VROM

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Biotechnology

VROM policy and granting of permits

Biotechnology can help to make our way of life more sustainable. The Ministry of Housing, Spatial Planning and the Environment (VROM) therefore seeks to promote biotechnology. However, biotechnology brings with it certain risks for people and for the environment. So, while looking to ensure that the opportunities afforded by biotechnology are utilised, VROM also works to protect people and the environment against the associated risks. VROM believes that the process of making decisions regarding biotechnology applications should be completely transparent. For the general public, for the business community and for the scientific community. This leaflet describes VROM's biotechnology policy and explains how policy is put into practice by VROM and other ministries.

What is biotechnology?
Biotechnology is a general term. It includes the science of making changes that couldn't occur in nature to the genetic material in living organisms. This science is often referred to as 'genetic engineering', 'genetic manipulation' or 'gene technology'. By changing the genetic material of a plant, for example, it is possible to create a strain with characteristics that the original plant did not have – such as pest resistance. An organism that has been changed in this way is known as a genetically modified organism (GMO). Biotechnology also includes the use of living organisms (or parts of living organisms) to make or improve products. This is something that people have been doing for a very long time. It is traditional, for instance, to use yeast, fungi and bacteria in the production and preservation of cheese and beer.

Biotechnology and sustainability
How can biotechnology be used to make the way we live more sustainable? VROM undertakes research to provide answers to this question. The purpose of such research is partly to find out how much environmental benefit can be obtained by introducing industrial biotechnological processes, and partly to determine the environmental effects of biotechnology applications.

Research has shown that industrial biotechnology can contribute significantly to the development of more sustainable products and production processes. However, the environmental value and ecological safety of biotechnology applications needs to be assessed separately in each case. VROM sees that biotechnology has the potential to be particularly useful in the chemicals industry.

Who may have dealings with VROM's biotechnology policy?
Anyone who wishes to work with genetically modified organisms in the Netherlands needs to apply to VROM for a permit. Applicants range from pharmaceutical and industrial manufacturers and plant breeders to universities and research institutes. VROM also considers objections submitted by individuals and organisations. In the past Greenpeace, organic farmers and private citizens opposed to the granting of permits.

Biotechnology policy
The Dutch government and parliament believe that biotechnology is a very important field of development for the economy and for society in general. Biotechnology has the potential to resolve problems in areas such as health care, sustainable agriculture, the environment and industry. However, it is necessary to ensure that safety, administrative transparency and personal freedom of choice are not compromised. Nor should the ethical implications be ignored; not everything that is technically feasible is necessarily a good idea. Dutch biotechnology policy does not exist in isolation, but is shaped by the policies developed at the European and wider international levels.

Responsibility for biotechnology policy in the Netherlands is shared by a number of ministries. Each of these ministries has its own role, and with these different roles they work together in many fields, for instance by developing joint policy documents.

VROM assesses genetic engineering applications to determine the risks they pose for people and the environment. All applications have to be assessed, whether they involve micro-organisms, plants, animals or human gene therapy. VROM also represents the Netherlands in international meetings on environmental matters. The other ministries that are involved in Dutch biotechnology policy are as follows:

- Ministry of Health, Welfare and Sport (VWS)
  VWS focuses on the use of biotechnology for the improvement of health and health care. VWS also works to ensure that genetically modified foods are safe and appropriately labelled, so that consumers can make informed decisions.
- Ministry of Agriculture, Nature and Food Quality (LNV)
  LNV focuses on the use of biotechnology for sustainable agriculture and clean crop production methods, the sustainable parallel cultivation of GM and non-GM crops (coexistence), the preservation of biodiversity and the ethical review and licensing of activities involving animal genetic engineering.

- Ministry of Education, Culture and Science (OC&W)
  OC&W's field of responsibility covers the acquisition of knowledge regarding biotechnology applications, the provision of public access to scientific information, biotechnology in education and training in the biosciences. One research field of particular significance for OC&W is genomics: the study of the composition and function of genetic material in all living organisms.
- Ministry of Economic Affairs (EZ)
  EZ's aim is to ensure that "Life Sciences" (biotechnology) contribute to the health of the Dutch economy. To this end, the ministry seeks to enhance the innovative capacity and competitiveness of the life sciences by, for example, funding research and giving grants to new enterprises. EZ also tries to make the Dutch life sciences industry more attractive to foreign investors and to remove obstacles for innovation and enterpreneurship.
- Ministry of Foreign Affairs
  This ministry focuses on the role that biotechnology can play in bringing about sustainable development and tackling poverty in developing countries. Foreign Affairs is responsible for coordinating foreign policy and hence Dutch input to European and international negotiations on biotechnology and biosafety.
- Ministry of Justice
  The Justice Ministry invests in biotechnology in the context of crime detection (e.g. DNA testing).

Policy principles
VROM wishes to ensure that the opportunities offered by biotechnology are utilised to the full, insofar as this is possible without compromising the safety of people or the environment. The impact of genetically modified organisms on people and the environment are by no means fully understood. It is conceivable that such organisms may have adverse effects that are irreversible or apparent only after some years. Dutch law requires any business or institution that wishes to work with biotechnology to obtain a permit. It is up to VROM (in consultation with other ministries as appropriate) to decide whether a permit should be granted. A permit is granted unless the activity to which an application relates entails unacceptable risk for people or the environment. When assessing a proposed activity, VROM does not consider the activity's potential benefit. However, if people or animals are involved, LNV and the CCMO do take potential benefit into account.

When formulating policy, VROM applies three key principles:
- **The risks for people and the environment must be acceptable.**
  In the Netherlands, all activities involving genetically modified organisms have to be permitted/granted a permit. VROM issues permits only if the risks are acceptable. If doubt exists regarding the possible repercussions of a biotechnological process, or if the effect is unknown, the ministry will require that appropriate control measures are put in place, or – in extreme cases – will refuse a permit. The precautionary principle is applied.
- **Transparency and participation in the decision-making process are vital.**
  The public is entitled to information and must be able to exercise influence over the decision-making process. Permit applications are accordingly placed in the public domain, so that people have the opportunity to object. Provisional decisions and details of issued permits are published in a database that can be accessed via the ministry's website.
- **The regulatory framework must be comprehensible.**
  No more rules and regulations should be imposed than are necessary to ensure safety. With a view to enabling the scientific and business communities to make biotechnological innovations more quickly and reducing the administrative burden, VROM is looking to simplify the regulatory framework.

The central message the government wants to convey:
Developments in the field of biotechnology offer opportunities for the resolution of key social issues through innovation in the fields of health care, sustainable agriculture, the environment and industry. Biotechnology is consequently of great potential value to the economy and to the community. Dutch government policy is therefore to take advantage of the opportunities available and to promote biotechnology. However, this is only possible if adequate provisions are made to ensure safety, transparency, public freedom of choice and ethical acceptability. Biotechnology policy embraces several ministerial policy domains. Each of the ministries concerned has responsibility for certain aspects of biotechnology policy within a general policy framework.

The regulatory position
As indicated earlier, a considerable portion of Dutch regulations on biotechnology is based on European and other international policy. The Netherlands seeks to maximise its influence by taking an active role in international negotiations in this field.

International legislation
The most important international agreement in the field of biotechnology regulating the environmental safety is the Cartagena Protocol on Biosafety, which forms part of the UN Convention

on Biological Diversity. This convention is designed to promote the preservation of biodiversity, i.e. the variety of plants, animals, landscapes and ecosystems that the earth supports. Biodiversity needs to be protected against, for example, any adverse impact that genetically modified organisms may have. Such matters are covered by the Cartagena Protocol.

This protocol, also known as the Biosafety Protocol, lays down rules on the transboundary movement of genetically modified organisms. A country is entitled to refuse the importation of genetically modified organisms, if it is feared that importation may do serious or irreversible harm to people or the environment. To enable the potential impact of GMO importation to be assessed, the exporter is required to provide scientific information regarding the organism concerned. All the available scientific data on genetically modified organisms that may be exported are managed by a so-called 'Biosafety Clearing House', established under the protocol. This international data repository also keeps information concerning the legal situation in the various signatory countries. Thus, would-be GMO exporters can readily ascertain what rules apply in a given country. The Biosafety Clearing House therefore satisfies the information requirements of both exporters and prospective destination countries.

Further information regarding the Cartagena Protocol and the Biosafety Clearing House can be found at www.biodiv.org/biosafety. Other international regulations governing this field are available from http://international.vrom.nl/ under environment/ biosafety and GMO's.

EU legislation on biotechnology:
EU regulations are directly applicable in the Netherlands, whereas European directives are implemented by the creation of corresponding provisions in Dutch law. The EU regulations that apply in this field are summarised below. For information about applicable directives and further details on the regulations covering biotechnology and the management of the risks to people and the environment, refer to http://international.vrom.nl/ under environent/ biosafety and GMO's.

- EU regulation on transboundary movements of genetically modified organisms (1946/2003/EC)
  This regulation implements the Cartagena Protocol (see 'International legislation'). Its purpose is to ensure that the movement of genetically modified organisms from country to country does not create hazards for the environment or for human health.
- EU regulation on genetically modified food and feed (1829/2003/EC)
  Human food and animal feed that consist entirely or partly of or are made with genetically modified organisms must not be hazardous to the environment or to human or animal health. Regulation 1829/2003/EC requires that the safety of such foods and feed is assessed before they are allowed on the market. The principle is applied that consumers must be able to see whether an item has been produced by genetic engineering, so that they can make informed decisions when purchasing.
- EU regulation concerning the traceability and labelling of GMOs and the traceability of foods and feed products produced from GMOs (1830/2003/EC)
  This regulation protects the environment against any adverse effect that might result from the use of GMOs in the production of human food and animal feed. It also requires the use of labelling to ensure that GMOs are identifiable along the entire production chain.
- EU regulation establishing a system for the development and assignment of unique identifiers for genetically modified organisms (65/2004/EC)
- EU regulation laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (178/2002/EC)

Dutch biotechnology legislation
- Genetically Modified Organisms Decree, passed under the Environmentally Hazardous Substances Act (GMO Decree)
  Passed in 1990, this decree regulates the use of genetically modified organisms under Dutch law. The decree requires anyone who wishes to work with GMOs in the Netherlands to obtain a permit. VROM acts as the licensing authority, in line with the statutory role of the Minister of VROM.
- Genetically Modified Organisms Regulations (GMO Regulations)
  The GMO Regulations are linked to the GMO Decree and lay down more detailed rules that apply primarily to the contained use of GMOs.
- Environmental Management Act and the Establishments and Permits (Environmental Management) Decree
  Anyone wishing to make contained use of genetically modified organisms requires a permit, as provided for in the Environmental Management Act and the Establishments and Permits (Environmental Management) Decree, which states requirements for facilities.

- Disclosure of Information on Disasters and Serious Accidents Decree (Biro)
  Under the Biro, a permit-holder has to provide the local municipal executive with information about anything that could lead to a disaster or serious accident. The decree also requires that a laboratory draw up a contingency plan for implementation under such circumstances.

VROM acts as the Netherlands' licensing authority in the context of all the legal instruments described above.

Other legislation (VROM not licensing authority)

- Biotechnology and Animals Decree and Experiments on Animals Act
  Under this decree, the genetic modification of animals requires not only a VROM permit, but also a permit from the Minister of Agriculture, Nature and Food Quality. Clearance must also be obtained from an animal experimentation board, established under the Experiments on Animals Act; in this context, the Ministry of Health, Welfare and Sport acts as the licensing authority.
- Medical Research Involving Human Subjects Act (WMO)
  Medical research in which people are used as research-subjects, e.g. gene therapy research, requires clearance from the Central Committee on Research Involving Human Subjects (CCMO).
- General legislation
  In addition to complying with the specific legislation and regulations referred to above, anyone wishing to work with GMOs must comply with any applicable legislation of a more general nature, such as the Pesticides Act, the Food and Commodities Act, the Working Conditions Act, and the Immunological Agents Decree.

Other actors associated with the GMO Decree

Bureau GGO
The Genetically Modified Organisms Office (GMO office) supports VROM's licensing activities by processing applications and providing information about notices and permit applications.

COGEM
The Commission on Genetic Modification (COGEM) is an independent scientific body, which advises the Minister of VROM regarding the risks to people and the environment associated with the use of genetically modified organisms and regarding corresponding protective measures. COGEM advises the minister both on request and on its own initiative. COGEM also informs the ministers involved on ethical and social aspects of activities with GMOs.

Inspectorate
Compliance with the legislation and regulations on biotechnology is monitored by the VROM Inspectorate from its regional office in Haarlem. The monitoring activities include on-site inspections, in the context of which compliance with the statutory requirements and permit conditions is checked with a view to minimising any risk. Where non-compliance is detected, corrective action can be taken under administrative or criminal law. In addition, permit-holders are obliged to appoint ministry-approved biological or environmental safety officers for internal compliance monitoring.

Granting of permits

VROM issues two general types of permits: permits for contained use (IG) and permits for deliberate release into the environment (IM). The type of permit that is required depends on whether the genetically modified organism in question is to be released into the environment. Market admission is governed by a European procedure. VROM is responsible for assessing requests submitted in the Netherlands.

The decision as to whether a permit should be granted is based on a risk analysis, which has to be carried out or commissioned by the applicant. VROM then reviews the risk analysis to make sure it has been properly performed. A risk analysis has to provide information regarding the extent and nature of the risks to people and the environment. To this end, the analysis needs to specify what might go wrong, how likely it is that something will go wrong, and what steps should be taken to reduce the risk that any undesirable effects on people or the environment will occur and to minimise such effects if they do occur. If the likelihood of an undesirable event cannot be estimated or no conclusive scientific evidence is available, the analysis should be based on a worst-case scenario, in line with the precautionary principle. This involves deliberately presuming the risk to be comparatively high. The control measures then have to be geared to the presumed level of risk, thus ensuring safety. A permit is granted if the risk is acceptable small.

Application forms and detailed information about the licensing procedure is available from the GMO Office's website: www.vrom.nl/ggo-vergunningverlening.
Contained use permits

Activities carried out in a confined area, such as a laboratory, greenhouse or stable require a contained use permit. In addition, an environmental permit has to be obtained for the premises in question from the municipality or province where the premises, installation or equipment is located. Various degrees of containment are recognised, depending on the genetically modified organism concerned. The requirements that apply to each degree of containment are specified in the GMO Regulations.

Contained use permits are obtained from the GMO office. VROM has to rule on an application within 45 days of its submission.

Other features of a contained use permit:
- A contained use permit specifies the organisms that may be worked on and the degree of containment applicable, by reference to the provisions of the GMO Regulations.
- A lpermit-holder is obliged to appoint a government-approved biological safety officer (BSO), who has responsibility for ensuring that the applicable conditions are met. The duties and powers of the BSO are specified in the GMO Regulations.
- Anyone who wishes to make genetic modifications to animals also has to be granted a permit under the Biotechnology and Animals Decree by the Minister of Agriculture, Nature and Food Quality. The Biotechnology and Animals Commission acts as an independent consultancy in this context. In addition, clearance is needed from the Animal Experimentation Board associated with the institution where the work is to be undertaken. The board's task is to review the ethical acceptability of the proposed work.

Deliberate release permit
A deliberate release permit is necessary for, for example, field trials. A field trial involves the non-commercial use of genetically modified organisms. So, for example, the cultivation and processing of genetically modified crops for research purposes counts as a field trial. (Anyone wanting to use GMOs commercially needs consent under EU legislation; see below.)

A deliberate release permit is also required for gene therapy work. The term 'gene therapy' covers medical procedures involving the use of genetically modified organisms, introduced to the human body to, for example, rectify a 'defect' in the patient's genetic material. GMOs are also used for veterinary purposes, such as making vaccines for cats. This type of activity needs a deliberate release permit as well. The use of gene therapy to treat people additionally requires the approval of the Central Committee on Research Involving Human Subjects (CCMO). The CCMO is responsible for deciding whether the benefits of the proposed gene therapy are sufficient to justify the medical and ethical risks involved for the patient.

Various bodies are involved in the licensing of human gene therapy activities. The Gene Therapy Office is responsible for the coordination of all gene therapy licensing procedures. At present, the GMO Bureau is acting as the Gene Therapy Office.

Other features of the deliberate release permit application procedure:
- An application for a deliberate release permit has to be dealt with within 120 days. However, the application processing period is suspended pending the receipt of any additional information that VROM requires from the applicant.
- In practice, VROM always seeks the advice of the COGEM regarding deliberate release permit applications.
- All permit applications and the associated provisional decisions made by VROM are available for public perusal at the VROM library. Anyone who is unhappy with a provisional decision may lodge an objection with VROM. The final decision will make appropriate reference to the application, to COGEM's advice and to any registered objections.
- If someone who has registered an objection to a provisional decision feels that the final decision takes insufficient account of the objection, he or she may appeal to the Council of State.
- A permit-holder is obliged to appoint a government-approved Environmental Safety Officer (MVF), who has responsibility for coordinating activities involving GMOs and ensuring that the applicable conditions are met.

Consent for deliberate commercial release into the environment
Before a genetically modified organism may be marketed for use in a way that will involve deliberate release into the environment, e.g. through inclusion in foodstuffs or through cultivation, consent must be obtained in accordance with European environmental legislation. Once secured, consent is valid throughout the European Union. The procedure is as follows:
- An application for consent must be made to the competent authority in an EU member state. In the Netherlands, the Bureau GGO is responsible for processing such applications.
- The competent authority in the country in question assesses the environmental risks associated with the proposed release, then

forwards the application and the assessment findings to the European Commission (EC). A copy of the application and the assessment findings is also sent to each of the other member states. If neither the EC nor any member state objects, consent is given for the release.
- If an objection is made, the member states enter into discussion with a view to securing consensus.
- If consensus cannot be reached, the member states vote on whether consent should be given for the release; a two-thirds majority is required for consent to be to given or withheld at this stage. The Netherlands' role in this context is limited: the country has a vote, but has no power of veto.
- If no two-thirds majority is obtained, the European Commission decides whether consent should be given.
- An application to market a GMO is made available for public perusal twice: once when it is considered by the EU member state where the application is submitted, and once after it has been forwarded to the other EU member states for consideration. On each occasion, the application is published at http://gmoinfo.jrc.it – the website of the European Commission's Joint Research Centre.
- Products are covered by certain special rules, in addition to the general conditions that apply to consent for release. Any product that consists of or contains GMOs must be labelled or otherwise recognisable as such.

Transparency and public participation in the licensing procedures

Contained use
Once a decision has been made regarding an application for a contained use permit, the name of the applicant, the title and the date of the decision are published. Parties concerned may submit written objections to the following address: Ministerie van VROM, p/a Bureau Genetisch Gemodificeerde Organismen (BGGO), Postbus 1, 3720 BA Bilthoven, the Netherlands.

Deliberate release into the environment
Applications and (provisional) decisions are published in full, except insofar as information identified as confidential by the applicant is withheld. An application for a deliberate release permit is made public by the publication of a provisional decision to grant a permit in the Government Gazette, the Volkskrant, the NRC Handelsblad and a regional newspaper covering the municipality in which the activities are to take place. Details of all currently effective deliberate release permits are held in a permit database, which may be consulted via www.vrom.nl/ggo. Details of provisional decisions and the associated OGEM recommendations can also be viewed on line. In the case of an application made since 1 June 2004, the complete file may be consulted on line. Where applications submitted before 1 June 2004 are concerned, only summaries are available on line; hard copies of the complete files may, however, be consulted in the VROM library (Rijnstraat 8, 2515 XP, The Hague). The designation '(provisional) decision' (Dutch: "(ontwerp)beschikking") indicates that the dossier (including the permit) is open to public comment or objection; dossiers without this designation have progressed beyond the stage where public comment or objection is possible.

VROM takes public feedback into account when deciding whether to definitively grant a permit. When a definitive decision is published, VROM's response to such feedback is explained. Anyone who has expressed reservations regarding a provisional decision and remains unhappy with the associated definitive decision may submit an objection. The case is then considered by the Council of State.

Deliberate commercial release into the environment
Requests for consent for deliberate commercial release into the environment are published on the website of the EC's Joint Research Centre (JRC). The site's address is http://gmoinfo.jrc.it. EU citizens can use the site to submit comments regarding individual cases.

If consent has been given at the European level for the cultivation of a genetically modified organism, cultivation of the organism is automatically deemed safe for people and the environment in the Netherlands. However, additional regulations often need to be complied with before a crop may be grown in this country. For example, all crops (whether genetically modified or not) must be included on the official crop varieties list.

The GM Register is a public record of all locations in the Netherlands where genetically modified organisms are cultivated on a commercial basis. The register, which is accessible via the VROM website, is maintained by the Regulations Department at the Ministry of LNV.

With VROM towards a sustainable future

The sustainability of our way of life depends on developing new approaches to production and consumption. VROM believes that biotechnology can contribute to sustainable development and to the resolution of social problems. VROM therefore attaches great importance to the promotion of sustainable biotechnology applications. The ministry is seeking to encourage the further development of biotechnology and the identification of applications that can form the basis of cleaner production processes. VROM is an active participant in international discussion forums, thus helping to shape international biotechnology policy. At the same time as promoting the sustainable use of GMOs, VROM works to ensure that biotechnology does not threaten the safety of people or the environment.

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More information

- More information about biotechnology and both Dutch and international biotechnology policy can be found on VROM's website: http://international.vrom.nl/pagina.html?id=10534 (English) and www.vrom.nl/biotechnologie (Dutch). Via the site you can also access the permit database and the GM crop register.
- Written responses to decisions made by VROM concerning the granting of permits should be addressed to: Ministerie van VROM, p/a Bureau Genetisch Gemodificeerde Organismen (BGGO), Postbus 1, 3720 BA Bilthoven, the Netherlands.
- Permit applications and the associated (provisional) decisions can be consulted at the VROM library: Rijnstraat 8, 2515 XP, The Hague, the Netherlands. The same information is also stored in the permit database accessible via the VROM website.
- Information about how to apply for permits, application forms, details of issued permits and procedures are available from the GMO Bureau website: www.vrom.nl/ggo-vergunningverlening.