Denmark’s regulation of agri-biotechnology: co-existence bypassing risk issues

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Three different accounts of precaution have defined the risk issues of GM crops and framed the contending views of these crops. Despite the Liberal-led Government elected in 2002, the Danish restrictive policy towards agri-biotechnology has continued because a ‘GMO-cautious majority’ in Parliament has extended precaution to several issues: the moratorium; traceability; labelling; co-existence; and liability. The reframing of GM policy around co-existence has broadened the range of politically-relevant uncertainties. For official expertise, precaution offers a means to raise new questions, to identify technical uncertainties and to justify restrictive measures. However, official expert accounts consider only biophysical risks, not wider perspectives such as hidden values and assumptions in the regulatory process, nor alternative agricultural options. In this way, the polarised Danish debate has not affected basic regulatory assumptions. Only the future will show whether marketing of GM crops would be publicly acceptable under such a regulatory framework.

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Diverse approaches to precaution

In Denmark, three different accounts of precaution or precautionary approach have defined risk issues of GM crops, with uncertainty as a key issue. These accounts correspond in general with stakeholders’ views (including value judgements) on GM crops.

The narrow account comes from the Danish Agricultural Council (DAC):

GM crops represent a positive future for agriculture because they might be used to solve the problems of industrialised agriculture by offering opportunities for more sustainable practices. Precaution is the general requirement for GM products to undergo a prior authorisation procedure based on science and therefore value-free and beyond public discussion (Danisco, 1998; SNIF, 2003; DAC, 2002).

A middle account comes from the Danish Forest and Nature Agency (DFNA), the National Environmental Research Institute (NERI) and the Danish Plant Directorate (DPD) and partly the 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’). Precaution is considered only in risk management, which should be based on evidence of risk and uncertainty, in order to investigate and clarify uncertain risks before final regulatory decisions are taken. Even if no clear evidence of potential risks is documented, extra market-stage controls, for instance, monitoring or preventing a potential risk, might be imposed (Kjellsson, 2003; Skov- og Naturstyrelsen, 2003; DAC, 2002).

The broader account comes from environmental NGOs, the National Union of Organic Farmers (NUOF) and to some extent the Danish Consumer Council (DCC):

GM crops represent a threat to sustainable agriculture (including organic agriculture), because they impose unpredictable hazards and would further intensify agricultural methods, thus accelerating the loss of biodiversity. 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 (Greenpeace, 1998; NOAH, 2002; NUOF, 2002; DARCOF, 2000; Nedergaard, 1998).

Regardless of whether stakeholders explicitly voice these different accounts, they frame contending opinions of the same issue, for instance, 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 various practices in risk research, risk assessment and risk management
also seem to be informed by these different accounts of precaution.

Policy context and conflicts

The November 2002 general election in Denmark resulted in a new Liberal-led Government. It could govern with the support of the Danish Peoples’ Party (a populist, ultra-right wing party) alone, without needing support from the centre parties, which had been the basis for the former Social Democratic-led governments. This change meant large cuts in the environmental administration (one in seven posts lost) and 18 environmental boards and councils were closed down or their funding withdrawn.

Although the new Government withdrew resources for environmental protection in general, a new ‘GMO-cautious’ majority in Parliament emerged. The Danish People’s Party, which in general forms the basis of the Liberal-led Government, joined the opposition’s more restrictive line on agri-biotechnology issues including GM crops. Thus, the previous Danish policy, which was restrictive towards GMOs, has been continued in several ways. The Government introduced a Danish co-existence strategy for GM and non-GM crops; it has also pressed the European Union (EU) for common rules on co-existence and for liability rules to cover harm from GMOs to the environment and to non-GM farmers.

These initiatives might be linked to precaution since such rules anticipate adventitious presence as if it were environmental harm. In line with this policy, several NGOs continued to express their main overall agri-environmental concerns, for example: whether the present course of agro-food development is sustainable, since it is dependent on pesticides; prospects for intensification versus sustainability; and their view that alternatives to GM technology does not fulfil such a role. Almost no independent environmental advisory board that might have dealt with such concerns exists any longer, since the Liberal-led Government has closed them down and replaced them with Lomborg’s Environmental Assessment Institute, with the purpose of “getting the most environment for the money”.

The result has been a growing polarisation between industry and NGOs. Both have formed alliances and used websites to strengthen support for their view. Major transnational agricultural biotechnology companies, such as Bayer Crop Science, Dupont, Monsanto, Plant Science Sweden, Svalöf Weibul, and Syngenta in association with DLF-Trifolium, have produced a website, focusing on the benefits of GM crops, in line with the narrow account of precaution.

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NGOs have formed a rapidly growing coalition among several environmental NGOs, consumer NGOs, organic farmers, some conventional small farmers, and trade unions. These groups prefer to discuss overall risk issues in a broader sense, in line with the broad account of precaution; such issues include social and environmental values and uncertainty, the fundamental rights of farmers and citizens to grow and eat GM-free products, the socio-economic effects, and the liability issue. They want to address these issues before any debate on whether/how and under what conditions to allow the growing of GM crops (Meldgaard, 2003).

Herbicide resistance vs farmland biodiversity

The controversy over the development of GM crops, especially herbicide-tolerant but also bacterial toxin (Bt) gene crops, has been framed within 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, groundwater quality and farmland diversity (GEUS, 2002, Bicheludvalget, 1998). This debate has meant that successive governments, together with Parliament, have promoted a restrictive policy towards pesticides to reduce their overall use and to reduce groundwater contamination from them, given that groundwater is used for drinking water. Any pesticides threatening groundwater quality were to be completely banned (Bicheludvalget, 1998).

This agro-environmental debate on pesticides has framed the debate about GM crops in Denmark. Regulatory policy is generally regarded as precautionary, since risk-assessment criteria encompass a broad range of plausible effects relevant to crop-protection methods. 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 (Toft, 1996).
This precautionary approach arises in an effort to investigate and clarify uncertain risks before regulatory decisions are made on GM crops, and in proposals for extra market-stage controls for managing uncertain risks, in line with the middle account of precaution. Such measures can be seen in responses to the marketing application for a Danish glyphosate-tolerant GM fodder beet. In this case, NERI research, focusing on the effects on biodiversity of growing this crop compared with conventional fodder beet, showed that the most important factor was farm-management practice, especially the time of 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 (Elmegaard and Bruus Pedersen, 2001; Strandberg and Bruus Pedersen, 2002.). Similar results came from the UK Farm Scale Evaluations (FSE, 2003), which likewise found that later spraying of GM crops improved farmland biodiversity (Miljøministeren, 2003).

According to the Danish pesticide policy, however, early spraying is the best choice because less herbicide is used then. Thus early spraying would benefit groundwater quality, but would disadvantage farmland biodiversity. Both Danish research and the UK FSEs found that farmers tend to use preventive (early) spraying. By mid-2005, still no solution to this dilemma was found; the Danish authorities acting as EU-wide rapporteur had not issued their risk-assessment report on glyphosate-tolerant GM fodder beet.

However, in February 2005, DLF-Trifolium applied for a five-year field release permit for the fodder beet. In April 2005, they announced that they would withdraw their application for the marketing of the fodder beet because of the slow EU regulatory system, which had prevented the marketing possibilities (Ingeniøren, 2005). At the same time, the Conservative Minister for Environment, who took over the Ministry from a Liberal Minister in August 2004, announced that she would look at the Danish attitude to GM crops in order to determine the benefits.

Product files requesting commercial use

In assessing product files, Denmark has always included agri-environmental uncertainties in the risk assessment. It has given reasoned objections to almost every product file for marketing. In addition, Denmark even commented on 25 of 75 applications for field trials in the EU in 2003 (likewise 20 of 67 applications in 2004), with an emphasis on conditions or experimental data that might be relevant for a later marketing release (Kjellsson, 2003). This indicates a change in the relationship between risk research and risk assessment, from being mainly sequential, to being more interactive.

This section focuses on specific product files: 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 and thus case-specific monitoring is unwarranted.

In the Danish consultation of stakeholders on these product files, only the Danish Food Industry supported these claims, in line with a narrow account of precaution. Scientific expert bodies (NERI) and DFNA opposed these claims by using the middle account of precaution. Environmental and consumer NGOs, and organic farmers opposed the claims using the broad account of precaution.

In the environmental risk assessment, harm is understood by NERI to include ‘undesirable effects’, not just ‘potentially dangerous effects’ as in the European Commission communication (CEC, 2000). In its environmental risk assessment, NERI had identified some uncertainties that warrant more rigorous science or specific management measures. NERI thus assumed that any negative impacts picked up by the extra market-stage controls (monitoring) could be reversed.

However, the basis for this judgement has not been transparent; NERI did not explain how it reached that conclusion. It generally states that there are no reasons to expect that a particular product will pose a risk to the environment or human health, but it rarely answers the question of whether there are adequate grounds to expect no harm. Such advice concerning uncertainty might 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.

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 glyphosate-tolerant rapeseed for grain import, for example, to monitor or prevent potential risks for which there is no clear evidence in the risk assessment (Skov- og Naturstyrelsen, 2003). This judgement is based on the general NERI approach: even if there is only a marginal or small risk of undesirable effects, a GM crop might be approved for marketing only under certain conditions, for instance, monitoring. Such an approach can 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’ (Skov- og Naturstyrelsen, 2004a).

In response to its objections, Denmark received additional information via the Commission. In general, NERI assessed this new information as unacceptable (for instance, for rapeseed, simply a claim that no environmental risk can be demonstrated) or
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Co-existence strategies


In this way, Parliament treated co-existence as an environmental issue linked to precaution, since such rules anticipate adventitious presence as if it were environmental harm.

The Liberal-led Government saw a possibility to bypass the fundamental questions of the risks of GM crops and instead to focus on their management GM crops in economic terms. Co-existence was regarded solely as a management issue, where solutions to any problems might be found. In fact, 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 (Tolstrup et al, 2003).

The management of co-existence between two or three productions systems is not an easy task. It opens up complicated issues such as separation distances and buffer zones, labelling and traceability, thresholds and liability. Thus the reframing of GM policy around co-existence broadened the range of policy-relevant uncertainties.

NGOs argued that the whole idea of co-existence between GM crops and non-GM crops is unrealistic, as gene transfer from GM fields to non-GM fields is inevitable. This raises a fundamental question of acceptable thresholds for GM presence in non-GM products (Meldgaard, 2003; Greenpeace, 2003).

Thus NGOs regard GM crops as unsustainable and GM material as "contamination", in line with the broad account of precaution.

Industry and agriculture would like to establish a feasible threshold (Fødevareindustrien, 2003). Industry and to some extent DAC regard GM crops as sustainable and GM material as 'contamination', in line with the narrow account of precaution. By contrast, the NGO coalition holds that 'GM-free' should mean 100% GM-free seeds and a free choice between food produced with and without any GMOs (Greenpeace, 2003; Meldgaard, 2003).

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 (Meldgaard, 2003). This stance was subsequently adopted by the GMO-cautious majority in Parliament, which forced the Liberal-led Government to propose 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 cover ‘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. After the European Commission’s July 2003 guidelines devoted responsibility for segregation to the national level, the liability issue, including harm to the environment, was incorporated into the final Danish strategy for co-existence (Denmark, 2004).

Restructuring expertise

The risk regulation system in Denmark has emphasised a separation between scientific expertise and decision-making, as recommended by the EU (CEC, 2000). This has meant structural changes that functionally separate responsibilities for risk assessment and risk management.

In May 2000, responsibility for the environmental risk assessment of GM crops was transferred from the DFNA to the NERI (an independent research institution under the Danish Ministry of Environment). This step might be regarded as broadening the expertise for the environmental risk assessment, since the NERI staff come from a broad range of scientific disciplines such as agriculture, ecology, and social science. Likewise responsibility for risk assessment and risk management in food safety was functionally separated in 2003, when the new Institute for Food and Veterinary Research took over the responsibility for risk assessment, while leaving the risk management and control to the Danish Food Directorate (DVI-IFSE Arbejdsgruppen, 2003).

No institutional changes were made in relation to agricultural scientific advice. The DPD operates within the Danish Ministry for Food and thus within the political/administrative system. This arrangement continues, even though scientific advice from DPD to DFNA is sent through the Ministry for Food, thus leaving open an opportunity for political influence on the advice.

Despite these changes in responsibilities, advisory practice has continued largely as before. Theory is one thing and practice is another. In the assessment of product files for market approval 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, that is, risk management.

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 of specific product files; such a separation would limit the relevance of the advice. As another possible reason, the scientific advice can comment on possible options for monitoring: according to the Deliberate Release Directive, monitoring should be linked with the risk assessment. In any case, DFNA decides whether or not to follow the advice and so far has done so.

Stakeholders, especially NGOs, have demanded greater openness in decision-making as a precautionary approach (NOAH, 1998; NOAH 2002). 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 relationship between risk research, risk assessment and risk management has changed. Previously it was sequential: risk informs risk assessment, which in turn is the basis for risk management judgements. The relationship has become more interactive: risk management, especially post-release monitoring, has emerged to deal with the remaining uncertainty and thus becomes risk research. Yet 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 that.

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

Denmark has opposed attempts to centralise responsibility for risk assessment in negotiating new EU legislation, which eventually established the EFSA and the GM Food and Feed Regulation. Denmark doubted that EFSA would have sufficient competence to cover the ecological and environmental differences of the regions of the EU, unlike the national competent authorities. On both laws, Denmark was 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 (Økonomi- og Erhvervsmilisteriet, 2001).
Conclusion

In Denmark, three different accounts of precaution or a precautionary approach have arisen for the risk issues of GM crops, where a key issue is uncertainty. Industry views precaution as a general requirement for a product category to undergo a prior authorisation procedure based on science. 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 justifiably imposed. For NGOs, precaution means a greater focus on scientific uncertainty and lack of knowledge, in an iterative process that entails both risk assessment and risk management. Different stakeholder accounts of precaution also frame the contending accounts of the same issue; for example, GM crops as un/sustainable agriculture, GM material as ‘contamination’ or as ‘adventitious presence’, and co-existence as im/possible.

Despite the Liberal-led Government elected in November 2002, the Danish restrictive GM policy has continued because a ‘GMO-cautious majority’ has emerged in Parliament. The Danish GM policy has included several measures that might be seen as precautionary, for example: the moratorium (allowing time to develop more stringent measures); traceability (acknowledging and managing uncertainty); labelling (allowing choice in cases in which consumers regard the safety of GM products as uncertain); co-existence (limiting dispersal of GMOs in the environment); and liability (anticipating adventitious presence as environmental harm).

At the same time, the Liberal-led Government fundamentally changed the environmental policy to focus on “getting the most environment for the money”. In this context, co-existence was seen as a possible means to bypass fundamental risk issues of GM crops and instead focus on their management in economic terms. The re-framing of GM policy around co-existence broadened the range of politically-relevant uncertainties, such as separation distances, labelling/traceability, thresholds and liability.

In assessing product files, precaution has emerged in efforts to investigate and clarify uncertain scientific risks before regulatory decisions on GM crops and in proposals for extra market-stage controls for managing uncertain scientific risks — even risks for which there is no clear evidence. This indicates that the relationship between risk research, risk assessment and risk management has changed from being mainly sequential to being more interactive. This practice contradicts political effort to ‘functionally separate’ responsibilities for risk assessment and risk management, given that value judgements also implicitly enter risk assessment.

In conclusion, official Danish expertise has generally supported the middle account of precaution, as a means to raise new questions, to identify technical uncertainties and to justify restrictive measures. This account has been challenged by EFSA safety claims at EU-level, illustrating a more narrow account of precaution. The official Danish approach has also been challenged by NGOs, which emphasise wider perspectives on risks (including the hidden values and assumptions) in the regulatory process, and alternative agricultural options, thus promoting a broader account of precaution. Thus the polarised debate has not affected official regulatory assumptions, which remain limited to uncertainty about biophysical risk of GM crops. Only the future will show whether marketing of GM crops would be publicly acceptable under such a regulatory framework.

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