

Genetically modified organisms – the possible and the reasonable

A summary of RiR 2006:31

Genetiskt modifierade organismer - det möjliga och det rimliga.

Summary

The Swedish National Audit Office (SNAO) has audited the work done by the Swedish Government and responsible government agencies in connection with genetically modified organisms (GMOs) in feed, food and agriculturally derived commodities for industrial use. The audit has focused on the influence of EC law on the Swedish GMO work, the efforts of responsible agencies, and the role of the Government in the work. The audit's findings were published in the report entitled *Genetiskt modifierade organismer – det möjliga och det rimliga* (Genetically modified organisms – the possible and the reasonable) (RiR 2006:31). The decision to prepare the report was adopted in December 2006.

Genetic engineering and genetically modified organisms

Genetic engineering is the generic term used to describe the techniques that are used to isolate, duplicate, change and map genetic material or to transfer genetic material between organisms. The following description of genetic engineering is taken from the SNAO's report.

Genetic engineering is based on the fact that the information-carrying genetic material is structured in the same way in all organisms, from bacteria and mussels to giraffes and human beings. The genetic material consists of genes that are built up from a DNA molecule. The genes control the manufacture of proteins which form the basis for the processes of life. The similarities between the fundamental constituents of the different organisms enable the genetic make-up to be transferred from one organism to another. The result is a *genetically modified organism* – a GMO.

A GMO is characterised by the fact that it has a combination of genes that do not occur naturally. The following definition is provided in Chapter 13 section 4 of the Swedish Environmental Code:

A genetically modified organism is an organism in which the genetic material has been modified in a way that does not occur naturally by mating or natural recombination.

Possibilities and risks associated with GMO

Genetic engineering gives rise to completely new possibilities for influencing organisms. It is now possible to transfer genes between organisms that would never have crossed naturally, for example crops that are foreign to the species. The technology also permits more dramatic transfers of genes, such as from bacteria and animals to plants. The development potential within genetic engineering is deemed by most experts to be very great. At the same time, genetic engineering can result in a situation with many unknown factors – medically, ecologically, economically and culturally.

Possibilities for improved products and processes

Up to now, genetically engineered modification of crops has been used primarily to achieve increased harvests. The GM characteristics added to the crops have been an increased resistance to pests through a built-in insecticide in the plant or an increased ability to cope with disease and a special vegetable poison. With the aid of genetic engineering it may also be possible to produce foods with improved quality or a reduced content of natural toxins, as well as so-called functional foods, i.e. foods designed to increase well-being or to improve health.

There may also be future applications with positive environmental effects. Bioengineering processes can be used, for example, to cleanse polluted or contaminated ground and to produce bioenergy. It may also be possible in the future to develop weed-killers that are kinder to the environment than those used today.

Risks for biological diversity, environment and health

Genetic engineering can also give rise to actual and potential risks. In most cases, the criticism levelled against GMOs is that there is a lack of knowledge of the characteristics that have been modified and that GMOs can have serious consequences for biological diversity, the environment and animal and human health. According to the SNAO's findings, there is also concern that bioengineering companies may develop positions of power as regards the crops and plants that are cultivated, for example by making farmers dependent financially and also with respect to what they can produce. Some of the potential changes can have both positive and negative environmental effects.

Many organisations are working actively to raise awareness of the risks attached to using GMOs. In Sweden today, there is a certain resistance among both consumers and farmers to genetically modified (GM) food,

animal feed and crops. In the academic world, opinion is split. Some people believe that the dividing line goes between molecular biologists, who are working on developing GMOs, and ecologists, who are more critical.

Grounds for and direction of the audit

The SNAO grounds the audit on the basis of both the possibilities and the risks associated with genetically modified organisms. The Swedish Riksdag (Parliament) and the Swedish Government have in different contexts highlighted the need for greater public control in order to protect health and the environment and to ensure that ethical concerns are taken into account when handling genetically modified organisms, but have at the same time emphasised the importance of maintaining a technology-friendly climate in society.

This balancing between the technically possible and the ethically and environmentally reasonable is, in the SNAO's view, an important task for the Government and various government agencies. The audit therefore asks the following overarching question: Are the Government and the responsible agencies succeeding in maintaining the balance between the technically possible and the ethically and environmentally reasonable in the GMO work, i.e. the preparedness for and protection against threats to humans, animals and the environment, while at the same time preserving the possibilities offered by genetic engineering?

The sub-questions asked in the audit are as follows:

1. *The influence of EC law on the Swedish GMO work:* Have the Swedish rules and regulations been amended and applied in accordance with EC law?
2. *Responsible agencies' GMO work:* Are the Swedish central government agencies fulfilling their remits under Swedish legislation and EC law? Is their preparedness for GMO-related threats satisfactory? Are the agencies accounting clearly for the balancing of considerations that are made?
3. *The Government's role in the GMO work:* Has the Government designed a fit-for-purpose authority organisation for the Swedish GMO work? Does the Government's steering provide good conditions for the responsible agencies' GMO work? Is the Riksdag receiving sufficient information about the GMO work to enable it to determine whether set goals are being attained?

Limitations and documentation

The audit concerns GMOs in feed, food and agriculturally derived commodities for industrial use. The abbreviation GMO or GM will be used below only to denote the genetically modified organisms that are dealt with in the audit.

The audit is limited to seven Swedish agencies – the Gene Technology Advisory Board, the Board of Agriculture, the National Food Administration, the Environmental Protection Agency, the Chemicals Inspectorate, the Board of Fisheries, and the Forest Agency – and four ministries, namely the Ministry of Justice, the Ministry of Agriculture, Food and Consumer Affairs, the Ministry of the Environment, and the Ministry of Enterprise, Energy and Communications.

Contained GMO activity, for example in laboratories, as well as at the GMO agencies the Work Environment Authority and the Medical Products Agency, is not treated directly in the audit. The same applies to stem cell research and other genetically engineered applications to humans.

To perform the audit, the SNAO engaged an expert on the legal regulation of environment and GMO activity. Data on the business and work of the individual agencies has been collated and analysed, particularly for the period 2000–2006. The Government's role has been mapped on the basis of written documentation. Information has also been obtained with the aid of interviews with representatives of the agencies and ministries concerned, and via seminars and conferences.

Terms and acronym

Deliberate release	The deliberate introduction of GMO into the environment without any special containment, normally in field trials. The release is part of the work of attaining market approval.
Contained use	An activity where specific containment measures are used to limit the contact of GMOs with the public and the environment. Most contained use occurs in laboratories or in special greenhouses.
The EU's de facto moratorium	The de facto moratorium occurred after five EU Member States declared in June 1999 their intention to block all new permits for GMOs until the adoption of new EC regulations on GM traceability and labelling. The moratorium lasted until 2003, when the most recent EC regulations were introduced.
EFSA	The European Food Safety Authority
The Deliberate Release Directive	The Deliberate Release Directive (2001/18/EC) regulates the deliberate release of GMOs and the placing on the market of GMO products. The directive has in practice been replaced by the Regulation on Genetically Modified Food and Feed.
Regulation on Genetically Modified Food and Feed	Regulation (EC) NO 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. The responsibility for examination under this regulation is centralised to the European Food Safety Authority (EFSA).
The environmental guarantee	The 'environmental guarantee' within the EU enables Member States to maintain or introduce national rules which derogate from EU rules, provided Member States are able to present new scientific evidence on environmental protection or the protection of the working environment in the context of a problem which is specific to the Member State in question.
Co-existence	Rules governing co-existence between GM crops and other crops are important for the ability of farmers to make a practical choice between different kinds of crop production – conventional, organic and genetically modified – in compliance with the legal obligations for labelling and/or purity criteria. These are practical provisions for cultivation aimed at avoiding the undesirable spread of GMOs, and dealing with responsibility, liability etc. for the spread of GMOs should it occur.

Findings and conclusions regarding the regulatory system

Goals and rules have several purposes

Genetic engineering is fenced about with legislation which includes requirements for GM production permits, investigations, product labelling, and so on. This regulation has several purposes – not only to reduce or minimise the risks of genetic engineering but also to meet the goals for sustainable development and to ensure the free movement of safe and healthy GMOs within the EU.

Both international and national rules

There are GMO rules at both European and international level, for example within the EU and the WTO, and also at national level. Six of the sixteen Swedish environmental quality goals laid down by the Riksdag are also affected by GMOs. The Swedish GM legislation is bound up with several other pieces of legislation and in the SNAO's view is difficult to get a general overview of it all. There are many provisions in the Swedish Environmental Code and in corresponding ordinances and regulations. There is also EC legislation that is directly applicable in the Member States. In some cases it can be difficult to determine which rules apply, for example when there are both national and international rules, or when there are no provisions at all.

National freedom of action is limited

The SNAO's audit shows that the EC rules in the area of GMOs have largely been incorporated into the Swedish regulation. EC law has a far-reaching impact on Swedish law. From an environmental point of view, the SNAO's findings show that the national law has been both strengthened and weakened by EC law. The regulation has been strengthened in so far as a number of areas and aspects are regulated in detail – but at the same time EC law can put obstacles in the way of individual Member States choosing their own appropriate precautionary level. The “environmental guarantee” provides certain possibilities for maintaining or introducing national rules which derogate from EC rules. However, this requires Member States to present new scientific evidence on environmental protection or the protection of the working environment and also demonstrate that the problem is specific to the Member State in question. All in all, EC law permits few or no exceptions for Member States with regard to GMOs.

The possibilities that exist in EC law for Member States to take their own temporary protective measures in relation to GMOs were utilised by five EU Member States between 1999 and 2003 (the “de facto moratorium”). Several EU Member States still have national restrictions on the use of GMOs. A GMO panel within the WTO ruled, however, in the autumn of 2006 that these national protective measures were contrary to current WTO rules.

There are no rules governing co-existence, environmental responsibility, liability and compensation

Potential environmental damage that can be caused by GMOs may be a reduction in biological diversity or the GM contamination of other growers' fields. In the latter case, rules on co-existence are an important issue. These rules are required so as to enable farmers to make a practical choice between different types of crop production – conventional, organic, and genetically modified – in compliance with the legal obligations for product labelling and/or purity criteria.

Matters concerning co-existence and related issues of environmental responsibility, liability, compensation and the remediation of GMO-contaminated land are not completely covered by EC law. In this area Member States may draw up their own detailed rules. In Sweden, therefore, legislative work is going on to deal with these matters. Rules governing co-existence should contain practical provisions for cultivation aimed at preventing the undesired spread of GMOs as well rules aimed at dealing with responsibility and liability in the event that GMOs nevertheless spread. These issues have been investigated several times over a long period but have not yet resulted in any legislation.

The SNAO's findings show that there is currently great uncertainty regarding which rules apply in matters of environmental responsibility, liability and compensation in connection with the use of GMOs. The SNAO takes that view that the inadequacies in the regulatory system are the cause of the uncertainty among the affected parties, which makes it more difficult to utilise the possibilities offered by genetic engineering.

Findings and conclusions relating to the agencies' GMO work

Under the Swedish Environmental Code, permits or notifications are required for all activity involving GMOs. Such activity must always be preceded by an investigation on which a risk assessment of the activity can be based. Permits are granted only if the activity is ethically defensible. The scrutiny preceding the issue of permits is based both on EC law and on the Swedish rules in the GMO area, primarily the Environmental Code.

Limited experience at agency level

GMO-related matters are dealt with by many agencies and ministries, the SNAO has found. Most of the audited agencies have had no or very little business relating to GMOs. Therefore, it is difficult, in the SNAO's opinion, to judge their preparedness as regards weighing up the technical possibilities against the risks associated with GMOs. The deliberate releases of GMOs that have been carried out in Sweden thus far have been under highly controlled conditions. In the SNAO's opinion, the experience gained from GMO release can hardly be said to form an adequate basis for judging what the risk picture is likely to be at a later stage, once the introduction to the market of the GM products is a fact and GM cultivation is more extensive.

A number of agencies, including the Board of Agriculture, the Swedish University of Agricultural Sciences (SLU) and the Environmental Protection Agency, emphasise the need for further research in the area. A Swedish research report has stressed the fact that, generally speaking, knowledge of secondary GM spread is inadequate.

Scrutiny of field trials with GM crops

The Board of Agriculture has scrutinised several applications for the deliberate release of GMOs into the environment, i.e. limited release without any special containment. The SNAO's audit reveals that the Board has not scrutinised all the risks that need to be scrutinised nor has it accounted for all the considerations that are required to be balanced under the Environmental Code.

In order for an activity to be granted a GM permit, it must be deemed to be ethically defensible. This means in effect that the activity will only be permitted if it brings some social benefit. In the cases examined in the audit, no developed arguments were presented concerning ethical issues or the activity's contribution of some social benefit. In the SNAO's opinion, the

agencies' ethical judgements are difficult to comprehend and poorly developed. At the same time, it is pointed out that the Gene Technology Advisory Board has provided principles for conducting the ethical evaluation and that the *Bioteknikkommittén* (Bioengineering Committee) has described the method that should be used.

In the cases the SNAO has examined, the Board of Agriculture's risk assessment is focused on the direct risks and effects of GM crop production, despite the fact that the legislation contains an investigatory requirement that also includes indirect risks. The SNAO considers that this deficiency means that the Board has failed to fulfil its remit on all points and that it is therefore reasonable to assume that its preparedness for managing GMO-related risks is inadequate. The SNAO also considers that it is unclear whether the provisions in the Environmental Code concerning requirements for early consultation also apply to genetic engineering activity.

Approval of GM foods

With regard to food, it appears to the SNAO that the legislation and the approval process for GMOs are totally harmonised at EU level. Safety evaluations are carried out by the European Food Safety Authority (EFSA), which is able to consult with or work together with the responsible national agencies. The Member States have frequently been unable to agree on GM market approval, which in these cases has meant that the matter has been decided by the Commission. It appears to the SNAO that disagreement as to the risks and long-term effects of GMOs has been quite common.

If the placement of GM products on the market should prove to have negative effects, the SNAO emphasises that it will be difficult to withdraw approvals. It is therefore up to the national agencies and the Member States to deal with these issues at an early stage. The representatives of the Swedish Gene Technology Advisory Board consider it absolutely essential to examine EFSA's proposed decisions and take the view that in this context the national agencies have an important part to play. According to what the Swedish National Food Administration itself says, it currently does no risk assessment for GM market approval of its own, but relies on EFSA and the investigations that other Member States are able to make.

The SNAO considers that it is important that the competent national authorities should examine EFSA's work and be active in the processes regarding GM market approval.

Information to the public can be improved

The right of the public to have access to environmental information is laid down in both national and international rules. The EU Deliberate Release Directive assumes, like the UN Aarhus Convention from 1998, that the public has access to information, is able to participate in decision-making, and also has access to justice in environmental matters.

The social information on GMOs provided by the agencies cannot, in the SNAO's view, be considered inadequate, although there is great potential for improvement. The public ask a great many questions about GMOs. The issue of genetic engineering gives rise to both disquiet and expectation. Within the areas covered by the audit, the attitude of the public is often negative or sceptical. According to the SNAO's findings, there is no overall official channel for dealing with questions from the public and to provide more in-depth information on GMO matters.

In the SNAO's view, it is not quite clear how the agencies are meant to deal with the public's right of access to environmental information. The SNAO considers that the inadequacies in the social information concerning GMOs lessen the agencies' preparedness for dealing with GMO-related risks and jeopardise the public's confidence in them.

Findings and conclusions concerning organisation, control and reporting

No separate organisation for GMO matters

There is in Sweden no separate organisation for GMO matters, but responsibility is in the main divided among the sector agencies who already possessed the best knowledge of the respective areas of application. This division of responsibilities means that GMO is only one issue among many dealt with by the respective agencies. Two agencies, the Gene Technology Advisory Board and the Environment Protection Agency, have co-ordinating and advisory remits within the area, but no right to make decisions when GM scrutiny is carried out. GMOs are a minor issue within the Environment Protection Agency, and the Gene Technology Advisory Board is a very small agency (two to three employees).

The SNAO has also found that the control exercised by the Government through appropriation directions and instructions for the work of the agencies is not especially directed at GMO matters. The Government's reporting requirement for the agencies has been limited. The division of responsibilities among the ministries also makes big demands of co-ordination within the Government Offices.

The SNAO considers that the organisation is largely fit for purpose but that it has nevertheless contributed to the inadequacies that emerged in the audit. The special sector issues can, with the present system, have too large a role, while sector-wide issues like risk assessments and ethical considerations can have a subordinate role.

Few possibilities for the Riksdag to take a position

Several of the problems which emerged in the audit – such as the lack of rules governing co-existence, environmental responsibility, liability and compensation, and the fact that the requirements for issue of GM permits are unclear and that there is a lack of openness and access to information – have in the SNAO's view been known for a long time. Despite this, the Government has not delivered any proposals to the Riksdag concerning these parts of the GMO area. The *Bioteknikkommittén* (Bioengineering Committee, SOU 2001:103), which among other things looked into the division of responsibilities among the agencies concerned, has dealt with a number of issues concerning the same problems that emerged in the SNAO's audit. However, the Government has put forward no proposals in connection with the Committee's report.

The SNAO has carried out a review of a large number of private member's bills on GMO matters that have been introduced in the Riksdag. The SNAO has found that these bills frequently express disquiet and uncertainty at the prospect of the application of GMOs. Some of the information that the bills ask for concerns basic issues relating to GMOs, including the rules and regulations for the use of GMOs and their application. During the period 2000–2006 the Government introduced three bills concerning GMOs and genetic engineering. Many of the matters dealt with in the private member's bills have not, however, been taken up by the Government, nor have the budget proposals contained more than very limited information about GMOs. Thus, the SNAO finds that there has been no opportunity for the Riksdag to take a position on these matters.

The SNAO's overall assessments and recommendations

GM issues are expected to become increasingly important

In Sweden there is as yet no commercial cultivation of GM crops, and trialing of GM crops has up to now been limited. The SNAO does however point to the fact that there are a number of circumstances to indicate that GM issues are set to become increasingly important: the cultivation of GM crops in other countries has increased considerably in the past ten years. Developments have been most rapid outside the EU, but also certain EU Member States have begun cultivating GM crops. There have also been extensive GM trials of various kinds. In addition, there is the fact that the "de facto moratorium" within the EU has ended and GM applications are once again being scrutinised and considered. All in all, therefore, GMOs are bound to become a major issue for the responsible authorities in Sweden.

The SNAO's assessment

In accordance with the Riksdag's decision and under the applicable EC regulation, the development and use of GMOs must be carefully scrutinised. The Swedish Environmental Code contains requirements for this examination through the basic rules concerning consideration, for example the precautionary principle, rules stipulating the use of the best possible technology and alternative methods, and special ethical considerations including the evaluation of social benefit and public welfare.

The SNAO considers that these scrutiny requirements are not being fully complied with. The scrutiny that is done in practice is not as broad and detailed as the rules demand. There is no balancing of a number of difficult considerations. Where a number of matters are concerned there is an absence of rules which are important for cultivation of GMOs, as well as rules on co-existence, environmental responsibility, liability and compensation. As a result of these inadequacies, there is a risk of more serious consequences in the future when there will be more GMO matters to deal with.

In the SNAO's opinion, the inadequacies that emerged in the audit mean that risks are not being dealt with satisfactorily and that public confidence is being jeopardised. That will also make it more difficult to utilise the possibilities of GM technology to the full. The SNAO considers that if the balance between the technically possible and the ethically and environmentally reasonable is going to be maintained, the present rules and their application must be developed on a number of points.

Most of the SNAO's recommendations are for measures which should be considered by the Government and which the agencies should also work on.

Recommendations addressed to the Government

The SNAO recommends that the Government should

- develop the way in which the requirements in the Environmental Code and in EC law with respect to *risk assessment* prior to scrutiny of all use of GMOs should be satisfied, including how the balancing between different considerations should be accounted for,
- establish a system for providing better and more accessible *social information* about GMOs,
- draw up *rules* for environmental responsibility, liability, compensation, remediation and co-existence,
- take measures to compensate for the split *reporting* on GMOs,
- investigate the uncertainty as regards the applicability to the GMO area of the provisions in Chapter 6 of the Environmental Code concerning *early consultation*.

Recommendations addressed to the agencies concerned

The SNAO recommends that the agencies concerned should

- develop methods for the way in which the requirements in the Environmental Code and in EC law with respect to *risk assessment* prior to scrutiny of all use of GMOs should be satisfied, including how the balancing between different considerations should be accounted for (the preparatory works to the Environmental Code could be used as a basis for this work),
- account for how the different considerations are *balanced* during the scrutiny,
- provide better *social information* about GMOs.

The Board of Agriculture and the National Food Administration should *participate* more actively in the EU's approval process.

The Board of the SNAO delivered a report to the Riksdag in March 2007 in connection with the audit described above – see 2006/07:RRS23.