# Towards an integrated framework for the assessment of social and ethical issues in modern biotechnology

COGEM Advisory Report to the State Secretary for Housing, Planning and the Environment (CGM/030618-02)

**Commission on Genetic Modification (COGEM)**
The Netherlands Commission on Genetic Modification advises the Government on the potential risks of genetic modification to human health and the environment. Besides this the Commission brings ethical and social issues linked to genetic modification to the attention of the ministers involved. This is a statutory task regulated by the Environmental Management Act.

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## Summary

*Background*

In this report the COGEM describes the general features of an integrated socio-ethical framework for the assessment of modern biotechnology. In principle this framework can be applied to a wide range of developments within biotechnology. The report also specifically discusses the role of the COGEM, which advises and reports to the Government on issues concerning the production and handling of genetically modified organisms.

There has been increasing interest in the ethical and social implications of modern biotechnology in the past few years. This is also true in the political arena, as evidenced by the parliamentary consideration of the Integral Policy Document on Biotechnology[1] in January 2002. That policy paper itself drew attention to the ethical and social questions government policy would have to address in the field of biotechnology.[2] At the same time the task of the COGEM was explicitly defined as: providing technical and scientific advice (solicited and unsolicited), but with the significant addition: "taking account of societal developments in the field of genetic modification while remaining open to the need for discussion".[3] It was announced that the COGEM would be enlarged with several members having expertise in the fields of ecology, ethics and the social sciences. The Dutch Lower House of Parliament requested the then Minister of Housing, Planning and the Environment to prepare an integrated framework for the assessment of biotechnological developments.[4] In his answers the Minister again stressed the importance of social and ethical issues and the role of the COGEM. [5] Against this background the COGEM undertook the task of preparing an advisory report on the assessment of social and ethical issues in modern biotechnology.

*Preparation*

By way of preparation the COGEM first commissioned two reports, one on ethical issues in relation to genetically modified organisms (GMOs) in agriculture and the other supplying building blocks for an ethical assessment framework.[6] A symposium was held on these reports on 13 June 2002. Then, on

[1] *Integrale Beleidsnota Biotechnologie,* Tweede Kamer, vergaderjaar 2000-2001, 27 428, nr. 2.
[2] Ibid., p. 7.
[3] Ibid., p. 26.
[4] Cf. *Motie Ross-van Dorp c.s.*, Tweede Kamer, vergaderjaar 2001-2002, 27 428, nr. 18.
[5] Cf. Tweede Kamer, vergaderjaar 2001-2002, 27 428 etc. Nr. 10, pp. 46-47.
[6] H. Verhoog, *GMO's in de Landbouw: Maatschappelijke en Ethische Aspecten,* 2002; F.W.A. Brom et al., *Een Integraal Maatschappelijk Ethisch Toetsingskader als Morele Opdracht. Bouwstenen voor een maatschappelijk ethisch toetsingskader voor biotechnologische ontwikkelingen,* 2002.

28 June 2002, the COGEM sent a first advisory report to the Minister, based on the results of the symposium. In the months since then the COGEM has further considered the details of an integrated socio-ethical assessment framework. At the European level the extent of Member States' powers in the field of the ethical and social implications of biotechnology has been indicated.[7] The Commission has also published general policy guidelines on collecting and using expert advice on sensitive issues such as biotechnology. In December 2002 the COGEM organised an international workshop for fellow organisations which are also engaged in providing ethical and social advice to governments on biotechnology and genetic modification in Europe. Recently the Dutch Scientific Council for Government Policy (WRR) presented the Government with a report on making policy decisions about biotechnology, which also considered social and ethical aspects.[8] On the basis of the above the COGEM prepared a discussion paper, which was presented at a symposium on 11 June 2003 to experts, interested parties and members of related committees which also advise on social and ethical aspects of biotechnology. At the same time comments were received on this discussion paper through the website of the COGEM. All these sources have been used in preparing the present advisory report.

*Definition of terms*

Before presenting an integrated socio-ethical assessment framework, it is important that the meaning of the key terms should be clear. For our purposes the term "assessment framework" means the substantive and procedural rules with which to establish consistently and unambiguously whether or not something satisfies implicit or explicit standards or criteria. Moreover, it is an essential feature of an assessment framework that there is an authority responsible for carrying out the assessment. In this connection the term "socio-ethical" indicates, on the one hand, that a specific case or trend is being examined in the light of current ethical standards, values, principles and theories. On the other hand it implies that the impact, nationally and internationally, on existing social structures and on the stability of those structures will be estimated and the desirability of that impact assessed. For the purposes of this advisory report, the term "integrated" means that the framework applies to biotechnology as a whole, comprehensively. Here, comprehensively refers both to the socio-ethical component, which is by nature constantly changing and dynamic, and to the subject of the assessment. In other words it refers not only to the end product but also to the development process as a whole, in which values and science are

[7] Cf. Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.
[8] Wetenschappelijke Raad voor het Regeringsbeleid, *Beslissen over Biotechnologie*, 2003.

involved in a constant interplay. It also refers to those involved in the process, which in principle means the public at large.

*Socio-ethical assessment and the policy cycle*

It is impossible to be more explicit about such an integrated socio-ethical assessment framework without first having some appreciation of the shared values that have already been laid down in policy through the democratic process: the legislative framework for biotechnology in the Netherlands. This advisory report therefore first presents an outline of the existing regulatory framework. But an integrated socio-ethical assessment framework must also be receptive to new experiences. This means that at various stages room will explicitly have to be made to allow reconsideration and for an open articulation and enumeration of conflicting and competing views. This would then be followed by a phase in which the various interests and values could be weighed against one another and ranked by Parliament. The COGEM would like to stress the dynamic nature of this process and urge that government policy should take account of this in its decision-making and policy measures. The COGEM presents a model that does justice to the integration of socio-ethical assessment and the policy cycle.

*A five-step plan*

As soon as consensus has been achieved on the relevant values and interests, five steps will have to be followed to arrive at an unambiguous and consistent assessment in any individual case. These five steps are central to the procedure in the assessment process.

*Step 1:* Exploring the parameters and creating the conditions for a fair and just consideration of the issues. At this stage it will be important to ensure that all stakeholders have an opportunity to have input.

*Step 2:* Checking whether limit values have been or are likely to be exceeded and whether any previous socio-ethical assessment has been carried out. The COGEM proposes using a “gate” and “balance” model for steps 2 to 5. The gate, described in step 2, can halt an application. Have the basic limit values already been exceeded, or is this likely to happen? Or has the case already been subjected to a similar socio-ethical assessment in the past. If so, the assessment stops at this stage. The gate remains closed. However, if the conditions of step 2 are fulfilled, the gate is passed and the assessment can go on to consider the relevant merits of the values and interests in question.

*Step 3:* Description of potentially affected values and interests using a checklist.

*Step 4:* Description of intended aims and goals, also using a checklist.

*Step 5:* The relative merits of goals, values and interests are considered and a decision reached. The assumption is that some goals may serve to justify certain actual or potential effects on values and interests. All the relevant goals, interests and values are placed in the balance, which then tips one way or the other. This means that the proportionality principle is deemed to apply at this stage. In step 5 the politically responsible authorities take the ultimate decision whether or not to grant a licence.

The decisions resulting from this process will contribute to establishing case law and formulating future limit values. However, this case law and these limit values have only temporary validity due to the dynamic nature of this type of assessment. Consistency, coherence and co-ordination are nevertheless important criteria for policy, as the WRR noted.[9] They must be taken into account during the five steps.

When the integrated socio-ethical assessment framework is being applied the significance of the relevant values and aims must be considered in the widest possible sense. All parties should be given plenty of opportunity to express their views. It is important that the Government plays a pro-active role in this respect. Nevertheless, the Government will also have to make choices. It will not be possible to take all views on board, nor will it be possible to avoid all negative effects. How any given choice – and in particular the socio-ethical aspects of that choice – is justified, is therefore essential.

Where policy on biotechnology is concerned, particular attention must be paid not only to the substantive evaluation of interests but also to the procedural side of any ethical and social assessment. Transparency, information, integrity, respect for plurality, consistency and independence are essential procedural criteria both in terms of the advisory process and the actual assessment. They are indispensable to the legitimation and acceptance of decisions and crucial to public trust in government policy.

*The role of the COGEM*

The second part of the report deals with the role of the COGEM. It indicates how the COGEM can contribute in the various phases of the cycle of assessment and policy-making outlined above, by carrying out evaluations, organising public meetings, identifying trends, consulting interested parties, publishing advisory reports, etc.

[9] Cf. ibid., pp. 229-230.

*Assessment in practice*
Part III of the report gives several examples of how the integrated socio-ethical assessment framework can be applied in practice.

*General recommendations*
Based on its analysis of what is required for an integrated socio-ethical assessment, the COGEM makes the following recommendations:

1. An integrated socio-ethical assessment framework includes both substantive and procedural assessment criteria. Its use presupposes an authority responsible for carrying out the assessment. This authority must have the appropriate expertise. If this expertise is not immediately available, the COGEM recommends that it should be sought.

2. Biotechnology assessment should not confine itself to weighing economic benefits against scientific risks. The COGEM recommends expanding the category of risks considered to include the impact on values and to include the benefit to society of the intended goals among the benefits.

3. An integrated socio-ethical assessment framework should on the one hand be sensitive to the dynamics of evolving opinion on moral issues and to developments in science. On the other hand it should provide structure and legal certainty once certain interests and values have been given priority over others through the democratic process. The COGEM recommends that both these aspects should be taken into account by making the assessment cyclic.

4. This means that the Government should not confine itself to ad hoc decision-making and policy measures connected with the ethical and social acceptability of modern biotechnology. In order to ensure the quality, consistency and relevance of policies the COGEM recommends adopting a responsive, methodical approach involving periodic evaluation and agenda-setting, surveys of public opinion, followed by prioritisation and regulation.

5. The assessment framework includes the existing legislative framework on biotechnology in the Netherlands. An analysis of existing legislation reveals that the proportionality principle is not applied in all fields, even though this would be desirable from the point of view of coherence and consistency. The proportionality principle forms the basis for any weighing of potential risks against potential benefits in this connection. The COGEM therefore recommends that the proportionality principle should be declared explicitly applicable to all relevant fields.

6. Care should be taken to avoid duplication when the assessment framework is applied. One and the same case should not be subjected to a similar socio-ethical assessment twice.

7. Various committees carry out socio-ethical assessments within various legal frameworks. Some cases will be presented to different authorities at different stages of development. It is important to be aware of these links in an integrated assessment framework. The COGEM therefore recommends co-ordinating the activities of the various committees and authorities.

*Recommendations concerning the socio-ethical assessment of gene technology*
Based on its analysis of its own role within the integrated socio-ethical assessment framework and in line with the above general recommendations, the COGEM makes the following the specific recommendations:

1. In line with the first general recommendation, the Ministry of Housing, Planning and the Environment should have the appropriate expertise on hand to carry out its task in relation to gene technology. At present it does not have this expertise in-house, which is why the COGEM recommends that the Ministry should seek to fill this gap.

2. The proportionality principle mentioned in the fifth general recommendation is not mentioned in the Dutch legislation on genetically modified organisms (GMO Decree).[10] The COGEM recommends that the proportionality principle should be declared explicitly applicable to its field, identifying issues and advising on the production and handling of GMOs.

3. The COGEM has developed a risk-benefit questionnaire as an instrument for clarifying the advantages and disadvantages of certain developments in a dialogue with producers. The COGEM recommends that the Ministry of Housing, Planning and the Environment should make completion of this prestructured questionnaire compulsory for market entry applications in the Netherlands and for applications to carry out large-scale field trials.

[10] *Besluit GGO*.

# Part I
# Towards an integrated socio-ethical assessment framework for modern biotechnology

# 1. Introduction

In recent years Parliament has shown increasing interest in the ethical and social implications of biotechnology. The COGEM has also been given a part to play in this process. What prompted the development of an integrated socio-ethical assessment framework for biotechnology was the parliamentary debate on the Integral Policy Document on Biotechnology in January 2002. The Lower House of Parliament requested that the Minister for Housing, Planning and the Environment prepare an integrated assessment framework for biotechnological developments.[11] This framework was to show the relationship between the various statutory assessment frameworks and thus reveal the unity in the diversity of frameworks. It was also intended make the ethical and social considerations that play a part in biotechnology visible and thus give them a place of their own within the social and political evaluation of biotechnology, both within and outside the judicial process. Moreover, the framework should be sufficiently flexible to be able to structure the ongoing public debate on the ethical acceptability of certain biotechnological developments.

The Integral Policy Document on Biotechnology that was presented to Parliament on 28 December 2000 by the then Government had already stated that any policy concerning new developments in biotechnology should not only give an opinion on unintended effects – whether beneficial or harmful – and an estimate of any attendant risks. It should also consider the relative merits of the benefit to society and the risks in the light of the precautionary principle and should take account of the social and ethical questions to which modern biotechnology gives rise.[12] The policy paper described the task of the COGEM as follows: "The task of the COGEM will be to provide solicited and unsolicited scientific advice, taking account of societal developments in the field of genetic modification while remaining open to the need for discussion. (...) In addition, in order to increase transparency, the COGEM will give a periodic insight, at a higher level of abstraction than in recommendations on individual cases, into the manner in which risk assessment will be carried out within the social context and will specifically consider scientific doubts and uncertainties."[13] The COGEM was also to be enlarged to include members with expertise in the fields of ecology, ethics and the social sciences. In the process of consultation with the temporary committee on Biotechnology on 21 and 28 January 2002, at which the need for an ethical assessment framework was discussed at length with the Ministers concerned, the then Minister for the Environment, Jan Pronk, assigned

[11] Cf. *Motie Ross-van Dorp c.s.*, Tweede Kamer, vergaderjaar 2001-2002, 27 428, nr. 18.
[12] Cf. Tweede Kamer, vergaderjaar 2000-2001, 27 428, nr. 2, pp. 6-7.
[13] Ibid., p. 26 and p. 35.

an important role to the COGEM, his scientific advisory Commission in the field of genetic modification. He stated that in an integrated assessment of biotechnological research it was first necessary to learn the possible effects, intended and unintended, beneficial and harmful, of the research. Next, the risks attaching to the proposed interventions would have to be estimated. Then the risks and the intended benefit to society would have to be weighed against one another, in the light of the precautionary principle, the safety implications, procedural requirements such as transparency of decision-making and individual freedom of choice, and general ethical acceptability. In fact the first two steps constitute the basis of every COGEM recommendation. However, the Minister emphasised the advisory task of the COGEM in relation to the process of forming an opinion on the relative merits of the risks and the benefit to society. He cited the risk-benefit questionnaire developed by the COGEM as an example of the application of an integrated assessment framework. The Minister for the Environment would then have the final word.[14]

[14] Tweede Kamer, vergaderjaar 2001-2002, 27 428 enz., nr. 10, pp. 44vv.; Tweede Kamer, vergaderjaar 2001-2002, 27 428 enz., nr. 33, pp. 47-48.

# 2. The background to this report

Given the political interest in an integrated biotechnology assessment framework and the role assigned to the COGEM in this respect, the COGEM felt it would be advisable to produce an advisory report on the subject. The present report describes the progress the COGEM has made on the design of an integrated social and ethical assessment framework for biotechnological developments.

A first report was published in January 2002, commissioned by the Ministry of Housing, Planning and the Environment on a proposal from the COGEM. This report, by COGEM member Dr H. Verhoog, summed up various social and ethical aspects of biotechnology in relation to agriculture. At the same time it described various assessment models from the literature. The risk-benefit questionnaire the COGEM had developed, in which producers are questioned about the added value, risks and social aspects of the GMOs they want to place on the market, was presented in this report.

The COGEM then commissioned Dr F.W.A. Brom, together with Mr F.L.B. Meijboom (both of the University of Utrecht's Centre for Bioethics and Health Law), Dr M.T. Hilhorst (Erasmus University Rotterdam) and COGEM member Professor H.A.E. Zwart to identify and describe the building blocks necessary to prepare a socio-ethical assessment framework for biotechnological developments. Their report was presented at the symposium the COGEM organised on 13 June 2002 and their opinions tested against those of other ethicists and interested parties.

On the basis of these results the COGEM sent a first – interim – advisory report to the then Minister for the Environment on 28 June 2002, to inform him of the progress in designing an integrated ethical and social assessment framework for biotechnological developments. In this report the COGEM proposed, as Brom et al. had proposed in their report, extending the risk approach the COGEM had used until then to include the impact on values. The report also discussed the nature of the knowledge to be collected, how such an assessment should be regarded as a process, and the consequent interaction between ethics and policy.

In the months that followed there was a change of government. An earlier date that had been set for a debate in the Lower House of Parliament was postponed given the lack of a government position. A caretaker government followed. Currently the new Government is preparing a position, which it will present when it has taken office.

In the meantime the COGEM has further considered the details of the present proposal for an integrated socio-ethical assessment framework for biotechnology. In particular the COGEM has focused on an analysis of decision

models that could be used in such an assessment and the details of its own proposal for this, a so-called "gate" and "balance" model, which will be discussed more fully below. In addition the COGEM organised an international workshop from 8 to 10 December 2002 with fellow organisations which also concern themselves with advising on ethical and social issues in relation to biotechnology in Europe. The theme of the meeting was the manner in which the various European countries assess social and ethical aspects of the marketing of GMOs. This is done on the basis of EU Directive 2001/18, which states among other things: "Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products."[15] From the presentations on the methods employed by the various committees it emerged that there were significant differences in the degree of progress in implementing them. The workshop did produce common focuses which should be taken into account in further recommendations on an integrated socio-ethical assessment framework. A key concern in this connection is "trust". All concerned – industry, the Government, assessment committees etc. – can win trust by means of information and transparency. Trust in ethical and social assessment is increased by allowing all relevant ethical views to be presented and by transparency. Consequently the conclusion must be that not only the substantive evaluation of interests is important, but that procedural aspects also merit particular attention.

At the same time, in preparing this advisory report, the COGEM has made use of the report "Deciding on biotechnology" which the Dutch Scientific Council for Government Policy (WRR) presented to the Prime Minister in January 2003.[16] There are significant similarities between that report and this advisory report, both in terms of the recommendations on the role and responsibility of Government, and on the necessity of independence and transparency in the assessment process. This report sketches the – difficult – task facing the Government of making and justifying policy choices on biotechnology without on the one hand frustrating developments while on the other hand taking account of the range of views people in society hold on the subject. Repeatedly, the report points out the importance of ensuring sufficient support for the choices made. It states that the Government is responsible for ensuring a careful moral evaluation allowing sufficient room for the input of various interested parties. At the same time the Government should, where appropriate, clearly state where it stands and arrive at an opinion of its own. And that opinion must "of course be open to public scrutiny".[17] With the integrated socio-ethical

[15] Directive 2001/18/EC of 12 March 2001, Recital 9.
[16] Wetenschappelijke Raad voor het Regeringsbeleid, *Beslissen over Biotechnologie*, 2003.
[17] Ibid., p. 116.

assessment framework for biotechnology presented below, the COGEM hopes to have made a concrete contribution in this respect.

On the basis of the above the COGEM prepared a discussion paper which was presented to experts and various interested parties at a symposium on 11 June 2003. The chairpersons of the Central Committee on Research Involving Human Subjects (CCMO)[18] and the Committee on Animal Biotechnology (CBD),[19] which also advise on social and ethical aspects of biotechnology, took part in the forum discussion at the meeting. Finally, comments on the discussion paper were received via the COGEM's website. Use has been made of all these contributions in the present advisory report.

[18] *Centrale Commissie Mens-gebonden Onderzoek*.
[19] *Commissie Biotechnologie bij Dieren*.

# 3. The European context

Developments in biotechnology are not confined to the Netherlands, they occur increasingly on an international, even global scale. And, as the WRR also observes, this globalisation has not only economic but also socio-cultural and ecological dimensions. Moreover, as far as the Netherlands is concerned legislation in this field is largely enacted at the European level. European policy largely determines Dutch policy in the field of biotechnology.[20] For this reason we here give a brief outline of the European context in relation to the part expert advice plays in influencing government policy on biotechnology.

European legislation provides general guidelines concerning the ethical and social aspects of the biosciences and biotechnology. The "European Group on Ethics in Science and New Technologies" should, for example, be consulted with a view to obtaining advice on ethical issues of a general nature regarding the deliberate release or placing on the market of GMOs.[21] But Member States explicitly retain a competence of their own as regards ethical issues.[22] Both at the European and the national level there is provision for consultation on the ethical implications of biotechnology. This requires that information is exchanged on the experience acquired studying the ethical aspects, and that the consultation is conducted according to strict rules of openness, transparency and public accessibility.

In 2001 the European Commission published a White Paper on Governance.[23] This argues that what is needed is a reinforced culture of consultation and dialogue in the European institutions. On the one hand, it observes that scientific and other experts play an increasingly significant role in preparing decisions – and as the advent of biotechnology raises unprecedented moral and ethical issues, the experts concerned come from a wide range of disciplines and experience. On the other hand, it is often unclear who is actually deciding – experts or those with political authority.

At the same time, a better-informed public increasingly questions the content and independence of the expert advice that is given. The issues become more acute whenever the EU is required to apply the precautionary principle in risk assessment and risk management. The Commission announced that from June 2002 it would be publishing guidelines on collection and use of expert advice in order to ensure the accountability, plurality and integrity of the expertise used. These guidelines could form the basis for a common approach for all Institutions and Member States. It argued that this was necessary on the basis of

[20] Cf. ibid., p. 22.
[21] Cf. Directive 2001/18/EC of 12 March 2001, Recital 57.
[22] Cf. ibid., Recital 60; Ibid., Article 29.
[23] Commission of the European Communities, COM(2001) 428 final, 25 July 2001.

more general principles, too: openness, participation, accountability, effectiveness, coherence, proportionality and subsidiarity.[24]
These guidelines were published in December 2002.[25] The interplay between policy makers, experts, interested parties[26] and the public at large was described as an essential part of policy-making. It was stressed that attention had to be focused not only on the policy outcome but also on the process followed. Three principles were formulated which form the basis of the guidelines whenever expert advice is collected. These are:

*Quality*. Three factors determine the quality of advice: the excellence and independence of the experts, and pluralism.

*Openness*. Transparency is required in connection with the way issues are framed, experts are selected and results handled. It also implies a strategy for proactive communication and information, adapted according to the issue. It must be possible to justify and explain the way experts have been involved and the decisions that have been made based on that advice. This requirement of accountability also extends to the experts themselves. In some cases too much openness may damage the legitimate interests of those concerned, but even then it is important to be as transparent as possible about the reasons for not being open.

*Effectiveness*. The methods for collecting and using expert advice should be in proportion to the task in hand, taking account of the sector concerned, the issue in question and the stage in the policy cycle. In any case, a system of routine monitoring, evaluation and review will be needed to be able to improve the methods on a continuous basis.[27]

Various countries are implementing the European Commission guidelines in various manners. Expert committees are positioned in various ways in relation to the policy process.[28] During the international workshop on the implementation of EU Directive 2001/18, for committees with a similar task to the COGEM, it emerged that most European countries have not yet made provision for systematically obtaining expert advice on ethical and wider issues

[24] Ibid., pp. 10.
[25] Commission of the European Communities, COM(2002) 0713 final, 11 December 2002.
[26] In this connection an "interested party" is an individual or group that is concerned or stands to be affected – directly or indirectly – by the outcome of a policy process; or represents the general interest of groups concerned by such an outcome, within and outside the EU, cf. ibid., note 4.
[27] Cf. Commission of the European Communities, COM(2002) 0713 final, 11 December 2002, paragraph 3.
[28] Cf. S. Glynn et al., *Science and Governance: describing and typifying the scientific advice structure in the policy making process – a multinational study*, 2001.

in the advisory committees that concern themselves with policy on biotechnology. Nor has provision been made for broader public consultation in all Member States. Incidentally, it emerged that there were significant differences in public perceptions of gene technology.

The methods employed by the various committees also differ. The Netherlands is unique in developing an integrated framework within which licensing, policy processes, and consultation and advice on social and ethical issues are all involved. At the workshop appreciation was expressed for the Dutch approach. A European network has been set up, with the COGEM in the Netherlands acting as its secretariat, and it has been agreed to provide one another with feedback each year at a European level.[29]

[29] The second meeting of the European Network will be held in Bern (Switzerland) on 25 and 26 September 2003.

# 4. A clarification of terms

To make it clear what the assessment framework entails, we must first clarify the meaning of the terms used. What do we mean by an "assessment framework" in respect of biotechnology? And what is specific about a "socio-ethical" assessment framework? Finally, we shall explain what we mean by "integrated".

*Assessment framework*

For the purposes of this report the term "assessment framework" means the substantive and procedural rules used to determine whether a thing, a person or an organisation meets an implicit or explicit standard or criterion. One example of an assessment framework is a legal framework, where the assessment is carried out in relation to laws or other legally valid arrangements. But there are other contexts within which assessments in this sense can be carried out. It is essential that the assessment framework is formulated in such a way that assessment in the light of the standards applicable in any given field produces an unambiguous and consistent outcome: something is permitted or it is prohibited, it is acceptable or it is unacceptable. Moreover, the idea of an assessment framework presupposes that there is an authority responsible for carrying out the assessment. This authority must clearly possess appropriate expertise.

*Socio-ethical*

The combination of the words "ethical" and "social" is not self-evident in the context of an assessment framework and therefore requires clarifying. An ethical assessment implies that a specific case is reviewed in the light of ethical standards, values, principles and theories.[30] This may concern a specific product, but also an entire development process. A social assessment implies that the impact, national and international, on existing social structures and arrangements is considered in a specific case, and how desirable that is. At the same time the way the producer in question handles forces in society will be considered. Economic and sociological theories and concepts provide a relevant frame of reference.

[30] One definition of ethics, which is for example used in the WRR report (p. 117), is that of critical research of the fundamental principles and concepts used in a moral debate. Ethics aims to analyse and clarify arguments and to examine the justification of moral claims. It is a practical, normative science. In other words, ethics cannot confine itself to describing the moral rules that govern our behaviour but must above all evaluate and correct these rules, and sometimes even replace them by new, better rules. Ethics is not solely a form of disinterested reflection, it implies evaluation and correction of human behaviour.

One important difference between an ethical and a legal assessment framework is that the criteria are often not crystallised or "established". This means that an ethical assessment will have to be far more flexible, dynamic and open than a legal assessment, and allow more room for plurality. The answers (the outcome of the assessment) will also be less categorical: besides outcomes like permitted and prohibited, other outcomes such as "desirable", "recommended" and "acceptable" should also be possible. This certainly applies where what is being evaluated are relatively new forms of biotechnology such as gene technology.

*Integrated*

In this report the term "integrated" means relating to the whole, comprehensive. In relation to an assessment framework that addresses the ethical and social evaluation of modern biotechnology, the term "integrated" can refer to:

1. The socio-ethical component:
   - From this perspective integrated means: a comprehensive overview of the general standards and values that play a part in the social debate. Existing discussions are taken on board. It is important to strive to be comprehensive and not to exclude certain arguments or visions in advance.
   - From this perspective integrated also means: unity in the shared values that already play a part (that have become "established" in the existing legal frameworks) in the ethical assessment of biotechnology in relation to humans, animals, nature and the environment. This means a better, coherent overview of what has already been regulated.
   - Integrated also means giving the ongoing ethical and social discussion on the acceptability of certain biotechnological developments a place within the framework. It implies that the dynamics of developing moral judgments are taken into account by being receptive to new experiences and providing guarantees against rigidity and fossilisation.

2. Framing the issues:
   - In this sense, integrated means that the assessment involves not only the direct ethical implications of the products and the intended results, but also takes account of the indirect impact on the relevant social context.
   - An integrated assessment concerns not only the product, but also the development process and the trends, the paradigmatic context.
   - Biotechnology is regarded as an integral part of the agro-industrial and medical production chain, which consists not only of technical but also social codes (scripts). This means that not only technical developments

are assessed, but that social and ethical shifts are also taken into consideration.

3. Actors:
   - From this perspective, integrated means that every individual, every citizen has the democratic right to participate in the ethical dialogue. The extent to which this ideal of participation can truly be achieved will partly determine the degree of public support for biotechnology. Trust in policy is promoted by encouraging people to form their own opinions (access to underlying facts and analysis) and by taking the outcome of public debates seriously.

# 5. Ethical expertise and government policy

Having made the characteristic features of an integrated socio-ethical assessment framework more explicit, we shall now present a model which describes such an integrated ethical and social assessment as a process while also placing it in the government policy cycle. As has already been mentioned, an integrated socio-ethical assessment framework must take account of the ongoing discussion about the ethical acceptability of biotechnological developments. However, the government's role in this discussion will not always be the same. An analysis of the type of problem concerned will make this clear. The problems are characterised according to the degree of consensus that exists at a given time about values and facts. That determines what type of government policy is appropriate. Figure 1 illustrates this.

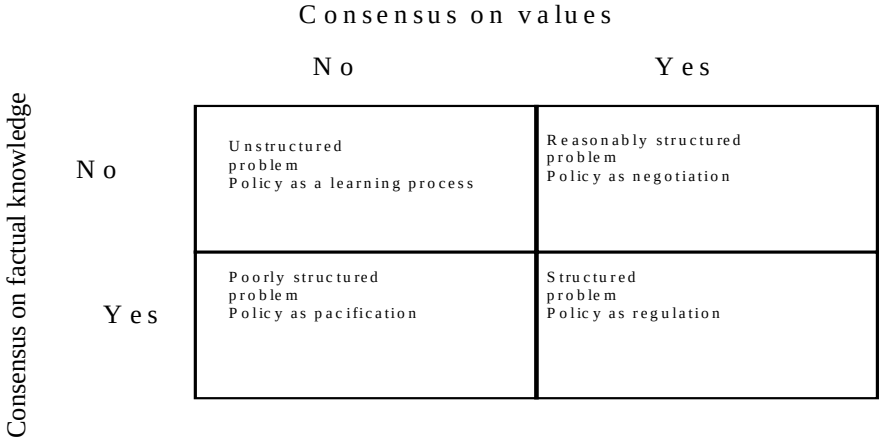


***Figure 1:*** *The relationship between the characteristics of a problem and the appropriate government policy.*
*Typology based on L.E. Paula, "Biotechnologie bij dieren ethisch getoetst?" Rathenau instituut 2001*

Socio-ethical issues generally enter the public domain of government policy as an unstructured problem (Figure 1, top left). They are a problem because there is no consensus about the values concerned and there is disagreement as to the correctness and relevance of the scientific facts. By encouraging scientific research the discussion about the facts (harmfulness, threat to the environment etc.) can be resolved. This puts us at the bottom left of the diagram. On the other hand, various forms of consultation can help us find common values, and this also makes the problem easier to handle. In that case we can proceed to the top right corner. In some cases it is possible to reach complete agreement both about the relevant facts and about values that should be respected. The problem is then

optimally structured and can generally be “tamed” in clear rules and regulations. This does not mean that every ethical problem that arises can then be dealt with in a routine fashion. Even in the most “regulated” of practices, where there is an ethical conflict of interests a considered choice must be made; the dilemmas have not been resolved.
Scientific research (for example a risk assessment) is often based on certain hypotheses, which are not value-free. Making such hypotheses explicit can also breathe new life into the discussion about the facts. Agreement about facts and values is therefore only of a temporary nature. Developments in science lead to new insights, which do not always fit in with existing factual knowledge. And common positions, about which agreement had once been reached, are likely to face renewed criticism with the passage of time. Consensus on values, like consensus on facts, is merely one of the phases in a cyclical process in which socio-ethical and scientific opinions are shaped, it is not the final phase. Policies should take this into account. An integrated socio-ethical assessment framework is intended as an instrument that provides structure according to democratic principles where conflicts exist. It must do justice to the prevailing opinions and existing discussions. It should provide firm ground when policy issues are being discussed and when future and present developments are being considered. At the same time it should provide for concrete case-oriented assessment and monitoring. But an integrated socio-ethical assessment framework will also have to be open to new experiences. After all, the fact that it is integrated implies that it takes account of developing opinions on moral issues.

These considerations bring the COGEM to the model below, in which the cycles of socio-ethical assessment and government policy are integrated. The model distinguishes four phases in each of these cycles. The squares indicate the various ethical phases, the arrows the phases of the policy cycle. This integrative model shows how certain problems surface and how the Government and those with political responsibility can deal with them. The type of decision-making involved is indicated at each transition from one phase to the next. This model does not apply specifically to the assessment of modern biotechnology, it can also be applied in other sectors.

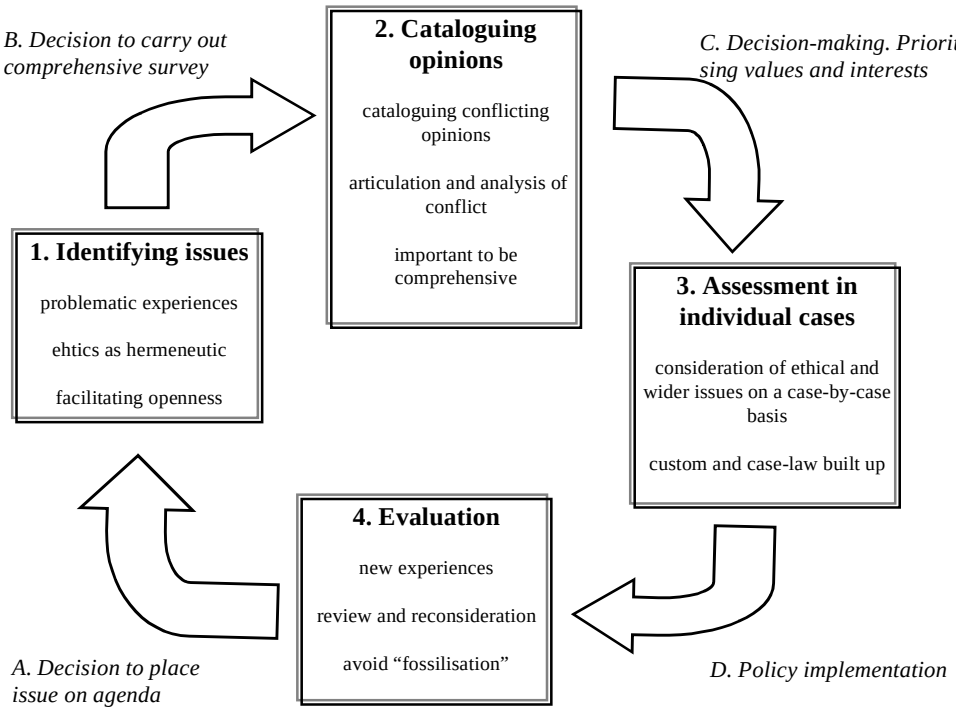


***Figure 2:*** *Cycle of socio-ethical assessment and government policy. A letter indicates elements of the policy cycle. A number indicates phases in the ethical cycle.*

The cycle consists of the following steps:

*A. Decision to place an issue on the agenda*

The cycle starts when people experience a problem or feelings of unease in a given situation or in respect of a given practice, and this experience is often not shared by all concerned. This does not mean, as the WRR also observes,[31] that people have already formed an opinion or started to discuss ethical considerations. The moral concern which surfaces here and there does however demand political attention.

*1. Identifying issues*

Ethicists detect problematic experiences, make them explicit and clarify them critically. This is what is meant by the term "ethics as hermeneutics". It is necessary to be receptive to new problems. During this phase it is important to highlight conflicts and clarify them. Advisory bodies such as the COGEM identify ethical problems and inform the Government about them.

[31] Wetenschappelijke Raad voor het Regeringsbeleid, *Beslissen over Biotechnologie*, 2003, p. 117.

*B. Decision to carry out comprehensive survey*

Once a problem has been identified this will often prompt a decision to catalogue the various opinions on the subject, and at this stage comprehensiveness and openness are important criteria. Interaction between policymakers, interested parties, experts and the public at large can be encouraged, for example by organising public meetings. This can be delegated to various advisory bodies.

*2. Cataloguing opinions*

In this phase as many opinions as possible should be heard. In order to be comprehensive, it is important to give alternative visions an opportunity and to place forgotten considerations on the agenda. Prevailing conflicts should be articulated and understood as normative tensions.

*C. Decision-making. Prioritising values and interests*

In this interactive phase the multiplicity of opinions is restricted. This is the stage when consensus must be achieved and the discussion must harden into decisions. During this phase various forms of public debate will play a part. They are important to determine whether there is public support for any given decision. Finally values and interests are prioritised. Choices are open to democratic scrutiny. Moral experiences and insights are expressed in terms of principles and concepts. It becomes possible to weigh one against the other. A degree of consensus emerges, a regulated practice. Note that visions expressed at one stage of the democratic process but not acted on at that time may well become relevant in later phases.

*3. Assessment in individual cases*

In this phase custom and case law are built up. The socio-ethical assessment is carried out within an established and well-defined legal framework by specially appointed ethics committees, which consider each case within a fixed structure. Transparency of the decision models used and consistency are important criteria here.

*D. Policy implementation*

After a while the priorities, decisions, the implementation and monitoring of these decisions and the results of the policy should be subjected to regular critical review. This review serves in the first place to ensure the quality, consistency and relevance of the decisions, but can also be triggered by appeals procedures or by external factors.

*4. Evaluation*

Sooner or later the opinions and ethical deliberations will also have to be subjected to review. It is inevitable that the consensus that has been reached will sooner or later be challenged on the basis of new conflicting experiences. There will be a period during which the perspective will broaden, the issue will be reconsidered and new interpretations will emerge. After all, ethics must not only express established points of view, but be proactive and anticipate new developments and new issues.

During each phase of this cycle, policy and ethics play a different part. This is consistent with the dynamic nature of the integrated socio-ethical assessment framework outlined in section 4.

# 6. The existing socio-ethical assessment of biotechnology

The "Integral Policy Document on Biotechnology" formed the Government's answer to the then recent and anticipated developments in modern biotechnology. It expressed the Government's policy principles and its policy plans. The Government saw opportunities for better health care, more sustainable agriculture, cleaner production methods and a better environment. But at the same time it felt that the exploitation of these opportunities must go hand in hand with optimal guarantees for safety, transparency of decision-making, individual freedom of choice and ethical acceptability. Opportunities must be exploited in a responsible and careful manner.[32] The Government's vision received the support of Parliament. It was however noted that the advisory bodies operating in the various areas of biotechnology, which each examine applications in their own field in the light of social, ethical and legal considerations, should co-ordinate their activities in such a way as to avoid too much, undesirable, overlap.[33] At the same time the Government was asked to prepare an overview. On 23 December 2002 the State Secretary for the Environment responded to these motions. He noted that the activities of the various advisory bodies that concern themselves with modern biotechnology, the COGEM, the Committee on Animal Biotechnology (CBD), the Health Council's Committee on Safety of New Foods (CVNV),[34] the Council for Health and Care (RVZ),[35] the Council for Healthcare Research (RGO)[36] and the Central Committee on Research Involving Human Subjects (CCMO), which is an independent body, do show certain similarities but that there was no question of overlapping responsibilities.[37] If an integrated assessment framework was used, it would be important to ensure that this did not change and that the same assessment was not carried out twice by different committees.

Not only are there various advisory bodies concerned with developments in biotechnology, there are also various Ministries involved in policy in this area. After all, there are numerous different values and interests at issue, ranging from employment to justice, and from protection of man and the environment to improving healthcare. Assessment of social and ethical issues is carried out within different statutory frameworks.[38] In an annex to an earlier advisory report

[32] Cf. Tweede Kamer, vergaderjaar 2000-2001, 27 428, nr. 2, pp. 4-7.
[33] Cf. Tweede Kamer, vergaderjaar 2001-2002, 27 428 en 27 543, nr. 21 & nr. 25.
[34] *Commissie Veiligheidsbeoordeling nieuwe Voedingsmiddelen* of the *Raad voor Volksgezondheid*.
[35] *Raad voor Volksgezondheid en Zorg*.
[36] *Raad voor Gezondheidszorg Onderzoek.*
[37] Cf. Tweede Kamer, vergaderjaar 2002-2003, 27 428 en 27 543, nr. 36.
[38] For example the *Wet medisch-wetenschappelijk onderzoek met mensen* [Medico-Scientific Research on Humans Act], *Gezondheids- en welzijnswet voor dieren* [Animal Health and Welfare Act], *Besluit Biotechnologie bij dieren* [Animal Biotechnology Decree], *Wet op de dierproeven* [Animal Tests Act],

published on 28 June 2002, the COGEM supplied a schematic overview of the statutory frameworks and values underlying the activities of the CCMO, CBD, and COGEM. This overview is supplied in Annex 2.

Within these various frameworks certain constants can be distinguished in the strategies and criteria used. In the present framework it is important to increase their consistency and coherence. Some cases will be put for consideration before different agencies at different stages of their development. An integrated socio-ethical assessment framework will have to take account of these links. Co-ordination between the various bodies is desirable, as regards both procedural and substantive consistency. An integrated socio-ethical assessment framework must, finally, remedy any gaps, duplications and inconsistencies. For this reason we consider below the underlying principles and choices that characterise policy on biotechnology. Where change is desirable, this is indicated.

As noted above, the Government's aim of taking advantage of the opportunities biotechnology affords in a responsible and careful manner is supported in various areas by advisory committees. The members of these committees have expertise in various fields. Their functioning as members of the committees and the functioning of the committees as a whole are subject to the requirements described above in relation to Europe: quality, openness and effectiveness.[39] The requirement of quality includes the excellence, independence and pluralism of the experts. The requirement of openness implies the necessary transparency in relation to the way issues are framed, experts are selected and results handled. It also implies a strategy for active communication and information, and explanation and justification of the manner in which experts have been used and of the policy choices based on their advice. The last requirement, effectiveness, implies that the methods for collecting and using expert advice should be in proportion to the task in hand.
The Government has adopted a two-pronged approach to careful policy-making: on the one hand a "No, unless" approach and on the other a "Yes, if" approach. In the former approach any act is prohibited, unless there are good grounds for exemption. This means the burden of proof is on the applicant and not on the licensing authority. Where there are no valid arguments, the ban remains in force. The latter approach implies that something is permitted, provided the conditions of due care are fulfilled. In this case the burden of proof is on the licensing authority. If there are no valid arguments opposing what has been requested, the applicant can proceed. Where a more cautious assessment is

*Wet milieugevaarlijke stoffen* [Environmentally Hazardous Substances Act], *Besluit GGO* [GMO Decree].
[39] Cf. Commission of the European Communities, COM(2002) 0713, 11 December 2002, paragraph 3.

desirable, for example where the risks are unknown, an ethical framework with a “No, unless” construction is the preferred option. Both approaches are found in the legal frameworks and methods of the advisory committees mentioned above.

Virtually all the legislative frameworks incorporate the proportionality principle, which requires ethics committees to arrive at a fair and just consideration of the issues. In this context fair and just means that the relative merits of the interests and values concerned are considered in a manner that can be explained and justified. For example, in the field of medical biotechnology it implies that the purpose of a trial involving patients/persons is examined in relation to the risks those patients/persons may run. The proportionality principle is also applied where developments in biotechnology have consequences for animals. The Committee on Animal Biotechnology (CBD) balances the intended aim – which must, incidentally, be important – against the possible impact on the health and welfare of the animals and other ethical objections, such as violating the integrity of the animal (changing its genome, species-specific behaviour, and its appearance). The remit of the Animal Experiments Committees (DECs) includes weighing the interests of the purpose of an animal experiment against the maximum expected suffering.
However, the proportionality principle is not applied when assessing the possible impact of gene technology on the environment. The GMO Decree requires an estimate of the size of the risk to man and the environment, and a recommendation on whether this risk is acceptable. Acceptability is not however related to the possible gain. Thus at present the assessment of the socio-ethical acceptability of “green” gene technology in particular (the assessment of experiments on animals and humans is dealt with by other bodies) is not based on a fair and just consideration of the potential advantages and disadvantages. Up to now this kind of decision has been “left to the market”. All kinds of signals indicate that the public at large no longer regard this as acceptable. The COGEM would like to draw attention to the following: it has emerged from public consultations that people are prepared to accept risks if they are offset by clear benefits (extrinsic values). On the other hand, intrinsic values are also felt to be important and often operate as a veto. Banks draw up ethical codes which they apply before making investments. Very occasionally these codes also refer to biotechnology. An activity must have “added value” for society or the user before it will qualify for financing. The “Danish action plan for biotechnology and ethics” states: “A precondition for the acceptance of possible risks is that the technology does not solely entail economic benefits, but also contributes to improved quality of life, for example in the form of better

foods, cleaner environment or improved health."[40] The report on the public debate on "Food and Genes" indicates that the Dutch public considers utility to be a very important factor in the assessment of applications of gene technology. Indeed its first conclusion on government policy on biotechnology and food is: "the public feels that developments should be subjected to thorough examination in the light of their potential benefits and necessity."[41] The COGEM feels that the lack of the proportionality principle is moreover incompatible with the principles of an integrated socio-ethical assessment framework. It therefore argues that an explicit statutory basis should be created for the consideration of potentially affected values in the light of their intended aims.

Ethics committees not only consider the relative merits of interests and values, they also often apply absolute criteria, established when they were set up and/or after extensive parliamentary discussions. These criteria function in the assessment process as limit values, which may not be exceeded under any circumstances, or only in very exceptional cases. Examples of these are the ban on reproductive cloning and the ban on animal testing for the development of cosmetics. If an application is submitted in which the limit values are violated, the application is rejected. In this case it is unnecessary to subject the application to further appraisal.

Government control of the quality of the functioning of the various advisory committees is generally regulated when the committees are established, as is the possibility of objecting to decisions taken by these committees. They are publicly accountable for the arguments they use and the choices they make by means of public (e.g. annual) reports and other publications. In this way the public is also enabled to follow the activities of the committees critically.

[40] *BioTIK action plan*, 2001, p. 2; Cf. also: *The Danish Government Statement on Ethics and Genetic Engineering*, 2000, p. 10.
[41] *Eten en Genen. Een publiek debat over biotechnologie en voedsel*, 2002, p. 20.

# 7. Socio-ethical assessment in practice

In terms of the practical application of the assessment framework the crucial phase in the cycle of socio-ethical assessment and government policy outlined in Figure 2 above is the decision-making phase. By that time consensus has been achieved concerning the relevant values and interests, rights and duties through the democratic process. The framework within which individual licence applications must be assessed has – at least provisionally – been established.

In order to arrive at a consistent and unambiguous opinion in any individual case, as may be required of an assessment framework, a number of steps must be followed. The COGEM distinguishes five steps in this process:

- Step 1: Exploring the parameters within which the process must be carried out and creating conditions so that it can be carried out fairly and justly;
- Step 2: Checking whether limit values have been or are likely to be affected and whether a previous socio-ethical assessment has been carried out, i.e. deciding whether the "gate" can be passed;
- Step 3: Describing potentially affected values which can be taken into consideration;
- Step 4: Describing the aims to be achieved;
- Step 5: Considering the relative merits of the aims and values concerned.

Step 1 describes the necessary preparation for the assessment process. A transparent and open procedure must ensure a proper hearing to the wide range and plurality of visions of the various actors. Experts in scientific and socio-ethical matters address their advice, which must fulfil the above requirements, to the Government and Parliament. This is not an exclusive prerogative. Other interested parties can also present relevant arguments. In principle, everyone is entitled to participate in and have input in an integrated socio-ethical assessment. This means that accessibility, and making input from all sides possible, are important issues in the preparatory phase.
In step 1 all the arguments that have been collected are initially regarded as of equal value. Extreme positions are not excluded, nor are arguments of a more personal nature based, for example, on religious considerations. An effort is made to find ways of dealing with these positions. Clearly it will not always be possible to achieve priorities that are agreed by everybody. Fundamental interests and values are by their very nature sometimes conflicting and incompatible. Articulating, accepting and respecting differences nevertheless

constitutes a precondition for careful consideration of the issues and for advising on their relative importance. It is a requirement for public support after decision-making by the responsible authorities.
There are various methods to enable these different views to be expressed. Apart from expert advice and consulting multidisciplinary expert committees there are, for example, discussion forums on the Internet, dialogue meetings with interest groups and active consultation of citizens in panels, with due consideration being given to the need to be representative and comprehensive.[42]

The following four steps, culminating in prioritisation, are illustrated in the model below.

In step 2 the application is examined to determine whether it fulfils the criteria that apply as limit values in the relevant sector. A check is also carried out whether the case has already been subjected to a similar socio-ethical assessment in the past. These questions must unambiguously be answered with a "yes" or a "no". An example of limit values that might apply is given in the following list:

A. Has fulfilled the requirements set by the licensing authority, for example:
- Proper scientific basis
- Thorough risk analysis
- Adequate safety and emergency measures
- Monitoring plan
- Equality before the law, consistency in respect of earlier policy

B. Complies with international, European and Dutch treaties and legislation, e.g. on:
- Human rights
- Freedom of choice, autonomy
- Freedom of information, right to information
- Precautionary principle

C. No previous, similar socio-ethical assessment has been carried out

If the application turns out not to meet the requirements, no further socio-ethical assessment is carried out. The gate which gives access to consideration of the expected advantages and disadvantages remains closed.[43] Otherwise, the values which may be affected, but may also be offset by certain benefits, the expected aims, must be described in step 3. Negative considerations which do not result in the proposal being rejected out of hand are examined. The intended goals are explicitly formulated in step 4. In steps 3 and 4, which directly precede the weighing of values against aims, use is made of a checklist of values, goals and

[42] Denmark has acquired greater experience with public consultation on socio-ethical aspects of biotechnology, see also www.biotik.dk.
[43] This does not imply that the licensing authority will not take a decision.

interests which may be weighed differently according to the situation.[44] It is not intended that the checklist should produce clear-cut answers in the sense of "there is an effect" or "there is no effect", or "there is an aim" or "there is no aim". What is above all important is that the various values that are affected and aims that are intended should be described and interpreted in a way that focuses on the specific case in its specific context. An example of such a checklist is the following:

**Checklist of potentially affected values and intended goals**

- Biodiversity
- Communication
- Conflict with religious views
- Cultural appreciation of food
- Cultural appreciation of food production
- Cultural diversity
- Doing good
- Economic (in)dependence
- Economic benefits
- Economic disadvantages
- Employment
- Freedom
- Genetic diversity
- Health of humans, animals, plants
- Increased knowledge superiority (or inferiority), technological collaboration
- Integrity of humans, animals, plants, ecosystems
- Justice
- Pluralism
- Product innovation
- Quality of life of humans and animals
- Quality of the environment; reduced environmental burden
- Respect for humans, animals, plants, the environment
- Respect for life
- Responsibility of those concerned, accountability
- Safety of humans and animals
- Social (in)dependence
- Social advantages and disadvantages
- Social stability
- Solving the food issue
- Sustainability
- Technological innovation
- Tradition
- Unintended consequences for third parties: industry, farmers, manufacturers, alternative methods of production, consumers, freedom of choice, animals etc.
- Welfare of humans, animals, plants

This process is not only about the relative weight attached to each item. Where a significant impact on values is anticipated it is important to know more about

[44] It is important to aim to be comprehensive and to include as many values and goals as possible: values that stem from various types of ethics (deontological or teleological) as well as those that may operate at different levels (global, national, local, individual). They may relate to various areas: man, society, animals, nature and the environment. They may involve various roles: man as a producer, consumer or part of a chain. The possible consequences may also operate at different levels: local, national, international or global. They may occur at different points in time: immediately, in the near future or in following generations. At this stage the aim is to be descriptive and it may be counterproductive to impose a structure.

the nature of the goals. Moreover, in some cases it can be relevant to specify alternative ways of achieving the goals stated, each with its own specific potential negative implications.

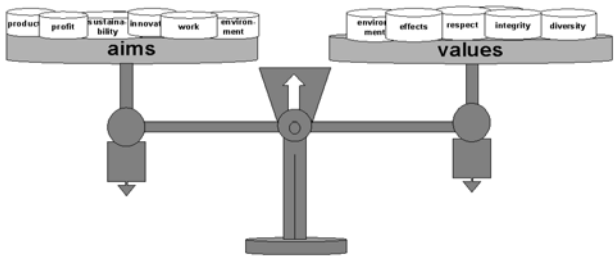


***Figure 3:*** *Description of values and goals*

Ultimately, in step 5, the values and goals that have been identified are placed on opposite sides of the balance, resulting in various options. The actual decision is made by the responsible authorities. These decisions contribute to building up case law and formulating future limit values. In practice it may prove possible to scrap certain elements from the checklist. It follows from the dynamic nature of socio-ethical assessment that case law and limit values have only relative historical validity. A careful retrospective analysis, both of individual cases and of series of cases and of trends, is therefore an important evaluation instrument.

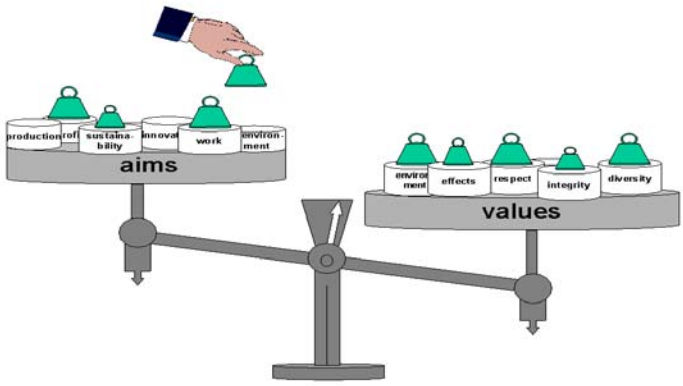


***Figure 4****: Weighing of values and goals*

# 8. General recommendations

Based on its analysis of integrated socio-ethical assessment the COGEM makes the following general recommendations:

1. An integrated socio-ethical assessment framework includes both substantive and procedural assessment criteria. Its use presupposes an authority responsible for carrying out the assessment. This authority must have the appropriate expertise. If this expertise is not immediately available, the COGEM recommends that it should be sought.

2. Biotechnology assessment should not confine itself to weighing economic benefits against scientific risks. The COGEM recommends expanding the category of risks considered to include the impact on values and to include the benefit to society of the intended goals among the benefits.

3. An integrated socio-ethical assessment framework should on the one hand be sensitive to the dynamics of evolving opinion on moral issues and to developments in science. On the other hand it should provide structure and legal certainty once certain interests and values have been given priority over others through the democratic process. The COGEM recommends that both these aspects should be taken into account by making the assessment cyclic.

4. This means that the Government should not confine itself to ad hoc decision-making and policy measures connected with the ethical and social acceptability of modern biotechnology. In order to ensure the quality, consistency and relevance of policies the COGEM recommends adopting a responsive, methodical approach involving periodic evaluation and agenda-setting, surveys of public opinion, followed by prioritisation and regulation.

5. The assessment framework includes the existing legislative framework on biotechnology in the Netherlands. An analysis of existing legislation reveals that the proportionality principle is not applied in all fields, even though this would be desirable from the point of view of coherence and consistency. The proportionality principle forms the basis for any weighing of potential risks against potential benefits in this connection. The COGEM therefore recommends that the proportionality principle should be declared explicitly applicable to all relevant fields.

6. Care should be taken to avoid duplication when the assessment framework is applied. One and the same case should not be subjected to a similar socio-ethical assessment twice.

7. Various committees carry out socio-ethical assessments within various legal frameworks. Some cases will be presented to different authorities at different stages of development. It is important to be aware of these links in an integrated assessment framework. The COGEM therefore recommends co-ordinating the activities of the various committees and authorities.

# Part II
# The role of the COGEM

# 1. The task of the COGEM within the integrated socio-ethical assessment framework for modern biotechnology

The tasks of the COGEM are laid down in the Environmental Management Act.[45] Its remit is as follows:

> 1. It is the task of the Commission:
> **a**. To advise Our Minister about notifications and applications for a licence with respect to the production or handling of genetically modified organisms and on safety measures which must be taken in connection with this to protect man and the environment;
> **b**. To advise the administrative body which is authorised to grant licences (…), concerning applications for a licence with regard to establishments designated by general administrative measure to the extent these applications concern the production or handling of genetically modified organisms;
> **c**. To advise the administrative body which is responsible for monitoring the production or handling of genetically modified organisms concerning that monitoring.
>
> 2. The Commission will, at the request of Our Minister or the Minister concerned or on its own initiative, inform the Minister concerned if ethical or social considerations which it considers important are involved in the production or handling of genetically modified organisms.

In the Integral Policy Document on Biotechnology the Government and the Lower House of Parliament established that the precautionary principle was the underlying principle for the assessment of licence applications.[46] This means that whenever applications involving genetic modification are envisaged a risk assessment must be carried out, in which:

- the potential risks are identified, and
- the measures that must be taken to manage potential risks are determined.

The Minister or State Secretary for the Environment is responsible for granting the licence. Their decisions are prepared by the GMO Office (BGGO).[47] Compliance with licence requirements is monitored by the Environmental Inspectorate[48] (a department of the Ministry of Housing, Planning and the Environment).

[45] Cf. § 2.3 of s. 2.27 *Wet Milieubeheer*, as it applied on 14 May 2003
[46] Cf. Tweede Kamer, vergaderjaar 2000-2001, 27 428, nr. 2, e.g. p. 6.
[47] *Bureau Genetisch Gemodificeerde Organismen*.
[48] *Milieu Inspectie*.

The COGEM underpins Government policy on genetic modification by giving scientific advice and producing socio-ethical advisory reports. It provides information and advice; it presents its analyses, scientific and socio-ethical, to the Minister. But it does not give a final judgment. Decisions are the prerogative of the Government.

## 2. How the COGEM operates within the integrated socio-ethical assessment framework for modern biotechnology

The COGEM fulfils its informative task in the field of ethical and other wider aspects of genetic modification firstly by calling on its expert members in the Ethics and Social Aspects subcommittee.[49] They are specialised in the ethical and social aspects of biotechnology. They contribute their expertise by advising and by drafting advisory reports. Besides this the COGEM uses its website, where private individuals can make their opinions and arguments known on cases on which the COGEM is advising or intends to produce an advisory report. As far as identifying specific trends in the field of genetic modification is concerned, the COGEM would like to work more closely with agencies that research social aspects of biotechnology and initiate discussion on them (university research groups, Rathenau Institute etc.).

The way the COGEM operates corresponds with the cycle of socio-ethical assessment in relation to government policy as outlined in Part I.[50] Depending on the place in the cycle it fulfils an advisory or issue-identifying task, which may enhance the quality of government policy.

- Where the COGEM detects new developments in biotechnology or in the public perception of biotechnology which may give rise to ethical and social questions, it can prepare an advisory report for the Minister responsible so that the issue can be placed on the political agenda (see Figure 2, phase 1). We shall be giving an example of this in Annex 1.

- The COGEM can contribute to the collection of the various experiences required to broaden the discussion by consulting interested parties (see Figure 2, phase 2). During the decision-making phase the COGEM can produce advisory reports to help focus and regulate the debate.

- Once the priorities have been established, the COGEM can play a distinct role in assessing individual cases, while retaining its distance, by assisting the assessment practice (see Figure 2, phase 3). At this stage the COGEM operates, as was also indicated in the advisory report published on 28 June 2002, according to the five-step plan described in Part I. In this phase, too, the COGEM has an advisory, informative task. Decisions on licences are made by the competent authorities.

[49] *Subcommissie Ethiek en Maatschappij*.
[50] See Part I, Section 5, Figure 2.

- In the evaluation phase the COGEM can contribute to the necessary review by means of evaluative studies of its own, for example trend analyses (see Figure 2, phase 4). If people are clearly dissatisfied with and critical of the prevailing system, the COGEM can contribute to the debate by, for example, organising public meetings. The website can also fulfil a useful function at such times.

In its socio-ethical assessment of biotechnology the COGEM explicitly takes account of the requirements of quality, openness and effectiveness referred to above. The COGEM will also devote attention to the co-ordination with related committees which also advise the Government on ethical aspects of biotechnological developments.

For the purpose of making the potentially affected values and intended goals explicit the COGEM has developed a risk-benefit questionnaire, which should be completed by the applicant. After all, the applicant is the person who can supply the most information on anticipated positive and negative effects. Completing this questionnaire not only supplies data for technical or economic analysis. It also addresses other forms of added value or undesirable effects in the social and ethical field. The purpose of these questions is to provide a readable statement which contains both relevant factual information and socio-ethical information and is moreover made public. The applicant may use relevant parts of his answers in publications on, for example, socially responsible entrepreneurship.[51]

**The risk-benefit questionnaire**:

- What is the added value of the product for your company?
- What is the added value of the product for the production chain?
- What is the added value for the consumer?
- What added value do you foresee for the environment?
- What demand do you foresee for the product?
- What risks are there for the production chain?
- What risks are there for people in your company and the production chain who work directly with your product?
- What risks are there for the consumer in long-term or frequent use?
- What risks are there for the environment?
- What risks are there for the ecosystem (or agroecosystem)?
- What socio-economic consequences can you foresee for the Netherlands, Europe and worldwide?
- In your view, how does the added value of the product compare with the attendant risks?
- What precautions has the company taken?
- Is the product a result of development by your company acting alone or in a joint venture?
- Does your company devote attention to ethical and social issues?
- Are you in any way involved in the public debate on biotechnology?

[51] Cf. e.g. the website of AVEBE, http://www.avebe.com/website/avebe.nsf/frameset?openform&cor2.

As regards the different types of application the COGEM considers, the following can be added:

Introduction into the environment:
*Market-entry applications submitted in the Netherlands*. As the WRR has pointed out, it is primarily a responsibility of the Government to assess the acceptability of applications of biotechnology. The Government must create an environment in which responsibilities are allocated and borne. One of these responsibilities, according to the WRR, is that private parties must as far as possible make the consequences of their actions for society transparent and publicly account for them.[52] The COGEM subscribes to this position and takes the view that this certainly applies where market entry is concerned. European Directive 2001/18 makes it possible to require this at a national level. In our opinion, the producer is primarily responsible for formulating the implications in terms of socio-ethical responsibility of placing a product on the market. One of the aims of the risk-benefit questionnaire the COGEM has designed is to make it easier for the producer to fulfil this new responsibility. This questionnaire can be attached to the licence application as an annex. The COGEM recommends that the Ministry of Housing, Planning and the Environment should make this prestructured form of reporting a required part of market-entry applications. The producer is then also free to use the results in its publications.

*Large-scale field trials*.[53] The COGEM would argue that these applicants should also be asked to complete a risk-benefit questionnaire (to the extent it is possible to answer the questions in the development process). As part of the learning process the COGEM and applicants can consult one another concerning the information necessary for intended future market applications. The COGEM therefore recommends that the Ministry of Housing, Planning and the Environment should also make this prestructured form of reporting a required annex to applications for permission to carry out large-scale field trials.[54]

Contained use:
As regards these applications the COGEM will have to concentrate on identifying trends and, where necessary, publishing special reports on them.

[52] Cf. Wetenschappelijke Raad voor het Regeringsbeleid, *Beslissen over Biotechnologie*, 2003, p. 235.
[53] The term "field trials" refers to all experiments in which genetically modified organisms are introduced into the environment, other than by placing them on the market. They may be agricultural, veterinary or medical experiments.
[54] This will require that the risk-benefit form, which has been developed for market-entry applications, is transformed into a form that is appropriate to this phase of the process.

# 3. Recommendations on the socio-ethical assessment of genetic modification

The COGEM recommends that socio-ethical assessment of biotechnology should concern itself not only with products, but with the entire production process. As matters stand today assessment is generally carried out on a case-by-case basis after the fact. A product has been developed and the question whether it is socially and ethically acceptable is only raised publicly at the end of the development phase. This procedure corresponds with what can be regarded as the technocratic vision of biotechnology. As far as present day scientific research is concerned this vision is generally regarded as outdated, though it still has supporters among scientists and in industry. Instead of stressing the division between technology and society, the interrelationship and interaction between the two are generally emphasised today. This means that ethical and social issues are not confined to the end products, but are important during the entire development process.
The COGEM recommends bringing the assessment process into line with recent insights. For an ethical and social assessment framework to call itself integrated it cannot solely address the external assessment of end products. It must also address and regulate the entire development process. This means not only weighing the economic benefits against the scientific risks – which, incidentally, also include social considerations –, but that other forms of added value or adverse forecasts, social and other wider implications and possible alternatives are also important when forming a view.

Based on its analysis of its role within the socio-ethical assessment framework and in line with its general recommendations in Part I, the COGEM makes the following specific recommendations:

1. The Ministry of Housing, Planning and the Environment is responsible for carrying out the socio-ethical assessment of gene technology. In line with the first general recommendation it should then have the appropriate expertise on hand. At present it does not have this expertise in-house, which is why the COGEM recommends that the Ministry should seek to fill this gap.

2. The proportionality principle mentioned in the fifth general recommendation is not mentioned in the GMO Decree. The COGEM recommends that the proportionality principle should be declared explicitly applicable to its field, identifying issues and advising on the production and handling of GMOs.

3. The COGEM has developed a risk-benefit questionnaire as an instrument for clarifying the advantages and disadvantages of certain developments in a dialogue with producers. The COGEM recommends that the Ministry of Housing, Planning and the Environment should make completion of this prestructured questionnaire compulsory for market entry applications in the Netherlands and for applications to carry out large-scale field trials.

# Part III
# Annexes

# Annex 1 Assessment in practice

## 1. Three practical examples

In order to illustrate the manner in which the socio-ethical assessment framework can be applied in specific cases, this section provides a number of practical examples of issue-identification (phase 1) and assessment in individual cases (phase 3) as described in section 5 of Part I of this report. There it was said that custom and case law were built up in the assessment phase, once the prioritisation of values and interests had been completed. In this phase ethics committees set to work according to the five-step plan described in section 7 of Part I. Two case studies will illustrate this.

When the cycle of socio-ethical assessment and government policy was described it was indicated that advisory bodies can prepare an advisory report for the minister responsible whenever new developments in biotechnology are observed, or when public perception of such developments raises social and ethical questions about them. That advisory report will often formulate the social and ethical issues that have been raised. We shall also be giving an example of this.

In the examples that follow the procedure followed at the time is reconstructed applying the assessment framework presented here, including the use of the proposed instruments. It should be stressed that the analyses present a reconstruction rather than a description of the historical process as it occurred.

*Case study 1 – the amylopectin potato*

In 2002, by agreement with the producer, the COGEM carried out an analysis of the socio-ethical aspects of marketing potatoes with an increased amylopectin content. This was an industrial application in the non-food sector. The producer had submitted an application to carry out field trials and was co-operating with the analysis on a voluntary basis. Use was made of the risk-benefit questionnaire developed by the COGEM. Completion of the questionnaire by the producer was intended not only to clarify the values and goals concerned but also to improve the questionnaire.

At the time the application was assessed, the COGEM did not use the five-step plan described above, nor the integrated socio-ethical assessment framework now proposed. The analysis must be seen as a reconstruction along the lines of this advisory report.

The producer’s answers to the risk-benefit questionnaire indicated that there was no question of a violation or potential violation of relevant limit values. Nor had the environmental risk assessment given any cause to reject the application, and

no previous socio-ethical assessment had been carried out. There was therefore no insurmountable objection to going on to a consideration of the issues. In our terms the gate can be passed and the proportionality principle applied. The values that may be adversely affected can be considered along with the values and goals that may justify granting the application.
This means using the checklist to describe the values which, though they may be adversely affected, will not necessarily result in the application being rejected, along with the goals. This produces a positive score for communication and accountability. The company proved receptive to opinions from outside and was prepared to account for its actions. Sustainability also seems to benefit from the development. The reduced environmental burden will benefit the quality of the environment. Cheaper production and an improved competitive position were viewed as likely economic benefits, as was increased economic independence for the company. This was expected to produce social benefits such as stability, independence, and certainty etc., and to benefit local employment. The product also scores well in terms of product innovation and technological innovation. The potential disadvantages that were foreseen are the possible adverse impact on genetic diversity, a violation of the integrity of and thus lack of respect for plants – in this case the potato –, and the unintended adverse consequences for third parties, the industry, farmers, manufacturers, alternative production methods, consumers, freedom of choice, animals etc., which can never be ruled out entirely.

In other words, the following elements are relevant and must be considered:

| **Intended positive values and aims** | **Foreseen adverse effects on values** |
|---|---|
| Accountability | Genetic diversity |
| Communication | Integrity of humans, animals, plants |
| Economic independence | Respect for humans, animals, plants, the environment |
| Economic benefits: cheaper production, better competitive position | Unintended consequences for third parties, the industry, farmers, manufacturers, alternative production methods, consumers, freedom of choice, animals etc. |
| Employment | |
| Increased knowledge superiority, technological collaboration | |
| Quality of environment. Reduced environmental burden. | |
| Product innovation | |
| Social advantages and disadvantages | |
| Social independence | |
| Social stability | |
| Sustainability | |
| Technological innovation | |

Now all the pros and cons have been listed, the next step is to consider their relative merits. This step, the decision whether or not to grant approval, is the responsibility of the minister concerned, in this case the Minister or State

Secretary for the Environment. The decision is open to democratic scrutiny and it is possible to appeal against the decision to the Council of State.[55]

*Case study 2 – adenoviral vectors in monkeys*

In December 2002 the COGEM presented a general advice to the State Secretary for the Environment on adenoviral vectors in apes.[56] The apes in question were rhesus monkeys and chimpanzees. This document not only contained a scientific advice but also identified an issue, given that experiments with rhesus monkeys and chimpanzees give rise to ethical and social questions. Because there was no question of new developments in biotechnology or a new socio-ethical appreciation of animal tests involving apes, the advisory report provides an illustration of the way the COGEM operates in the assessment of individual cases. It should be noted that, as in the example above, the COGEM did not use the five-step plan described above at the time the advice was presented, nor did it apply the proposed integrated socio-ethical assessment framework. This analysis must therefore also be regarded as a reconstruction in terms of the present report.

If we apply the five-step plan to the application of adenoviral vectors in experiments with rhesus monkeys and chimpanzees, this produces the following result. In step 1 the preliminary steps must be taken to ensure it is possible to carry out an adequate assessment: exploring the parameters and creating conditions for a fair and just consideration of the issues. These steps pose no problem in this case. In step 2, however, the check whether limit values have been or are likely to be exceeded and whether a prior socio-ethical assessment has been carried out, it emerges that it would not be appropriate for the COGEM to carry out a socio-ethical assessment in this case. This is because the Animal Experiments Committee will carry out a similar ethical assessment before the experiments can proceed. In this case the gate is not passed and the COGEM will not apply its checklist.

The COGEM attaches great importance to the procedural side of its advisory task. This is why we stressed in the advisory report that the arguments used in the assessment process and the Animal Experiments Committee's decision itself must be openly available to the public, precisely because this type of experiment is so controversial. The State Secretary was therefore advised that in future it would be desirable in respect of this complicated issue to make the choices that had been made and the reasons for making these choices more accessible.

[55] *Raad van State*.
[56] Cf. CGM/021216-03, COGEM advies Adenovirale vectoren in apen.

*Case study 3 – terminator technology*

In 1999 an advisory report[57] was presented to the Ministers for Housing, Planning and the Environment, Agriculture, Nature Management and Fisheries, and Economic Affairs and the Dutch Lower House of Parliament concerning terminator genes, in other words genes which are placed in a plant to ensure that the plant will no longer produce fertile seeds. In this scenario the producer supplies fertile seeds but is able, before supplying them, to trigger the mechanism which ensures that plants which grow from these seeds will themselves be unable to produce fertile seeds. This technology was developed by one company, which had applied for the patent.

Though the terminator technology existed only as a concept, it was considered likely that the technology would work in practice. In that case other companies would also be able to apply it under licence. It was thought not unlikely that this kind of technology might be widely applied in the plant improvement industry. It was for this reason that the COGEM wanted to publish an advisory report and so contribute to the wider public discussion it felt the subject deserved. The report illustrates how an advisory committee acts in respect of new developments how it operates during the issue-identification phase. As with the other examples, it should be noted that the COGEM did not in fact use the proposed integrated socio-ethical assessment framework at the time the advice was presented. The analysis must therefore be regarded as a reconstruction in terms of the present advisory report.

In the report terminator technology was considered from the perspective of a hypothetical application which would not exceed the limit values and would not therefore be stopped at the gate. Although the five-step plan is not used in the issue-identification phase and there is no clear prioritisation of values and interests, the checklist can nevertheless be used. Particularly in this phase it can be expanded to include new components and new interpretations.

It was assumed in the report, according to an implicit proportionality principle, that it would have to be possible to weigh potential advantages against potential disadvantages. Applying the present checklist to terminator technology as it was seen in 1999 produces the following results:

[57] Cf. CGM/990415-01. Signalering ethische en maatschappelijke aspecten van de ‘Terminator Technologie’.

| **Positive values and goals** | **Foreseen negative effect on values** |
|---|---|
| Economic benefits: better competitive position of the company | Cultural appreciation of food |
| Justice: protection of rights by means of patent | |
| Product innovation | Cultural appreciation of food production |
| | Economic independence of farmers and countries in Third World versus First World |
| Quality of the environment | Integrity of humans, animals, plants |
| Technological innovation | Social injustice. Inability to produce fertile seed disadvantageous to farmer |
| | Social stability |
| | Tradition, "farmer's privilege" |

In its report the COGEM presented the arguments for and against and noted that it does not take sides in the public debate. Terminator technology and the advisory report were debated in the Lower House of Parliament in late 1999, among other things in a parliamentary question and the reply by the Agriculture Minister, Mr Brinkhorst. [58] In his response on 15 October 1999 the Minister did not express an opinion on the socio-ethical admissibility of terminator technology. He did, however, indicate that if a patentee wanted to exploit an invention in the Netherlands, the application would be assessed in terms of risks for humans, the environment and food safety under the GMO Decree.[59] Terminator technology has never reached this stage and no actual decision based on a consideration of the issues, step 5, has therefore been made.

[58] Cf. Tweede Kamer, vergaderjaar 1998-1999, Aanhangsel 2050, p. 4131; Tweede Kamer, vergaderjaar 1999-2000, Aanhangsel 126, pp. 265-266.
[59] Tweede Kamer, vergaderjaar 1999-2000, Aanhangsel 126, p. 266.

# Annex 2 Biotechnology legislative framework

(See COGEM Advisory Report CGM/020628-03, Annex 2)

| | | | | |
|---|---|---|---|---|
| Dutch Constitution | 23 sections | 23 sections | 23 sections | 23 sections |
| Legislative framework | WMO<br>Medical Research Act | GWWD<br>Animal Health and Welfare Act | WOD<br>Animal Tests Act | Besluit GGO<br>Introduction into the Environment |
| Expert committee<br>*due care* | CCMO<br>Central Committee on Research Involving Human Subjects | CBD<br>Committee on Animal Biotechnology | DEC<br>Animal Experiments Committee | COGEM<br>Commission on Genetic Modification |
| "No, unless" policy<br><br>*in dubio abstini* | No tests on patients unless with informed consent and positive recommendation from METC<br><br>*autonomy principle*<br>*responsibility for the weak*<br>*academic freedom* | No modification of animals unless an important aim and no alternatives<br><br>*intrinsic value of animals*<br>*respect for humans*<br>*academic freedom (relevance)* | No tests on animals unless with a licence from the Health Ministry (VWS) and a positive recommendation from DEC<br><br>*respect for animals*<br>*respect for human interests* | No introduction into the environment unless risk acceptable<br><br>*respect for the environment*<br>*sustainability*<br>*biodiversity* |
| Due care further implemented through "Yes, if" policy<br><br>*ethical standards* | Local METC<br>Scientific quality<br>Risk to patient<br>Life expectation of patient<br><br>*responsibility for the weak*<br>*do good*<br>*do no harm* | Health<br>Welfare<br><br>*do good*<br>*do no harm*<br>*protection of integrity* | Reduction of numbers<br>Reduction of pain and suffering<br>Replacement in cell cultures<br>Training requirements<br>Animal testing expert<br><br>*aim to achieve reduction*<br>*aim to achieve more refined tests*<br>*aim to do less harm*<br>*aim at replacement*<br>*responsibility* | Restrictive measures<br>Training requirements<br>Biological safety official<br><br>*responsibility*<br>*do no harm* |

| | | | | |
|---|---|---|---|---|
| Consideration of relative merits<br><br>*proportionality* | Interest of patient versus interest of scientific understanding<br><br>*autonomy of patient*<br>*welfare*<br>*academic freedom*<br>*scarcity* | Interest of goal versus effect on welfare and other ethical aspects (integrity)<br><br>*respect for intrinsic value of animals*<br>*academic freedom*<br>*do good*<br>*do no harm* | Interest of goal versus likelihood of pain and suffering<br><br>*respect for humans*<br>*do good*<br>*respect for animals*<br>*do no harm* | RISK-BENEFIT<br>Benefit to society<br>Risk to society<br>Accountability<br><br>*respect for human interests (efficiency, effectiveness, the economy)*<br>*sustainability*<br>*biodiversity* |
| Limit values<br><br>*deontology* | No gene therapy in germ line<br>No reproductive cloning<br>No tests on people who are unable to give informed consent (and children)<br><br>*principle of reversibility*<br>*respect for unborn life*<br>*respect for the weak*<br>*dignity*<br>*(human rights)* | Trivial object<br><br>*do good* | No cosmetics research<br>No serious pain and suffering<br><br>*do good*<br>*do no harm* | |
| Accountability<br><br>*professionalism* | Health Inspectorate | Annual report<br>Food Inspectorate | Compulsory national registration<br>Food Inspectorate | Environmental Inspectorate |
| Transparency<br><br>*accessibility* | CCMO annual report and website<br>CCMO closed<br>METC closed | Procedure (preliminary recommendations) by means of extensive public hearings<br>CBD closed | Annual report "*ZoDoende*"<br>DEC: closed | COGEM annual report<br>Website<br>Proposed decisions announced in newspapers<br>COGEM subcommittees: open to the public |
| Civil response<br><br>*dialogue*<br>*appeal* | No | Case: public hearings<br>Objections to Chamber for Industry and the Business Community<br>Assessment framework: half-yearly debate | No | Objection to courts |