaic of conventional and GM improved crops in Denmark in 10 years (Høgh, Henrik 2000).

**Potential risk for organic agriculture**

Recognizing that the existing risk assessment of GM crops do not cover problems in relation to the organic farming systems, the board of Directors and user committee of the Danish Research Centre for Organic Farming (DARCOF) decided in 1999 to implement a knowledge synthesis in order to analyse, discuss and synthesise the existing knowledge on the potential risks of plant biotechnology development for organic production in Denmark. The main objective was to compile existing knowledge concerning the effects of genetically modified plants and crops and to analyse and discuss this knowledge in order to establish a knowledge base so that organic farming may actively address the consequences of any increased application of genetically modified plants (GMP) by suggesting concrete measures to avoid or to minimize the risks of GM-contamination (Kjellsson and Boelt, 2002).

In this way the scientific uncertainties in risk assessment in relation to organic farming systems were linked to the design of the risk research on the potential risks for the organic farming system in the light of the development of GM crops.

The report was issued in 2002 and sets out various risks of unintentional but controllable introduction of GMP, for instance when using non-organic products in organic farming. Similarly, the report analyses the significance of the natural non-controllable ways of spreading GMP through pollen, seed and weed hybrids. In continuation of this, the report describes models that may predict the spread of GMP. Also the possibilities of regulating and controlling the spread of GMP through existing EU legislation were set out.

The report finds that pollen of some species, such as oilseed rape, beet and maize, can, to some extent, disperse by wind or bees to distances up to 1 to 3 km. Oilseed rape is especially a problematic species because hybrids between rape and field cabbage or wild radish easily establish, are quite common and may become sources for further dispersal of GM-trait. Seeds of some grain crops survive for less than 1-2 years in the soil and consequently represent only a minor problem. However, seeds of oilseed rape and beet can survive for 5 to maybe 20 years and therefore precautions need to be taken to secure that GM-types do not survive.

Based on the analyses a number of proposals are presented with a view to reducing the consequences for organic farming of the controllable as well as non-controllable spread of GMP (Kjellsson and Boelt, 2002):

‘The consequences of biological dispersal of GM crops to organic fields may be minimised by modified cultivation measures as establishment of isolation distances between GM-crops and organic fields similar to those required for seed production. For dispersal-critical GM-crops as oilseed rape, beet and maize, the isolation distance should probably be increased (not be less than 2 to 3 km) in order to reduce the extent greatly. For both practical and political reasons longer isolation distances or GM plants-free regions are perhaps not realistic in Denmark’.

Another possible ways to reduce the risk of GM-pollen dispersal are:

- The use of protective safety zones around organic fields – research and modelling of crop specific requirements for this need to be developed.
- During crop rotation, it may, to some extent, be possible to use low-risk crops, which have no or only little risk of GM-contamination by pollen.
- Different cultivation techniques could also be used to reduce the GM seed bank in the soil and volunteers.
- Organic farmers takes actively position on the use of a concrete threshold limits for GM-content in organic products.

This study was followed by another study – as a benefit from the Danish co-existence strategy – on how much GM dispersal of pollen to organic fields, which could be expected under different conditions (the extent of GM farming, distribution of GM and organic fields in the landscape, field sizes, etc.) and how this GM dispersal may best be controlled. By computer modelling, NERI has made a so-called meta-analysis in order to summarise the results from a number of field trials with oilseed rape in e.g. England, France, Australia, Canada, USA, Denmark and Sweden. The main questions have been how the distance between fields affects gene dispersal and the effect of the field size on the total GM dispersal and the percentage of seeds containing GM (Kjellsson and Damgaard, 2003).

The preliminary results from model estimations indicate that the GM dispersal by pollen to organic fields primarily can be limited by the use of isolation distances. The results also indicate that because of pollen dilution, large fields are better protected from GM pollen dispersal than smaller fields. For large fields (i.e. field width > 200 m), the risk of dispersal from GM fields by pollen will be limited (approx. 0.1%) at distances above 100 m. For small fields (i.e. width = 50 m), some GM pollen dispersal (up to approx. 0.3%) may be expected even with an isolation distance of 200 m. If the fields are very close, the use of additional protective buffer zones may be required.

Several critical assumptions for the conclusions above should be mentioned. The employed method has some scientific restrictions (GM field and the organic field are relatively equal in size), which may result in a higher level of gene dispersal than indicated by the model results. The assumptions for the model include that varieties with normal fertility are used and pollen dispersal from hybrids between GM oilseed rape and weedy relatives or from GM-volunteers in the surroundings has not been included in the model simulations.

Furthermore, the present model results do not consider the topographic conditions or the different possible scenarios for the extent of GM cultivation in Denmark. Therefore, NERI is also constructing a model of atmospheric dispersion in order to predict the wind dispersal of pollen of oilseed rape and grasses in the landscape based on e.g., biological and meteorological data and the location of cultivated fields (Kjellsson and Damgaard, 2003).

3.1.2 Risk assessment

Risk assessment in Denmark has since the very start included agriculture as part of the environment. Thus risk assessments has always included both the direct effects of a GM crop on the environment and indirect effects of using the GM crop (Toft, 1996 and Toft, 2000). For herbicide-tolerant GM crops the assessment considers how the crop might effect weed-control measures now and in the future. This indirect or secondary effect of herbicide usage is seen to be caused by the GM crop and though part of the risk assessment.

This is also the reason why nearly all stakeholders supported the strengthening of the environmental assessment under Directive 2001/18/EC to include the direct or indirect, immediate or delayed effects of GMOs. Furthermore, several stakeholders have been in favour of the change in the safety clause so that it is now stated precisely that the use of the safety clause also could be based on an reassessment of the existing information (Miljøstyrelsen, 1998).
In a response to the CEC Consultation on a Strategic Vision for Life Sciences and Biotechnology in 2000, the Liberal-led Government stated the following on responsibilities for risk assessment: ‘Denmark has questioned the appropriateness in centralizing the responsibility for the risk assessment in the negotiations on the establishment of the European Food Safety Authority (EFSA) and in the negotiations on GM food and feed regulation as Denmark questions whether EFSA would have a sufficient competence to cover the nature and environmental differences in the regions of EU. — For Denmark it is important that the Member States maintains this competence and that the responsibility for the environmental risk assessment stays at the current CAs. It is a prerequisite for the public accept of biotechnological products that their risk have been assessed on the basis to knowledge to the national environmental conditions. The experiences so far with a centralized procedure has not in any convincing way shown that all aspects of the risk assessment has been considered’ (Økonomi- og Erhvervsministeriet, 2001).

The ecological risk assessment is performed in three steps according to NERI:

‘In the first step NERI identify these characteristics with the GM crop which might lead to undesirable effects on the environment e.g. crossing with wild relatives or effects on non-target organisms.

Then the potential consequences for the environment is assessed. In an example with an insect resistant Bt crop that the wild plants are being less attractive as feed for plant eating insects and that the plant is poisonous for other plant eating insects than the target organism.

Finally the probability that the undesirable effects will occur is estimated. This results for each identified ecological effect the size of the environmental risk: Risk= probability x environmental consequences. The risk that under normal conditions can not be quantified in numbers is being characterized after expected size after the scale: none, marginal, little, moderate or major risk. If is has been assessed that there exist a marginal or little risk for undesirable effects by the use of the GM crop on nature it would under normal conditions could be approved for marketing release but often under certain conditions’ (e.g. monitoring). — ‘If the risk assessment identified greater risk this will under normal conditions cause that the GM plant would not be approved and/or that additional information and scientific investigation is necessary’. (Kjellsson, 2003).

This NERI paper only speaks about risk, not uncertainty. In practice NERI’s advice clearly emphasises uncertain risk which lack evidence which could be viewed as an precautionary approach in scientific sense. Moreover, the advise itself recommends measures to manage uncertainty as for instance specific monitoring and the establishment of buffer zones(for details see 3.4).

The normative baseline for risk assessment has always been the crop, where the effects of GM crop is generally compared to effects on the similar non-GM conventional crop. For farming, this includes treatment with pesticides, fertilisers and other management practices. The only consideration to this choice of baseline is that it ‘is arguable the norm for comparisons based on overall importance and therefore also implemented in current regulation’ (Kjellsson, 2001). Thus it seems as choice of comparator is perceived as being value-free and beyond any discussion.

Thus, the ‘undesirable effects’ depends on this normative standard and hence informs the perception of uncertainties. ‘Undesirable effects’ is not defined by NERI as such, only broad examples of what it means is given: crossing with wild relatives or effects on non-target organisms.

The independent Nature Council has expressed criticism of this narrow approach and have called for a broader approach with stronger focus on the long term environmental effects, an explicit statement for uncertainty and lack of knowledge and a comparison between benefits and disadvantage with the use of GM production in both conventional and organic agricultural productions methods (as a nature friendly alternative). If the result of this weighing out results in an approval is given, long term
monitoring for possible effects on nature and biodiversity should be a demand before any release ((Hamann et al. 2001).

Some NGOs like NOAH has also criticised this choice of baseline for the potential effects of GM crops and have suggested that the effects of the GM crop (also) should be compared with the similar organic crop. Danish Food Industries and DAC have been quite happy with this choice. At present, the fact is that other comparators never has been used in the current risk assessments of GM crops.

In performing risk assessment, NERI made links to risk management. At present, even if NERI in their risk assessment finds that no undesirable ecological effects could be expected NERI also finds it reasonable specific to monitor for instance the dispersal of GM rapeseed and gene transfer to conventional and organic grown rapeseed. Furthermore NERI do not agree with the industry view that 'lack of indications of undesirable effects at a certain level in the risk assessment is a valid reason to exclude or limit monitoring'. Monitoring should according to NERI be implemented 'exactly in order to identify unexpected or unknown factors that the risk assessment has not identified' (Skov- and Naturstyrelsen, 2004a).

For several NGOs, current risk assessment is still seen as narrow and inadequate as it focuses on the science and does not include the broader concerns raised by NGOs (e.g. uncertainty on the unknown long term effects on the environment and society, the loss of biodiversity, the socio-economic impact, benefits to whom etc). NGOs has for many years been very sceptical to the existing regulatory concept and this scepticism still exist even with the revised Deliberate Release Directive.

The Food Industry and DAC on the other hand see the existing risk assessment as adequate and sometimes even too strong. These stakeholders also holds that the benefits of a certain GM crop outweigh the eventually identified small risk.

These strong positions were also highlighted at a conference on GM food – problems and perspectives, arranged by the Danish Board of Technology, where a broad spectrum of stakeholders and authorities were invited as speakers. One of the aim of the conference was to encircle those questions that need to be answered in relation to risk assessment (Teknologirådet, 2000). The conclusion from the conference was that several questions needed a clarification (Fra Rådet til tinget, 2000):

- Should the application of GMOs and the risk assessment include a description of the utility value of the GMO for environment, society and consumers?
- Should risk assessment also include ethical aspect and assessment of potential effects for society when using the GMO?
- Is the current risk assessment comprehensive enough also to include the cumulative effects of several different GM crops?
- Should risk assessments include a description of alternatives to GMOs?
- How should the PP be implemented in the approval process and the risk management?
- Should the public/consumers and other groups than experts from biotechnology be involved in the risk assessments?

The use of antibiotic-resistance marker genes has been debated in Denmark. On one side NGOs have taken a stance against any commercial products which contain antibiotic-resistance marker genes as their use could cause health problems and because good alternatives exists. The relevant expert body (IFST) on the other hand has not been especially opposed to the use of the current antibiotic-resistance marker genes (Toft, 2000).

These stance is still actual as the application for a Bt maize for import (C/D/02/09) shows. The Institute for Food and Veterinary Research (IFVR) assessed that the use of nptII (Kanamycin) would not give rise to any health problems and the risk for horizontal gene transfer were also assessed to be negligible. DPD assessed that no
health effects on animal could be expected (Skov- and Naturstyrelsen, 2003c). Both DPD and IFVR refer to the EU working group on antibiotic resistance where it has been suggested to work out a positive list over marker genes, that has been assessed to be unproblematic from a health perspective. The Kanamycin resistance gene nptII is recommended for this list (Skov- and Naturstyrelsen, 2003f).

Without scientific grounds to limit or ban the Bt maize the DFNA instead referred to the revised Deliberate Release Directive that emphasize this risk issue and thus that Denmark can not support approval of experimental release or placing on the marked of genetically modified organisms that transfer genes conferring resistance to antibiotics used in human veterinary medicine. Furthermore, that Denmark agrees with the Member States that presented reasoned objections or made comments indicating that a final decision should await the outcome of the ongoing work in the EU-working group on antibiotic resistance (Skov- and Naturstyrelsen, 2003f).

3.1.3 Risk management

Post release monitoring

Monitoring of GM crops exists in two different forms: Environmental monitoring in relation to Directive 2001/18/EEC where rules on monitoring on GM crops that have been approved for marketing could be found and monitoring of effects of the cultivation in order to ensure the co-existence between conventional and organic crops. Although the purpose of these two forms of monitoring is different, some overlap of the parameters exist as for instance dispersal of pollen, that is studied in both cases.

NERI has working with post-release monitoring in the last couple of years as part of their research and advisory tasks concerning environmental and ecological risk assessment of GM crops. According to NERI, some of the major problems in the farmland, which will require monitoring and development of specific protocols, include (Kjellsson, 2000):

• detection of direct and indirect effects of the GM crop to the wild flora and fauna in the agro-environment,
• detection of possible adverse effects of changes in cultivation practices from the use of GM crops compared to non-GM crops – for changes in herbicide use it would be relevant to examine effects on the weedy flora, to insects and perhaps to birds,
• loss of GM seeds during transport, handling, field treatment and harvest,
• detection of genetic contamination from GM crops to organic crops (includes pollen dispersal, hybridisation, volunteers, seed purity etc)
• occurrence of multiple herbicide-tolerant volunteers and hybrid weeds in the field and field surroundings – this is likely to happen in with increasing frequency in the future. Already, contamination with multiple herbicide resistance has been reported from field trials with GM sugar beet recently. This subject is not exclusively an agronomic problem because any changes in use of herbicides to treat volunteers and hybrids is likely to affect the wild flora and insects on farmland.

In the monitoring strategy in relation to 2001/18/EEC two forms of monitoring could be used: Case specific monitoring including all potential undesirable effects that has been identified in the risk assessment, for instance potential effects of pollen transfer from GM crops, their dispersal and survival. The aim of the general surveillance (monitoring) is to demonstrate eventual indirect, delayed and/or cumulated undesirable effects, that has not been foreseen in the risk assessment and could be undertaken as part of or as an addition to the existing surveillance of crops.
In the assessment of different product files for marketing releases, NERI made it clear that monitoring should be implemented ‘exactly in order to identify unexpected or unknown factors that the risk assessment has not identified’. Furthermore NERI do not agree with the industry view that ‘lack of indications of undesirable effects at a certain level in the risk assessment is a valid reason to exclude or limit monitoring’ (Skov- og Naturstyrelsen, 2004a).

In this way NERI made links between risk management and risk assessment. Even if NERI in their risk assessment found that no undesirable ecological effects could be expected NERI at the same time found it reasonable specific to monitor for instance the dispersal of GM rapeseed and gene transfer to conventional and organic grown rapeseed. (Skov- og Naturstyrelsen, 2004a).

Stakeholders holds very different views on post-release monitoring. These views showed up in the consultation of the revised Deliberate Release Directive. The DFNA had generally a positive stance to the revised Deliberate Release Directive as it is seen as a step in direction of higher level of protection, more transparency and a more appropriate decision process (Miljøstyrelsen, 1998).

Danisco Ingredients recommends on behalf of Danish Association of Biotechnology Industries that the demand for especially compulsory post-release monitoring should only be made in cases where potential undesirable risks has been identified in the risk assessment. The reason is, that it is a common procedure for industry to follow new products that is introduced on the market (Danisco, 1998).

The Danish Agricultural Council on the other hand recommends post-release monitoring as proposed as it is important for the further development of GM crops to implement a proper regulation that is also flexible (Landbrugsrådet, 1998b).

Environmental NGOs as Greenpeace and NOAH sees post-release monitoring to be in conflict with a precautionary approach: ‘By their very nature post-release monitoring and risk management are in conflict with precaution as they presuppose adverse effects. The danger is, therefore, that monitoring and risk management regimes will act as smokescreens used to sanction the placing on the market of risky GMOs and therefore must be clearly rejected’ (Greenpeace, 1998).

NOAH argued, that the risk to be monitored is unknown, that the potential harm might be irreversible, and that identifying even major harm will be impossible unless the GM crop is segregated from conventional crop. Thus, if there exist any doubt about the environmental effects of a certain GMO, the PP should be used to refuse the application and eventually initiate more research before any marketing approval (NOAH, 1998).

Co-existence

Co-existence is not primarily an issue for environmental considerations but links exist with respect to monitoring and traceability. This became clear when co-existence became a major issue in the parliamentary debate on the revised Deliberate Release Directive in 2002.

The first study to deal with co-existence between growing GM crops and organic crops was initiated in 1999, when the board of Directors and user committee of DARCOF decided to conduct a study in order to analyse, discuss and synthesise the existing knowledge on the potential risks of growing GM plants for organic production in Denmark (Kjellsson and Boelt, 2002). The study was a result of the fact that the existing risk assessment of GM crops do not cover problems in relation to the organic farming system. In this way uncertainties in risk assessment were linked to the design of risk research on the potential risks for the organic farming system.

The report sets out various risks of unintentional but controllable introduction of GM Plants and analyses the significance of the natural non-controllable ways of dispersal of GM Plants through pollen, seed and weed hybrids. Based on the analyses a number of proposals are presented with a view to reducing the consequences for organic farming of the controllable as well as non-controllable dispersal of GM Plants (see more details in section 3.1.1)
In July 2002 the Minister for Food, Agriculture and Fisheries was forced by the GMO-cautious majority in Parliament to develop a strategy for co-existence between GM, conventional and organic crops consisting of three elements: 1) a technical statement of the problems concerning geneflow and which means there exist to solve these problems, 2) a set of scenarios for co-existence (under Danish conditions), which could be the basis for a regulation, should be worked out on the basis of the technical report, and 3) a legal statement on the legal space for a regulation.

The work had been organized of a strategy group consisting of the Ministry for Food, Agriculture and Fisheries (as the leader) and the Ministry of Environment – although the environmental implications is not a subject in the scenarios. In order to secure openness and dialogue in the work, a contact group of stakeholders from industry, conventional agriculture, organic agriculture, consumer and environmental organisations has been selected to act as an active discussion partner for the work of the two groups.

For the technical statement, an expert working group chaired by Danish Institute of Agricultural Science evaluated the possibilities for several types of GM crops to be grown alongside organic and conventional crops in Denmark in their report (Tolstrup, K. et al, 2003a). The analyses, largely based on smaller model experiments and on simulated computer models, includes three scenarios for each crop:

- a 0% scenario: No GM varieties of this crop or GM crops with which it can cross-pollinate are grown in Denmark or in a region. However, adventitious presence is possible through cross border pollination or the import of seed from areas where GM crops are grown.
- a 10% scenario: There is moderate growing of the GM crop;
- a 50% scenario: There is large scale commercial growing of GM crops (corresponds to the very rapid development of GM crop cultivation in countries such as Canada).

An important assumption which the researchers made was that the threshold value for the presence of GMOs in conventional crops should be no higher than 0.9%. This value is based on the political agreement reached in November 2002 in the EU Council of Ministers for threshold values for GMOs of 0.9%.

In January 2003 the working group came to the following conclusions (Tolstrup, K. et al, 2003a):

- With a limited GM-production in Denmark of the crops maize, beets and potatoes, co-existence at the proposed threshold values is possible, as long as the measures suggested are adopted.
- If the GM-production of these crops becomes more extensive, further measures and stipulations in terms of segregation may become necessary.
- In order to ensure a GM-content in organic crops of close to 0 (detection level ~ 0.1%), further measures, as suggested, will become necessary.
- For the crop oilseed rape the problem is so extensive, that further evaluation is required, before production guidelines can be proposed. For oilseed rape, however, the extent of the problem differs between fully fertile varieties, hybrid varieties and varietal associations.

Based on the complexity of the subject, the working group suggests that:

- Their work is continued with a more thorough analysis of (a) the crop oilseed rape, (b) the significance of extent of GM crop distribution, and (c) the economic relations.
- An obligatory course in the cultivation and handling of GM crops is introduced for farmers – possibly as part of the farmer’s education.
The working group also identified a need for improved knowledge in respect of:

- the importance of the extent of GM crop cultivation for the control measures to be adopted,
- the effect of buffer zones,
- the extent of cross-pollination, including the effect of field size,
- conditions affecting pollination,
- the potential for cross-pollination with wild relatives and volunteers,
- the development of cropping systems to maintain purity of cultivars in seed production,
- analysis of the economic consequences of GM crop cultivation, and
- the presence of volunteers as weeds.

The working group has also tried to identify the cost of co-existence for the primary production – but not for measures (like segregation and labelling) that need to be taken further on in the food chain, for example by the animal feed industry, the food processing industry and retailers. These costs result from implementing the measures that should ensure that GM contamination of conventional and organic crops stays below the assumed thresholds. The researchers estimate that the extra costs are at (Tolstrup, K. et al, 2003):

- 0-2 % for conventional/organic maize, potatoes and cereals,
- 3-9% for conventional rape, beet, grass and vegetables, and
- 8-21% for organic rape, beet, grass and vegetables.

The first edition of the coexistence report was presented at an expert hearing in January 2003 in Copenhagen. Together with the authors also Jeremy Sweet, NIAB (UK), John Killpatrick, ADAS (UK) and Natalie Colbach, INRA, France were invited as speakers. This presentation was followed up by several initiatives both at the national and EU-level probably as an effort to set the terms of reference for the European-wide debate (Tolstrup, K. et al, 2003b):

In April 2003 the authors presented the Danish Report at the Round Table on research results relating to co-existence of GM and non-GM crops arranged by the EU-Commission together with DG-Research and DG-Agriculture. In May the Danish group arranged a national seminar where Geoff Squire, Scottish Crop Research Institute gave several contributions on British research in relation to coexistence including the ‘Farm Scale Evaluation Programme’. And Finally, in November the Danish Institute of Agricultural Science arranged the First European Conference on the Co-existence of Genetically Modified Crops with Conventional and Organic Crops – GMCC-03’ in November 2003.

The working group has looked further into problems concerning co-existence of crops such as oilseed rape, grass seed and clover seed, and has found that these crops to some extent also is able to co-exist with conventional and organic crops. However, because of the characteristics of these crops i.e. foreign pollination and/or prolonged survival of the seeds in the soil, there is a demand for more rigorous control measures such as greater distances between fields (Tolstrup, K. et al, 2003b).

An assessment of the costs for selected products associated with separating GM products from organic and conventional products in further steps of the production chain shows limited extra costs, except for GM-fodder-wheat where the extra expenditure will be around 24 %.

Based on the complexity of the subject and the limited experience, which is available concerning coexistence and handling of GM crops, the Group suggests that the introduction of control measures for ensuring coexistence is effected through a
phased procedure with a continuously updated evaluation of the suggested control measures (Tolstrup, K. et al., 2003b).

For the legal statement, an expert group was set up with the remit to identify and illustrate the problems in relation to the legal system in EU, WTO and the Danish system, that could be relevant in connection with development of a Danish strategy for co-existence, to assess the scenarios from the working group in relation to the legal system and to uncover the legal situation if no national regulation is implemented.

The working group concluded based on their analyses, that it is possible for Denmark to draw up national rules on co-existence between genetically modified, conventional and organic crops without violating EU law (Fødevareministeriet, 2003). The working group concludes, however, that under EU law there are clearly defined limits to how far a Member State may go. So it would constitute a breach of EU law to prohibit the cultivation of specific GM crops in Denmark if the crops in question have obtained a marketing authorisation in the EU.

In relation to the PP the working group stated that it would be very difficult to call on the PP in order to prevent growing a GM crop as ‘the PP is already used as basis for the regulation and as basis for the risk assessment in the approval process’. It would neither be possible to use the ‘environmental guarantee’ in art 95 as ‘the argument behind a regulation of growing a GM crop alone is to protect GM free growing and this could not justify the use of the environmental guarantee as the revised Deliberate Release Directive do not cover industry and trade considerations. An argument should be based on the protection of the environment – the natural flora and fauna’ (Fødevareministeriet, 2003).

Especially NGOs have been critical to the report from the working group on technical issues. Greenpeace, which have not been selected to the contact group of stakeholders, made some critical technical points to the report (Greenpeace, 2003):

- The result of the means that is suggested in the report will only be able to delay the GMO dispersal, not to stop it.
- No specific data on how much GMO contamination that would be expected at each chain is given. The report operates with assumptions and judgements which is not very precise and not reasoned. This makes it very difficult to evaluate the conclusions of the final report on its basis.
- The basic assumption of the working group had been that the general rules in order to secure seed purity could be used to stop dispersal of GMOs. Even experts from JRC has taken exception to this assumption at the meeting when the report was published. Thus, it is wrong to assume that the farmer could manage the whole security margin of 0,9%. There is an urgent need to clarify, how big the security margin would be for each chain.
- The assumption is that the seed for multiplication to a great extent should be GMO free. But from where this seed should come from is not considered in the report. The obvious means could be to establish GMO-free zones but this possibility is not even mentioned in the report.

In April the Minister for Food presented a draft for a Danish strategy for co-existence with the main message: Those who produce genetically modified crops should have the responsibility for keeping them segregated from organic and other GM-free crops (Fødevareministeriet, 2003b). The strategy implies that GM crop cultivation in Denmark becomes subject to a number of requirements. This includes, among other things, a separation distance requirement between fields carrying GM crops and neighbouring fields with GM-free crops, cropping intervals, control of volunteer plants etc. The strategy also proposes an obligatory course for farmers in the cultivation and handling of GM crops. The draft was then circulated for consultation among a number of stakeholders.
Stakeholders view on co-existence was divided. In general Danish Food Industry and DAC welcomed the strategy as they also saw this as an political acceptance to grow GM crops in Denmark. NGOs on the other hand made links to other regulation that also should be in place before any growing of GM crops could be acceptable e.g. threshold value in seed for multiplication, liability and labelling.

The Danish Food Industry (and DAC) welcomed the strategy and regards the strategy as a good basis to start growing GM crops as soon as possible. The Food Industry were also happy with the scope of the strategy as it should be seen in connection with the coming EU-regulation on traceability and labelling. These regulations will secure the separation further in the food chain – after the primary sector – and the coming rules for co-existence will cover the separation in the primary sector – agricultural production (Fødevareindustrien, 2003). The Ministry for Food has later agreed in this position in summing up the consultation.

DAC further states that it would be necessary to set a threshold for acceptable unintended content of GMOs. This should be set at a realistic level in relation to the existing analytical methods and should be common for the EU. The threshold should be as low as possible but lower than 0,9 pct (press release from Landbrugsrådet, May 8, 2003).

NGOs has criticized the scope of the strategy plan for being too narrow as it only covers the first stage of the food chain – the primary sector. Secondly, NGOs regards co-existence more than an economic concern as they made a clear link to the environmental issues like the de facto moratorium, the issues around GMO free seed for growing, the consumer issue of labelling and the liability issue (Meldgaard, 2003).

In fact, 11 NGOs agreed in a joint letter to the Minister for Food, upon these common objectives to the action plan (Meldgaard, 2003):

- A Danish GMO moratorium: There must be no growing or deliberate releases of GMOs in Denmark until national initiatives, which allow the existence and further development of GMO-free agriculture in Denmark, have been carried into effect. Parallel with this Denmark must uphold its support for the EU GMO de facto moratorium.
- GMO-free seeds: Ordinary plant seeds and seed grains must be kept absolutely GMO-free and may not, as now proposed in the EU, be contaminated with GMO in quantities of 0,3 – 0,7%. The negotiations on a threshold value in seed for multiplication should be lifted up to the political level in order to achieve as low a threshold as possible, in fact 0,1%.
- Liability for damages: A mandatory public liability insurance for growing and production with GMO must be introduced.
- Labelling: All goods produced by means of GMO must be labelled with a clear, recognisable label. Also egg, meat and milk products from farm animals which have been fed with GM feed must be labelled. If the possibly adopted EU labelling requirements for GM food do not reach this objective, the organisations urge the inclusion of national agreements which guarantee labelling of all food produced by means of GMO. Co-existence includes both the choice for conventional farmers and the right to consumers to choose non GM conventional products. Thus it is important that a real possibility still exist to avoid GM crops in the conventional farming practices.
- More research: More detailed research on rape seed is needed together with further work on the co-existence report to the next chains in the food chain with guidelines/regulations, that all expenses for separation and dispersal at all trade levels should be covered by those, who use GM crops. The consumer must be able to choose non GM products without any extra expenses.
The Agricultural University stated that Denmark in principle should wait to grow GM crops in greater size until more knowledge of the ecological, environmental and health effects of GM crops exist. The University don’t find it responsible to establish co-existence between GM oilseed rape, conventional rape and organic rape as ‘genes from GM crops inevitable would be transferred to fields of the same crop grown conventionally or organic and to all appearances to closely related wild varieties’ (KVL, 2003).

Liability

Liability (or the lack of liability) has been a growing concern by several NGOs and organic farmers. Some NGOs have linked liability with precaution (Greenpeace, 1999). Liability would change the burden of proof and would mean that an assessment of the economic risk in a given project is conducted – NGOs have even called liability an ‘economic precautionary principle’ (gendedebat.dk).

The liability question was raised at the same EU Council meeting in 1999, that lead to the de facto moratorium for further marketing releases. At this meeting, it was agreed among member states that a liability regime was needed. For some time it has been unclear whether the traceability and labelling issue was linked to the liability issue as a basis for the de facto moratorium as some member states has suggested, but this was denied by the Juridical Service of the Council in October 2002 when they declared that the two issues should be seen as independent of each other.

Since then several NGOs has criticised the proposal for an EU Environmental Liability Directive for not adequately covering the possible harms from GMOs on the environment and for economic losses to growers of non-GM crops. This stance were taken over by the GMO-cautious majority in Parliament that decided not to accept any new GMO regulations until the EU Commission has proposed or implemented a motion on changing the regulation for liability so it also covered compensation and liability from GMO production, including harm on the environment. Thus, the GMO-cautious majority again made an implicit link between co-existence and precaution as a strict liability regulation means more limiting and a higher degree of containing the extent of dispersal of GMOs in the environment.

This position meant that the Minister for Environment were forced to vote against the revised Deliberate Release Directive in December 2002 in spite of nearly all parties in Parliament were in favour if the Directive. Hence Denmark has since become a supporter of liability legislation for GMOs and also supports the continuation of the de facto moratorium until the liability regulation are in place.

In the debate on co-existence between GM forming systems and non-GM farming systems (including organic farming systems) the liability question has been a key issue as a potential economic problem. Who will be liable for the damage caused by growing GM crops (a damage that exist as gene transfer is impossible to avoid)?

The food industry finds it decisive, that a GMO farmer following the regulations for growing GM crops should not be liable for an eventually content of GMOs in another farmers crops. The principle must be that you can only be liable if you have incurred fault (Fødevareindustrien, 2003).

NUOF together with a coalition of NGOs hold to the ‘polluter pays principle’ which mean that any damage according to the polluter pays principle should be paid by the one who causes the damage. They prefer a model, where it should be the owner of the variety who should pay and not the farmer who had followed the rules. They see this as a political responsibility. If this model is impossible for some reasons it must be the producer, who uses GM crops that also should have the final responsibility for any damages (Meldgaard, 2003).

The liability question has been a key issue in the Danish co-existence initiative. One of the working groups dealing with the legal aspect of co-existence has made some consideration regarding the liability issue but without any conclusion or recommendation how to solve the problem (Fødevareministeriet, 2003).
3.2 Expert judgements

From the very start in 1986, the Ministry of Environment has drawn mainly on in-house expertise combined with a public consultation procedure for making safety judgement on GMO-releases. And unusually for Danish environmental policy, Parliament have a opportunity to participate in the value judgements on GMO releases.

This procedure provides a very flexible system, as it is able to ask all interested bodies for advise, while granting public access to several aspects of the regulatory decisions. In effect, this system could encourage open discussion on the more value-laden aspects, which are recognized as part of the decision making, rather than relegating these aspects to an advisory committee. There exist no specific advisory body on GMO releases in Denmark.

Regarding in-house expertise this meant in practice that the Danish Environmental protection Agency has had the overall responsibility and act as the Danish Competent Authority. In order to make their safety judgement, the Danish EPA formerly consulted at least three expert institutions for advice:

- a special department in the Danish Forre st and Nature Agency of the Ministry of Environment (DFNA) for the ecological risk assessment,
- the Institute for Toxicology of the National Food Agency of Denmark for an assessment of the techniques used for modifying the organisms, the function of the genes and all the health aspects involved in the use of the GMO,
- the Plant Directorate, Ministry for Food, Agriculture and Fisheries for an agricultural assessment, and
- the National Environmental Research Institute (NERI) in the case of microorganisms.

Until February 1999 the Danish EPA has had the overall responsibility for the Act. In February the responsibility was transferred to DFNA as a result of organisational changes in the Ministry of Environment. In practice this transfer meant no substantial changes since the responsible civil servants also were transferred to DFNA.

3.2.1 Independent expertise

Following the debate in Europe (and at the national level) on risk (for instance on BSE) and the clear recommendations from EU to separate risk assessment from risk management in order to restore public trust by opening the decision making process, the ecological risk assessment of genetically modified organisms (GMO), including plants and animals, were transferred from the DFNA to the National Environmental Research Institute (NERI) by 1 May 2000.

NERI is an independent research institute under the Danish Ministry of the Environment, independent of the political/administrative system when undertaking research and monitoring and presenting its findings. This independence is ensured by legislation, responsibility for the general affairs of NERI having been assigned to a Board of Governors. This step could also be regarded as broadening the expertise for the environmental risk assessment as the NERI staff comes from a broad range of different scientific disciplines like agriculture, ecologist, social science etc.

The same debate took also place on food safety issues at the EU level, where it was stated on risk, that there must be a clear separation between risk assessment and risk management because risk management is not only based on science (CEC, 2000). Also on the national level, several bodies (among them the Ministries own Advisory Research Committee) has suggested to reorganize the Danish Food Research Institutions (among others the Institute for Toxicology) in order to built an independent research institute under the Danish Ministry for Food, independent from the political/administrative system (Rapport om Fødevareministeriets organisation, 1997).
Other bodies like the Ministry for Food itself and the Danish Consumer Council was against this model of independence as they preferred the existing so-called integrated model, where research is close connected to the political/administrative system in order to secure that the vertical ways of decisions is short and consequently the possibilities for a quick reaction and decision making possible (Forskerforum, 2002).

DCC finds that such a research institution would be characterized by solving and researching in issues that nor universities or industry covers and issues that the Ministry has an interest in/need for in order to be able to look after properly preparedness and advise. The strongness of such institution would is that it could provide a necessary critical knowledge in relation to the research that is being conducted by industry and as delivering contributions to broader assessments on health and risk issues on the contrary to the more fragmented university research. Such institution(s) is viewed as independent (Forbrugerrådet, 2002).

The result of the debate was only minor institutional changes in the first hand. A new Institute of Food Safety and Nutrition (IFSN) was founded in January 2002, by merging the Institute for Food Safety and Toxicology with the Institute for Food Research and Nutrition but as part of the Danish Veterinary and Food Administration and though still part of the political/administrative system. The new Institute is in charge of maintaining and developing the research-based consultancy provided to public authorities regarding food safety and nutrition in the area novel food. The Institute make their own research as a baseline for their advice. The Institute has a Advisory Research Committee to give advice on their research.

But in 2004 major institutional changes were made in the Danish Food Research Institutions as a result of The Liberal-led Governments initiative to make all research institutions more effective. Thus, the Institute for Food and Veterinary Research (IFVR) was established on 1 January 2004 by uniting Danish Veterinary Institute and Institute of Food Safety and Nutrition. This was a result of the new liberal lead Governments effort to what they called streamline the different sector research institutions in general. This also meant that in relation to food safety there will be a separation between risk assessment and risk management: DFVR would be responsible for research and risk assessment and the Danish Food Directorate will be responsible for risk management and control (Rapport om etablering of Danmarks Fødevare- og Veterinærforskning, 2003).

No institutional changes were made in relation the agricultural advice. The (Danish) Plant Directorate (DPD) is a directorate under the Danish Ministry of Food, Agriculture and Fisheries and thus part of the political/administrative system. This connection has not been debated in spite of the fact that the scientific advice to the DFNA is send through the Ministry for Food, Agriculture and Fisheries and not directly as is the case for NERI and DFVR. This gives an opportunity for political influence on the scientific advice from the DPD that in principle could be changed.

With the new deliberate release Directive 2001/18/EC common principles for risk assessments of releases of GMOs in the environment were established. This was a challenge for the DFNA as no special methods for risk assessments has been used so far. Thus, the DNFA found it appropriate to seek advice from an independent research group to develop a methodical framework to improve future decisions concerning the commercialisation of GM plants (Rasmussen and Borch, 2002).

The study recommended to use the Oxera model developed by Oxford Economic Research Association for use of scientific advise in political decision processes, especially where it is recommended to involve stakeholders in the process in order to secure that all relevant political questions of more principal character will be discussed and considered (Rasmussen and Borch, 2002).

In decisions concerning risks in connection with GM crops there is a need for a process, where the basis for the decision and which choices that are made in the decision should be transparent. In planning the risk assessment the political and the scientific questions should be separated. In the scientific risk assessment significant elements of uncertainty should find expression and the consultants should be open about the uncertainty and which considerations that have been taken. Finally, the
report states that there is a need for a forum to discuss the more substantial elements of the principles and criteria in the decision process for approval of GM crops. This forum should involve stakeholders, citizens and experts with the aim to make the approval process more transparent (Rasmussen and Borch, 2002).

DFNA has also decided to fund a study on welfare economic and ethical evaluation of the use of GM crops conducted by NERI as a response to the debate on ethics and GM crops. The purpose with the study has been to assess the possibilities to conduct welfare economic evaluation of GM crops – in this connection limited to encompass plants that are resistant to herbicides, insect pests and plant diseases (Møller, 2003).

The first part of the welfare economic evaluation concerns description of the consequences of changes in the use of resources. The relevant consequences comprise both conventional and organic agricultural production according to the author:

- ‘Resource use and environmental consequences in connection with the development and production of GM crops.
- Changes in resource use by using GM crops compared to conventional or organic agricultural production – including protection against gene dispersal to neighbouring fields and sales problems relating to the crops from these fields
- Changes in yield by using GM crops compared to conventional or organic agricultural production
- Environmental consequences of using GM crops compared to conventional or organic agricultural production’ (Møller, 2003).

In welfare economic analysis these consequences are weighed together by use of so-called accounting prices that indicate how much each consequence marginally affect human welfare. An indicator of this is the marginal willingness to pay for the consequence.

It is concluded that pricing of these environmental consequences involves many problems. These relate on the one hand to the cause effect description of the relation between changed pesticide and insecticide loading and the final consequences for the general living conditions comprising the productivity of the environment as a production factor, recreational possibilities, health and aesthetical values. On the other hand it is in itself very difficult to price these consequences.

The second part of the study deals with the question of risk, uncertainty and ethics. The conclusion is, that the feeling of uncertainty about possible unknown consequences perhaps is the most important consequence of using GM crops. But unfortunately, a presumably pricing of this uncertainty is impossible. Thus, it is not like risk possible to quantify uncertainty and therefore it is not possible to price it either.

This uncertainty about possible unknown consequences also gives rise to ask important ethical questions about using GM crops:

- ‘Is it permissible to expose people to risk and uncertainty without their own accept?
- Do use of GM crops as well as use of pesticides and insecticides affect the living conditions of animals in a way that is ethical unacceptable?
- If the nature has inherent values that are threatened by the use of either GM crops or pesticides and insecticides how do you take this into account?
- Could ethical considerations be expressed as deontological limitations on the use of the welfare economic basis of evaluation?
• Should the use of GM crops be evaluated on the basis of its welfare economic consequences (consequentialism) or are other ethical theories more suitable (ethical utilitarianism is well known sometimes to allow too much)? (Møller, 2003).

Also another expert body has been involved in GMO issues. The Danish Nature Council was formed in February 1998 by the Minister of Environment and Energy under the Social democrat-led Government as a continuation of the Danish Nature Conservation Council and as an independent body consisting of four high ranking scientists coming from the natural sciences and physical planning. The Council were intended to take a prominent role in setting the national agenda for the debate about the sustainable development of the wildlife, the environment and the landscape. Thus the work of the Council has focussed on a more cautious, broad, and far-sighted context than by the other stakeholders in the environmental debate. The Council collaborated with the European Environment and Sustainable Development Advisory Councils (EEAC) which in 2001 consisted of around 30 advisory councils for environmental policy and sustainable development from 11 countries in the European Union and 4 accession countries.

Because of their work the Danish Nature Council issued a report in 2001 on invasive species and GMOs on the basis of a conference. The Danish Nature Council sees GMOs as invasive species which has been introduced by man if they have an ability to displace or change the original flora and fauna through competition (Hamann et al. 2001). Thus GMOs could be a threat to biodiversity. In relation to GMOs, the Danish Nature Council urged the Minister for Environment to set up guidelines in order to secure that the ethical and socio-economic aspects would become an independent and overall frame for the approval procedure. The risks for nature and environment could only be accepted if it an unambiguous usefulness for nature and environment could be documented.

In 2002 the Liberal-led government – as part of their strategy to close down several independent councils primarily set up by the former Social Democratic-led Government which has been very critical to the ongoing development – ceased further funding for the Danish Nature Council. The 4 scientist in the Council has though decided to continue by focussing on the biodiversity issue in Danish environmental policy on a voluntary basis without funding and thus with lower level of activities.

3.2.2 Bioethics

The Social Democratic-led Government has decided to focus on the ethical question in relation to genetecology as the latest developments within genetecology should challenge us to focus on fundamental values. This development necessitates that decisions on how we want to use this new technology have to take into account not only whether the proposed application leads to enhanced welfare but also whether ‘it helps develop a sustainable society’ (The Danish Ministry of Trade and Industry, 2000).

Thus, the following four basic ethical principles should comprise the foundation for the ethical considerations for the Government on the application of genetecology:

• Economic and qualitative benefits (a precondition for the acceptance of possible risks is that the technology does not solely entail economic benefits, but also contributes to improves quality of life)
• Autonomy, dignity, integrity and vulnerability
• Just distribution of benefits and burdens
• Co-determination and openness (The Danish Ministry of Trade and Industry, 2000).
The Social Democratic-led Government decided to spend the next four years (2001-2004) focussing on both the possibilities that genetic engineering offers, and the ethical principles that are to be considered in order to make the right decisions. Nine Danish Ministries have therefore joined a Task Force with the purpose to work for incorporating ethical principles in regulation of biotechnology, in decision making processes and as a basis for public consultation and information. The Liberal-led Government has continued this initiative without any substantial changes.

The Danish action plan has been named ‘BioTIK’ – a Danish abbreviation for biotechnology and ethics – Bioethics. The Danish action plan for biotechnology and ethics has formed the basis two groups of specific projects: international regulation and cooperation on biotechnology and ethics and public debate and information on biotechnology and ethics in Denmark.

At the international level the action plan in particular concerns ethical principles for using genetic engineering in the plants and foods area. The other part of the action plan concerns projects on public debate and information in Denmark. The BioTIK website is one of the major projects in this area. The website is divided into four major parts: news, debate, authorities and science.

The Social Democratic-led Government has also investigated the need and possibility for establishing a forum that should have the responsibility for advising on and initiating a more systematic debate on the consequences and ethical aspects of the application of genotechnology to plants and foods as no such forum exist. Several stakeholders has been in favour of establishing such a forum, but the Social democratic-led Government did nor establish such forum.

The Liberal-led Government made a draft proposal to expand the responsibility of the existing Danish Council of Ethics from only dealing with ethical problems in the biomedical field also to deal with ethical problems in fields of nature/environment and food area (Indenrigs- of Sundhedsministeriet, 2004).

### 3.3 Stakeholder roles

Denmark has a long-standing tradition of involving different stakeholders in connection with the formulation and design of regulations and specific authorisations and this tradition has been continued under the new Liberal-led government, at least on GMO issues. Such consultation could take form as a direct invitation to join a temporary group of influential stakeholders as has been the case with the contact group on coexistence where stakeholders from industry, conventional agriculture, organic agriculture, consumers and major environmental NGOs have been invited. It could also take form as formal consultations usually based on open lists from the authorities on which in principle all interested organisations may register. In the official decision-making basis for the Government’s and the Danish Parliament’s considerations these consultative responses are published in the form of official minutes from the responsible authorities.

Thus, the tradition in Denmark has been to involve stakeholders in all (new) authorisations for national field releases and EU-marketing releases of GM crops. In this consultation stakeholders receive a copy of the SNIF but it has always been possible for the consulted parties to request the whole dossier. Thus the only substantial change the revised Deliberate Release Directive has resulted in has been that even all citizens and organisations not represented on the consultation list from the authorities would have the possibility to send in their comments on specific applications for GM crops as the application could be found on the homepage from DFNA in the consultation period (see also 3.4).

The Danish Board of Technology has been used as a participatory policy instrument and have arranged both hearings and consensus conferences on GMO issues through the years. To these hearings and conferences several stakeholders have been given the opportunity to present of their view.
Stakeholders from industry to NGOs has used this consultation to in an attempt to influence legislation like the implementation of the revised Deliberate Release Directive, the regulation on traceability and the initiative on co-existence between GM and non-GM crops including a liability regulation. These attempts discover a continuing polarisation in the debate on how far the regulation should go, how stringent the regulation on traceability should be and the need for stringent rules for co-existence between GM and non-GM crops.

The Danish Food Industry has lobbied for a soft regulation as possible and have tried to influence the criteria for scientific evidence for environmental monitoring and have tried to influence the regulation on traceability and labelling to be as soft as possible and product based. NGOs on the other hand has lobbied for a stringent regulation as possible and have tried to influence the regulation on traceability and labelling to be as stringent as possible (including labelling of meat which originate from a farm animal that has been fed up by GM material) and process based. NGOs has initially characterized co-existence as impossible as unintended dispersal is impossible to contain but as the co-existence initiative were decided by a the GMO-cautious majority in Parliament NGOs together lobbied for as stringent rules as possible including liability regulation.

This is the formal way that stakeholders are able to influence the GMO agenda. Several stakeholders especially NGOs have also tried to influence the overall framing of the GMO agenda (e.g. agricultural context, social context etc.) – for which no formal fora exist – by participating in the public debate, by producing information material and critical reports, by direct actions on the marketplace and by lobbying the politicians. In the following several examples are given in order to highlight the changing role of stakeholders and the diversification in the strategies for the public debate on GM crops.

In the last couple of years the public debate on GMOs has shifted from a debate over risk of deliberate releases in an agricultural context to a debate over issues of labelling and traceability of GMOs and the (economics) of co-existence of conventional and organic crops. The underlying issue of this debate has been freedom of consumer choice: Will farmers and consumers be able to choose what they grow and eat – conventional, organic or genetically modified?

For freedom of consumer choice labelling is a key issue. Labelling has traditionally been a major point in former Danish debates on food issues from the principle that positive labelling prevails (meaning that products containing something should be labelled) and negative labelling is problematic (if too many product contains too many negative appraisals). The issue of traceability is known from other food areas but is new in relation to GM products. Co-existence is a new issue that showed up in Denmark in 2001 and became important, when the new Liberal-led Government started to work out a national strategy for cultivating GM crops.

This development with more consumer issues in focus in the GM debate has opened up new entry points in the debate and more stakeholders from a wider range of interests to be involved in the debate.

The role of the Danish Consumer Council (DCC) has shifted from being part of a dialogue Forum on Food and Gene Technology (with representatives from agriculture, industry, trade unions, but no other NGO) to join an alliances with other consumer NGOs, environmental NGOs and the organic farmers (NUOF). A consumer pressure group, the Danish Active Consumers, produced together with Greenpeace alternative labels and placed them on food items containing GM ingredients or on meat from animals fed by GM feed in the supermarket (Toft, 2000).

In this way Greenpeace and also another influential environmental NGO – the National Society for the Conversation of Nature (NSCN) – broadened their work on GMOs also to cover food in relation to consumer choice and Greenpeace even broadened their work also to cover GM feed with the reason that much of the GM crops actually are used as animal feed. NSCN has also made a shift from being critical to deliberate releases case by case without being a consequent opponent to be a more consequent opponent to several types of releases.
NUOF has also entered the GM debate much more active than before as they saw themselves threatened by the rapid development in approvals of GM crops, a threat because widespread releases of GM crops poses both an economic threat for organic farmers and a threat to erode the freedom of consumer choice as GMO free products could disappear from the market.

The result of this development has been that a wide range of NGOs has been forming new alliances in order to strengthen their weight of their arguments. Thus, in the year 2002, 11 different NGOs from the environmental, the consumer and the conventional and organic agriculture community has formed an strong alliance to deal with the commercialisation of GM crops in the first hand and with co-existence of conventional and organic crops in the second hand (Meldgaard, 2003). They have a common position on growing GM crops in Denmark here and now: This will not present any perceptible advantages to agriculture, consumers or society. Thus no growing or any deliberate releases of GMOs in Denmark should not take place until national initiatives, which allow the existence and further development of GMO-free agriculture in Denmark, have been widely introduced.

The same NGOs plus some more – but without the DCC – started in May 2003 also the campaign ‘GMO – no thanks’ in order to put a pressure on the political system and allocate for a GMO free Danish agriculture. The reason behind this no to GMO is mainly uncertainty in relation to risk for health and environment (that is ‘not carefully studied’) and in relation the socio-economic factors (as farmers that wish to be free of GMOs, to the rise of price of organic products as a result of new expenses in to liability (who should pay for the unintended dispersal of GMOs – consumers, organic farmers of the environment?). The campaign were directed to consumers, farmers and companies that wish to support their aim (gmonejtak.dk). The reason why DCC could not participate in this campaign were that DCC in not against use of GM crops per se.

Use of lawsuits has so far not been used by any NGO. The main reason for this is the Danish consensus culture where stakeholders in practice tries to persuade authorities and politicians with arguments during a decision process. Another reason is also that it could be very expensive to raise a lawsuit in Denmark and that NGOs do not have these money. A major NGO like NSCN use their money in the fight for a better environment with the management term ‘proactivity’. That means that NSCN uses arguments in the decision process and also uses all possibilities to complain in the environmental regulation but then they stop. ‘I think it would be extreme if we should take a legal action. We would like to be constructive and open and this is not the case in lawsuits where the fight is about to be right’ (Poul Henrik Harritz, president of NSCN, to the newspaper Information, September 18., 2003).

The major transnational agricultural biotechnology industry has responded to the development by extending its information activities by producing an internet website, biotikcenter.dk. This site has been produced by Bayer CropScience, DuPont, Monsanto, Plant Science Sweden, Svalöf Weibull and Syngenta. The site has also received financial support from Bayer and Dow Agroscience and the Danish company DLF Trifolium has been an associated member of the editors. The aim is to establish a ‘counterbalance’ to all the information from the GMO opponents that is brought in the media.

DAC has produced a leaflet on their position on the use of GMOs in agriculture and food industry where it was stated that the technology if used with ‘care’ contains a number of positive development possibilities (Agricultural Council, 2000). DAC has also supported the initiative for the public to have access to the field demonstrations plots with GM fodder beet in the years 1999 and 2000 in order to demystify the GM crops. The demonstration trials with GM fodder beet were supplemented by a special homepage set up by DAC where interested citizens could follow the demonstrations.

The Danish Parliament has also been part in the public debate on GM crops. There are several reasons for this, one is lobbying from different stakeholders, another is media coverage and a third is some active politicians in Parliament. For instance, the perspectives from different stakeholders have been used in the parliamentary debate
on the implementation of the revised Deliberate Release Directive into a revised Danish Gene Technology Act and in the parliamentary debate on the national strategy on co-existence between GM and non-GM crops especially organic crops.

The result of the debate on the implementation of the revised Deliberate Release directive has been that the GMO-cautious majority in Parliament against the Liberal-led Government decided to implement the revised Deliberate Release Directive into the revised Gene Technology Act with the following § 13,3: ‘The Minister for Food set up regulations within the EU regulation that strongly reduces the risk for dispersal to other fields, among others organic fields’ (Folketingets Miljø- og Planlægningsudvalg, 2002). In this way the politicians from the GMO-cautious majority made a link between the environmental regulation and co-existence as if the latter could manage environmental risks.

This debate was fuelled by the report ‘Scenarios for co-existence of genetically modified, conventional and organic corps in European agriculture’ (Joint Research Centre, 2002), leaked to the press by Greenpeace, because of the severe consequences for organic agriculture. The debate also showed that several members of Parliament looked at the GM contamination of fauna in the fields as not only an agricultural problem but also as an environmental problem.

Stakeholders especially NGOs has also been able to raise several questions in relation to GM crops in the parliamentary Subcommittee on the Environment. This committee has had an important role in the former debates on the applications of GM crops although they really never have used their possibility to take active part in the value judgements of GM crops (see also 3.4). The main part of the questions raised in this connection has been related to specific risks and use of the GM crop.

In the following section (3.4) the actions of national expert judgements among the competent authority (and their scientific advisers) and stakeholders from industry, agriculture, consumers and environmental NGOs will be shown on the basis of their comments to 4-5 product files for marketing applications.

3.4 Product files: expert judgements and stakeholder interactions

Since the revised Deliberate Release Directive has been passed in EU in march 2003 several products were put into the new procedure: The company notify a CA in one Member State and this CA then performs the risk assessment. The notification and the risk assessment are then circulated to CAs in Member States for comments.

In Denmark, the CA is DFNA.

In application for marketing releases of GM crops DFNA consults NERI for the ecological risk assessment; the Institute for Food Security and Nutrition for techniques used for modifying the organisms, the function of the genes and all health aspects involved in use of GMO, but not for human consumption; the DPD for agricultural issues. These experts bodies are also consulted if Denmark objects the marketing release in the first hand and thus receive additional material from the EU Commission. In the minutes from DFNA at least part of these recommendations are made public and stakeholders can request the whole document if interested.

Stakeholders from industry to NGO have also been consulted on the SNIFs in order to try to sort out differences in preparatory consultations. In order to improve the consultation process the process has been extended to allow all the major interest organisations to be represented in the Special Interministerial Committee for the Environment (SICE) (Toft, 2000). In this way SICE works both as an intergovernmental committee and as consultation forum where the draft from DFNA on the recommendations to the Minister for Environment on specific product files is available as the eventual new draft based on additional information also is available. In this way stakeholders have a possibility to follow the product files in the Danish regulatory system and also to express their views on the recommendations from
DFNA what the first consultation did not allow as the recommendation was not known at that time.

SICE is also consulted if additional material has been received because of Danish objections in the first hand. A draft with the assessment of this new information from the expert bodies and the following recommendations from DFNA to the Minister for Environment are send to stakeholders for comments.

Finally the parliamentary Subcommittee on the Environment is consulted. This committee has had an important role in the former debates on the marketing applications of GM crops although they in fact rarely have used their possibility to take active part in the value judgements of GM crops. The main part of their questions to the Minister for Environment has been related to specific risks and use of the GM crops, often questions raised by NGOs.

Denmark has given reasoned objections to all 6 marketing releases according to 2001/18/EEC from march 2003 to march 2004 for several reasons depending on the GM crop and its use. Inn the objections, Denmark has not refereed to the PP in any case as the PP is viewed as the basis for the risk assessment but the objections might nevertheless be an expression of the PP in practice.

For all marketing applications Denmark finds that the notifier in several of the product files should supply a specific PCR-method to detect the introduced DNA sequence and that EU Joint Research Centre should valuate the detection method (PCR-method) prior to the placing of the market on a specific GM crop. This stance is based on demands for traceability that depends on documentary control. A key for such control is a unique identifier for a certain product that should be provided by the company and according to the Danish stance should be available in order to make it possible to enforce traceability.

Moreover, Denmark wants the notification to be dealt with in the regulatory committee according to articles 18 and 30 of Directive 2001/18/EC. The reason for this is probably that it is important for Denmark that the responsibility for the environmental risk assessment stays at the CA level and not transferred to EFSA where Denmark in a response to the CEC Consultation on a Strategic Vision for Life Sciences and Biotechnology in 2000 has questioned whether EFSA have a sufficient competence to cover the nature and environmental differences in the regions of EU: ‘The experiences so far with a centralized procedure has not in any convincing way shown that all aspects of the risk assessment has been considered’ (Økonomi- og Erhvervsministeriet, 2001).

At last for those marketing applications since the revised Deliberate Release Directive came into force and until July 1 2003, Denmark in addition has drawn attention to the de facto moratorium and have called the Commission to establish a ‘system of environmental liability to supplement the regulatory framework necessary for development in the field of biotechnologies, as in other environmental fields’.

In the following some product files for marketing will be chosen to indicate actions of expert judgements among the competent authority (and their scientific advisers) and stakeholders from industry, agriculture, consumers and environmental NGOs.

The chosen product files for marketing has been glyphosate-tolerant rapeseed for import, BT and gluphosinate-tolerant maize for growing and for import and processing and glyphosate-tolerant fodder beet for growing.

Both NERI and DPD has provided advice on these market-applications submitted in other member states and some elements of this advice concerning uncertainty could be viewed as an expression of a precautionary approach in a scientific sense – demand for specific monitoring, the establishment of buffer zones, lack of sufficient knowledge and openness – although precaution has never been used in their terminology. This may be due to the fact that the Danish CA holds that the PP is and has always been the basis for the administration of the Danish Gene Technology Act.

Denmark objected all these marketing applications and as a consequence Denmark has received additional information via the Commission. This material has been
assessed by NERI and DPD but only in one case their stance has been given a more explicit formulation but in all the other they have found the additional material unacceptable (no environmental risk can be demonstrated) or insufficient (regarding geographical dissemination and preferences for habitats for butterflies and that no Danish or European butterfly has been included in the risk assessment). Thus, the additional information from the Commission has not solved the uncertainty and scientific disagreements.

NERI on the first hand found it reasonable specific to monitor the size of dispersal of GM rapeseed and gene transfer primarily to conventional and organic grown rapeseed despite they found that no undesirable ecological effects could be expected in their risk assessment. This reason for this recommendation is uncertainty as specific monitoring makes it possible to verify whether the conclusion from the risk assessment were right. After a response from the applicant, that argued that no viable seed would be imported, NERI insisted on one side that monitoring would be relevant in countries where the rapeseed is landed especially near harbours and on the other side that monitoring would not be relevant in Denmark (Skov- og Naturstyrelsen, 2003d). This uncertainty could be reduced by introducing specific monitoring according to NERI.

Uncertainty is also the basis for a recommendation to establish buffer zones around fields of GM Maize in order to reduce the uncertainty. NERI recommended establishment of buffer zones around the fields of one type of GM maize on minimum 1 metre to natural habitats and on another type of GM maize a 5 metre buffer zone to natural habitats where caterpillars of endangered butterflies exist, until it could be shown that ‘no risk for the caterpillar of the threatened butterflies exist’ (Skov- og Naturstyrelsen, 2003a and 2003e). The reason for this difference in distance to natural habitats (1 or 5 metre) depends on the character of the inserted Bt toxin.

Uncertainty in the form of lack of knowledge on the eventual long term effects is also basis for a recommendation for specific monitoring. NERI notes that ‘less knowledge exist on eventual long term effects as practical experiences is relative limited’ and thus recommends that specific monitoring of a Bt and gluphosinate-tolerant maize for growing (C/ES/01/0 and C/F/96.05.10) should be set up. In fact, NERI refused that ‘lack of indications of undesirable effects at a certain level in the risk assessment is a valid reason to exclude or limit monitoring’. NERI holds that the monitoring should be implemented ‘exactly in order to identify unexpected or unknown factors that the risk assessment has not identified’. In the case of GM maize (C/F/96.05.10) NERI notes that ‘no Danish or European butterfly has been included in the risk assessment’ (Skov- og Naturstyrelsen, 2004a).

Openness on monitoring results is found important for NERI. NERI recommends a yearly monitoring and that the monitoring result should be delivered to the relevant CA each third year and then they would in principle be open at least for (other) expert bodies. Such openness could be viewed as a precautionary measure.

DPD have used the term ‘care’ in their advice on the GM rapeseed: DPD finds it reasonable to demand ‘care’ in connection with transport of GM rapeseed (the set up of conditions to prevent unintended dispersal of GM seeds) as co-existence between GM, conventional and organic crops is of major importance for agriculture in Denmark. This despite the fact that the applicant argued that as no environmental risk can be demonstrated if a dispersal takes place there would be no need for special conditions (Skov-og Naturstyrelsen, 2003d). Thus, uncertainty can be reduced by a set up of conditions to prevent unintended dispersal of GM seeds.

Danish Food Industry has consistently been in favour of all the first 6 marketing applications according to the revised Deliberate Release Directive and find no ‘valid’ arguments to reasoned objections. In this way Danish Food Industries support the general industry view that if no or little risk has been identified there exist no reasons for extra conditions. In practice they only cite the general risk assessment from NERI and DPD that found no or small environmental effects and thus they did not support their recommendations or the following objections by DFNA which were based on uncertainty.
DAC have expressed different opinions on the first 6 marketing applications. In principle GM crops are viewed as valuable for farmers if they are used with ‘care’. In practice this generally means that DAC supports the recommendations from DFNA and thus the Danish expert bodies. But in some cases they have not been in line with the DFNA and in some cases they have even shifted argument during the consultation process from a blank yes to support the recommendations from the expert bodies and DFNA. Thus, DAC seems to accept uncertainty if the authorities define such in their risk assessment.

NUOF view GM crops as a threat to organic agriculture and farmers. This resistance is based on uncertainty on the long term effects on the environment and animal and human health. NUOF is very worried about the different GM Bt maize as the risk for development of resistance by the pests. Such resistance to pesticides is unnecessary as for instance the creation of pesticide volunteers may result in the use of added spraying in the subsequent crops. NUOF also made links to the new data in Denmark that showed that glyphosate and in particular its metabolite AMPA has been found in groundwater.

Only some NGOs have expressed their view on the first 6 marketing approvals after the revised Deliberate Release Directive. On one hand, several NGOs are invited to participate in the consultation process before any release of a GM crops, but on the other hand NGOs are only heard if they express their view in the narrow scientific language of risk. Other more broader view sometimes called other legitimate factors not presented in the language of risk – like for instance objections to the pesticide resistant strategy including both herbicide and insect tolerant crops – has been ignored.

This is the reason why several NGOs at present are very critical to consultation process. The process is viewed as one way system as stakeholders never receive a response to their comments on specific cases of approvals and often their argument is ignored as the authorities narrowly focus on questions raised in the language of scientific risk. The result has been that many NGOs don’t find it worth participating in all the consultation process in specific cases as they are not listened to anyway.

In the consultation only some NGOs still respond to nearly all marketing applications and of these DCC and Greenpeace have been those who responded frequently. Both Greenpeace and DCC uses the consultation to express objections of principal reasons like the herbicide resistance a wrong strategy and the lack of appropriate liability regulation. In contradiction to DCC, that has never criticised the scientific assessment from the expert bodies, Greenpeace also criticise the environmental assessment by focussing on uncertainties in the risk assessments in relation to biosafety – Greenpeace finds the biodiversity issue so uncertain that ‘any marketing should be banned of precautionary reasons’. For Greenpeace biodiversity means protecting plants form transgene flow.

NSCN has called the development of Bt GM maize as the ‘most foolish and short sighted construction in the fight against pests’ because of the many potential problems with development of resistance (e.g. resistance by the maize borer will render the actual careful and reasoned use of the Bt toxin as pesticide in accordance with need). Furthermore, the use of the crop will lead to reduce the biodiversity in farm land. In this way NSCN has focussed on the risk (in broad terms) and uncertainties of which some have been overlooked in the risk assessment from DFNA and the expert bodies and raised more broad questions of the use of this kind of GM crops.

Thus even the expert body looks beyond ‘risk’ in the conventional sense, e.g. by defining uncertain risk in a more broad scientific way this is still not in line with NGO critics, whose concerns go beyond go beyond biophysical effects.

The parliamentary Subcommittee on the Environment has not made any comments or raised any questions on any of the applications for marketing releases. This is in contrast to earlier where this committee has had an important role in the former debates on the marketing applications of GM (Toft, 2000). The reason for this could be many: The chair of the Committee is now in the hand of the Liberal-lead
Government, its members have changed since the last election, focus has been on the more overall initiatives on GM crops like traceability, labelling and co-existence, many applications has been send for comments in a short time and that several NGOs have given up to comment on all the marketing applications. The latter could be important as members from the committee formerly has used at least some of these comments basis for raising questions in more or less cooperation with NGOs.

In the following the selected product files for marketing will be examined in more detail in order to follow the product files in the Danish regulatory system and in order to indicate the actions of the different stakeholders industry, agriculture, consumers and environmental NGOs.

3.4.1 Glyphosate-tolerant rapeseed for import (C/NL/98/11)

In the application Monsanto has made the claim that any risk is 'effectively zero', as a basis for proposing no case-specific monitoring. The Dutch advisory committee has accepted this although they acknowledged that any escape could result in a transient feral population and accepted the application.

In Denmark, the consultation process showed that this claim has not been accepted by the scientific advisors to the DFNA. The adventitious presence of GM material were used as basis to recommend monitoring. The DPD recommended to set up conditions to prevent unintended dispersal in relation to transport. NERI found it ‘reasonable’ – despite their own risk assessment that showed that no undesirable ecological effects (e.g. loss of biodiversity and changes in soil conditions) could be expected (even with a considerable dispersal of GM rapeseed to nature and farmland) and if then be small and limited to the farmland that use glyphosate – to monitor the size of the dispersal of GM rapeseed and gene transfer primarily to conventional and organic grown rapeseed, secondary to the wild relatives (Skov- og Naturstyrelsen, 2003b).

DAC were in favour of the application on the Dutch recommendations but after the consultation in SICE, where they were presented to the recommendations from DNFA just before DNFA took their final decision, DAC shifted opinion and supported the recommendations from DFNA. The Danish Food Industries did not respond.

Two NGOs responded: DCC objected the application on principal reasons, as the herbicide resistant strategy is a wrong strategy for the future agriculture (see 2.4). Together with Greenpeace they also objected the application for uncertainty reasons as the environmental concerns in relation to growing is very important and thus should not be ignored even if the growing takes place outside EU. Greenpeace objected the application furthermore as the seeds inevitable will escape to the environment, e.g. during processing and transport and thus raise serious biosafety issues (as Europe is centre for biodiversity for rapeseed) and co-existence concerns especially for organic farmers. Finally Greenpeace referred to the de facto moratorium and thus to a precautionary approach.

The resulting Danish response to marketing application of the GM glyphosate-tolerant rapeseed for import (C/NL/98/11) were, 1) that conditions to prevent unintended dispersal in relation to transport should be included in the consent and 2) that the monitoring plan should include observations on dispersal and gene transfer to oilseed rape and wild relatives and 3) the assessment report from the Netherlands should be completed in accordance with Directive 2001/18/EC (DFNA, letter to DG Environment, March 24, 2003 and Skov- og Naturstyrelsen, 2003b).

As a response to these objections, Denmark received additional material on August 25 from the Commission referring to the first two objections but not on the last. In this additional material the applicant again argued that no environmental risk can be demonstrated if dispersal takes place and thus there would be no need for special conditions. But the new consultation again showed that this claim has been unacceptable for DPD and NERI. DPD found it reasonable to demand ‘care’ in connection with transport as the possibilities for co-existence between GM, conventional and organic crops is of major importance for agriculture in Europe. As
no viable seed will be imported to Denmark (as it probably would be in processed
form), NERI has concluded that the possibility for unintended environmental impacts
in Denmark will be reduced in such manner, that monitoring under Danish conditions
will not be relevant for the time being. However, NERI still found, that there would be
reasons to monitor populations of rapeseed in these countries where the rapeseed is
landed especially near harbours even if the seed is not viable.

The Danish Food Industries recommended strongly that the application should be
accepted for import despite the recommendation from the DPD. The Danish Food
Industries refers to the risk assessment from NERI that says that such unintended
dispersal will only have small effects. Thus no ‘valid’ argument to reasoned objections
exist nor now or in the spring 2003 nor with reference to unintended dispersal in the
primary import countries. As the additional information states that no liveable seed
will be imported to Denmark, the material emphasize that no real basis for an
objection exist. Finally, the Danish Food Industry finds that the basis to draw attention
to the moratorium has repealed as new regulations for GM Feed and Food and
labelling has been adopted. DAC on the contrary decided to support DFNA and thus
the Danish objections.

As a result of the consultation process, Denmark maintained its objections on all
three subjects (Skov- og Naturstyrelsen, 2003d).

3.4.2 Bt and gluphosinate-tolerant maize for growing

In fact two applications for this type of GM maize, Bt maize 1507 (C/ES/01/01) and Bt
11 (C/F/96.05.10). Probably no one of these GM maize would be grown in Denmark
as the pest maize borer currently is not a problem in Danish agriculture.

The risk assessment on C/ES/01/01 concluded, that there would be only a ‘negligible’
environmental impact resulting from potential interactions with non-target organisms
and thus the monitoring plans did not include non-target organisms.

In Denmark, the consultation process showed that this claim has not been accepted
by NERI. The risk assessment from NERI showed that there would be none or only
marginal environmental risk for plant and animal life. Although the inserted Bt-toxin
Cry1F is generally regarded as less poisonous to non-target organisms than most of
the other toxins in the Cry-group, less knowledge and thus uncertainty exist on
eventual long term effects because the practical experiences from field trials and
growing is relatively limited compared to the other types of GM maize (Skov- og
Naturstyrelsen, 2003e).

The marginal environmental risk that NERI identified under growing conditions were
that dispersal of pollen to feeding plants for rare caterpillar of butterflies could have
negative effects for these butterflies which existence in Denmark is already under
threat. Thus, NERI recommended that a buffer zone around the field on minimal 1
metre to natural habitats should be used until it has been shown that the growing do
not constitute a risk for the caterpillar of threatened butterflies.

Because of these ‘gaps’ in the general knowledge on eventually undesirable effects
on some groups of soil organisms NERI suggest that a specific monitoring of the long
term effects by growing the GM maize had to be set up. This should be done on a
yearly monitoring and both activities and results from each year should be part of the
report that is suggested delivered to the relevant CA each third year.

The Danish Plant Directorate has not assessed the agricultural implications of
growing the GM maize as they found it doubtful whether the GM maize would be
grown in Denmark.

The Danish Food Industries were in favour of the application, DAC did not respond
and the only NGO that responded (Greenpeace) objected the application for principal
reasons but also of specific reasons that questioned the scientific evidence e.g.
problems with the open reading frames and that the proposed monitoring plan lacked
monitoring between GM crops and non-GM crops in EU. Greenpeace in this way
made link to co-existence as a part of the environmental risk assessment.
The resulting Danish response to marketing application of C/ES/01/01 (Bt and gluphosinate-tolerant maize for growing) were that further information is needed concerning 1) an account of whether the transformation has resulted in the occurrence of open reading frames in the genome of the maize crop as well as of the potential consequences hereof, 2) additional information to clarify if there is a particular need to protect endangered butterfly species, and that 3) monitoring of the long-term consequences for non-target organisms, including soil organisms and butterfly species should take place, 4) the data collected over the years should be included as part of the monitoring report that are submitted every third year and finally 5) that Denmark wants to know the result of the validation of the detection method from the EU Joint Research Centre before any decision on placing on the marked is taken (Skov og Naturstyrelsen, 2003e).

As a response to these objections, Denmark received additional material on March 31, 2004 from the Commission referring to these objections. But the new consultation showed that NERI did not agree with the applicant regarding geographical dissemination and preferences for habitats for butterflies, as ‘no consideration has been taken to the mosaic structure that exist in some types of farmland areas, where small areas of nature and farmland often are mixed between each other’ (Skov- og Naturstyrelsen, 2004b).

In the SICE consultation, DAC found the additional material satisfying and were in favour of the application whereas DCC objected the application with reference to the moratorium and the lack of appropriate liability regulation.

After an assessment of this material by DFNA, it was concluded, that only the objection 1) has been sufficient solved in a way that sufficient information now exist concerning the open reading frames. Consequently, Denmark maintains its objections to the 4 remaining subjects (Skov- og Naturstyrelsen, 2004b).

The other application of a Bt and gluphosinate-tolerant maize for growing (C/FR/96.05.10) is mainly treated in a similar way by the Danish expert bodies, but some interesting differences showed up in the environmental risk assessment. The overall conclusion from NERI were the same but NERI suggested that a limitation in growing is introduced in order to protect endangered butterflies for instance by introducing a 5 m buffer zone to nature habitats where caterpillars of endangered butterflies exist. NERI also suggested that a specific monitoring of the long term effects on eventual undesirable effects on some groups of soil organisms by growing Bt maize with Cry1Ab-toxin, as ‘gaps’ in the present knowledge exist (Skov-og Naturstyrelsen, 2003a).

The Danish Food Industries were in favour of the application as the documentation were found sufficient to comply with the application. NSCN on the other hand were against the application because of the basic idea behind insertion of Bt toxins in crops in order to make the crop resistant to pests which was called the ‘most foolish and short sighted construction in the fight against pests’. NSCN refer to the many problems with development of resistance (e.g. resistance by the maize borer will render the actual careful and reasoned use of the Bt toxin as pesticide in accordance with need). Hence, NSCN is by principle against the insertion of Bt toxins in crops in order to make the crop resistant to pests as the character always would be dispersed to wild relatives and thus create ‘problem weed’ in part of the world. The use of the crop will also inevitable result in reduction of the biodiversity in farmland.

The resulting Danish response to the marketing application of C/96.5.10 (Bt and gluphosinate-tolerant maize for growing) were that additional information is needed to clarify if there is a particular need to protect endangered butterfly species, and that monitoring of the long-term consequences for non-target organisms, including soil organisms and butterfly species should take place (Skov- og Naturstyrelsen, 2003a).

After an assessment of the additional material from the Commission referring to these two comments, NERI found that the updated monitoring plan did not in a sufficient way consider the long term effects on soil organisms and European butterflies. NERI did not agree that ‘a lack of indications of undesirable effects at a certain level in the risk assessment is a valid reason to exclude or limit the monitoring.’ NERI holds that
monitoring should be implemented ‘exactly in order to identify unexpected or unknown factors that the risk assessment has not identified’. In this case ‘no Danish or European butterfly has been included in the risk assessment’ (Skov- og Naturstyrelsen, 2004a).

In the SICE consultation the Danish Food Industry found no scientific reason not to comply with the application and even DAC were in favour of the application, both against the recommendation from DFNA. Nevertheless DFNA (Denmark) maintained its objections on the points considered here (Skov- og Naturstyrelsen, 2004a).

3.4.3 Bt maize for import and processing (C/D/02/09)

In Denmark the consultation procedure resulted in Denmark objected the application for several reasons: 1) under the production in third countries the GM-maize line MON 863 and the hybrid line MON 863 x MON 810 risks to be mixed with conventional maize seeds – thus the two GM maize should be part of the already existing monitoring of maize seeds imported from third countries, 2) according to statutory order on deliberate release into the environment of genetically modified organisms, §3, Denmark can not support approval of experimental release or placing on the marked of genetically modified organisms that transfer genes conferring resistance to antibiotics in human veterinary medicine – final decision should await the outcome of the ongoing work in the EU-working group on antibiotic resistance, and 3) according to regulation (EC) No. 1830/2003 a system for development and assignment of unique identifiers to GMOs as well as technical guidance on sampling and testing of GMOs should be established. Prior to the establishment and implementation of such systems Denmark cannot support approval of the GMO (Skov- og Naturstyrelsen, 2003c).

The Danish Food Industries were in favour of the application as the dossier gives all sufficient documentation to comply with the application. DAC were also in favour of the application on the conditions that the antibiotic-resistant marker gene after the assessment from the Danish expert bodies would not cause any concerns for health. Greenpeace were against both as a principle but also on specific reasons as weakness of the scientific evidence and thus uncertainty, the existence of the antibiotic resistance marker gene and the lack of monitoring for food safety and unintended release into the environment. Thus, Greenpeace seems to have accepted monitoring as a mean to reduce risk.

Denmark has received additional material on September 24 from the Commission referring to these objections. After an assessment of this material, it was concluded, 1) that these new information has not changed the conclusion in the risk assessment. The DPD has noticed, that the applicant has suggested a threshold on 0,9 % for labelling of conventional maize seed for growing which is not in line with the threshold on 0,5% that the commission has suggested, 2) that the EU working group on antibiotic resistance is working on a positive list over marker genes, that seems unproblematic from a health perspective. Kanamycin is recommended for this list.

In the SICE consultation the Danish Food Industries again were in favour of the application as no Danish expert body have expressed any environmental or health concern especially in relation to the antibiotic marker gene. DAC were also in favour of the application whereas DCC finds that some new scientific results exist (on allergenic) that demand the health assessment to be reconsidered in accordance with these results.

Consequently, Denmark objects the marketing with the reason that 1) the threshold used for labelling of conventional maize seed for growing for unintended appearance by the two GM maize lines should follow the result of the negotiations, that takes place in EU at the time being, 2) that Denmark agrees with member states, that will not support marketing of GMOs, resistant to antibiotics that is used in human- or veterinary medical treatment and 3) that the work in the EU working group on antibiotic resistance should be brought to an end before any final decision is taken whether to approve the application (Skov- og Naturstyrelsen, 2003f).
3.4.4 Glyphosate-tolerant GM fodder beet for growing (C/DK/97/01)

Concerning the marketing applications for the glyphosate-tolerant GM fodder beet, DFNA has requested additional information from the applicant: The dossier should have been updated in order to comply with Article 13(6) of the Directive 2001/18/EC and the contradiction between previous experiments that showed that a small part of the backbone DNA could be found in the GM fodder beet and the molecular description in the SNIF where it is stated that ‘no genetic elements from outside the right and left border of the plasmid were transferred into the genomic DNA’ should be clarified. Furthermore DFNA has requested additional information on detection and validation methods and on the monitoring plan. This information has not been provided in full and the product file is still pending at the national level (March 2004) although the consultation by stakeholders in Denmark took place in February 2003.
4 Methods

The main method of the report has been document analysis and interviews as a basis for characterizing the political processes. In did extensive gathering of documentation, e.g. legal texts and acts, parliamentary debates on them, written material (statements, memoranda, articles, booklets etc.) representing various interests, reports and company applications for approval for the relevant authorities, monographs and policy statements from stakeholders in Denmark. Interviews have been made with key stakeholders to update their present view.

By using both document analysis and interviews with key stakeholders has given a good basis in order to analyse the stated rationales of the various stakeholders. Furthermore I have attended some relevant events in Denmark, e.g. conference on co-existence in January 2003 and conference on GM foods in April 2000.
References


Landbrugsrådet, 1998a: Kodeks for god GMO-praksis på landbrugsbedrifter.


Meldgaard, 2003: Kommentarer vedrørende den kommende strategi for sameksistens fremsendt på vegne af Forbrugerrådet, Danmarks
Naturfredningsforening og Økologisk Landsforening fremsendt til Fødevareministeren. 11/3 2003, underskrevet af Mette Meldgaard og Henrik Refslund på vegne af de 3 organisationer.


Skov-og Naturstyrelsen, 2003a: Aktuelt notat til Folketingets europaudvalg vedr. ansøgning om godkendelse til markedsføring i EU af genetisk modificeret majs (C/F/96.05.10) i henhold til Europa-parlamentets og Rådets direktiv 2001/18/EF. 17. Februar.


Skov-og Naturstyrelsen, 2004a: Aktuelt notat til Folketingets europaudvalg vedr. ansøgning om godkendelse til markedsføring i EU af genetisk modificeret majs (C/F/96.05.10) i henhold til Europa-parlamentets og Rådets direktiv 2001/18/EF. 17. Februar.


Økologiens hus, 2001: Handlingsplan til sikring af GMO-frihed i foder til økologiske bedrifter.

Annexes

Annex I: Websites

www.biotik.dk
www.biotikcenter.dk
www.gendebat.dk
www.globalegener.dk
www.gmonejtak.dk
Annex II: Advisory panel

In the first instance, some key stakeholders were contacted in order to gather information on important documents and to gather information about what they saw as important developments. Subsequently, some of the same stakeholders were interviewed face-to-face or by telephone, then e-mail contact enabled clarification of points if necessary. Relevant events in Denmark were attended, e.g. a conference on GM Food – Problems and Perspectives in 2000 and conferences on co-existence in 2003.
Annex III: Interviewees

Nine face-to-face interviews and six telephone interviews were undertaken:

Danisco Seed, October 5, 2002
Danish Agricultural Council, October 7, 2002
Danish Agricultural Advisory Service, October 10, 2002
Danish Consumer Council, 10, 2002
Danish Forrest and Nature Agency, October 31, 2002
Danish Society for the Conservation of Nature, October 11, 2002
Greenpeace, October 23, 2002
National Union of Organic Farmers, October 23, 2002
NOAH, October 9, 2002.