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Drs PLBA van Geel

| Your ref.: | Your letter of: | Ref.: | Date: |
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| | | CGM/060202-02 | 2 February 2006 |

Subject
Advisory Report, Genetic Engineering and Globalization

Dear Mr Van Geel,

I have pleasure in presenting you with the Advisory Report, Genetic Engineering and Globalization. In April 2005, the **Commission on Genetic Modification** or COGEM organized a workshop concerning the effects of the European legislation on genetic engineering on the economic and societal developments in non-western countries, and in particular the developing countries. In this workshop, a number of eminent speakers addressed subjects such trade barriers resulting from European environmental legislation on genetically modified organisms (GMOs), impediments to the internal development in African countries, the pitfalls of 'capacity-building' in the area of legislation, and the rapid technological developments in Asia.

As a result of the workshop, COGEM decided to draw up an advisory report on this subject. Attention was devoted to the intended and unintended effects of national and European regulations on the cultivation of genetically modified (GM) crops and the resultant GM products. In the report, attention is focussed on the unintended effects of national and European regulations on countries outside Europe. At the same time, consideration was also given to a number of unexpected effects that could arise in the Netherlands or the rest of Europe as the result of individual countries' regulations and the rapid development that GM cultivation is undergoing in some parts of the world.

COGEM is aware that the Dutch government is already involved in the quest for appropriate solutions for a number of problems. COGEM calls on the Dutch government to make every effort to have its approach to 'capacity-building' in developing countries – in which it is endeavoured to build up regulatory systems on

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the basis of the context of local policy, instead of implementing from above regulations that have been developed elsewhere – supported throughout the EU. COGEM is also a proponent of a further harmonized role for the Biosafety Clearing-House as the worldwide registration system for market approval and field trials of GM crops.

Yours sincerely,

Prof.dr.ir. Bastiaan C.J. Zoeteman

c.c. A.M.A. van Ardenne-van der Hoeven, Minister for International Co-operation
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# Advisory Report, Genetic Engineering and Globalization

## Suggestions for governmental policy in the field of genetic engineering in the light of increasing globalization

**COGEM Report CGM/060202-02**

**Netherlands Commission on Genetic Modification (COGEM)**
It is the task of COGEM to advise the government about the aspects of risk related to genetically modified organisms and to point out ethical and societal aspects of genetic modification (Environmental Protection Act §2.3).

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**Summary**

Legislation is generally intended to protect national or communal objectives. However, in addition to these objectives, side effects such as trade barriers or inadequate enforcement can manifest themselves. These side effects are sometimes intentional, but at other times not. Such unforeseen side effects should be taken into consideration at a later stage of policy development.

In this report, COGEM calls for attention to be paid to the (often unintended) worldwide side effects of national and European regulation with regard to genetic engineering. The focus here is centred in particular on regulation of the cultivation of genetically modified (GM) crops and the resultant GM products. The current extensive regulatory systems are for the most part directed at ensuring the safety of mankind and the environment, and at guaranteeing societal values such as the freedom of choice of consumer and grower. The unforeseen side effects of this regulation that are discussed in this report relate to the increasing difficulties experienced in tracing unknown genetically modified organisms (GMOs) and maintaining GMO-free chains, the lack of an adequately operating system of regulation in developing economies, and an inadequate worldwide registration of new GM crops.

COGEM is a proponent of, *inter alia*, a participative innovation approach with regions outside the EU that have different values, and of a further harmonized role for the Biosafety Clearing-House as the worldwide registration system for market approval and field trials of GM crops.
More attention should be devoted to this in the development of national and, in particular, EU policy.

The cultivation of GM crops and the worldwide trade in the resultant GM products has grown enormously in a short space of time. With an increase from 1.7 million hectares in 1996 to 80.7 million hectares in 2004, the acreage of GM crops increased almost five-fold in this period. There appears to be no end to this tremendous rate of growth.

At present, commercial cultivation is limited to some four GM crops with a maximum of two characteristics. The large number of worldwide field trials *and* the large variety of crops and characteristics used in this suggest that substantial expansion will occur in the future.

Genetic engineering is a relatively new key technology that carries with it potential risks for mankind and the environment. In order to limit these risks, certain regulations have been developed and implemented at national and supranational levels. The cross-border nature of the cultivation of GM crops and the trade in GM products has the effect that (supra)national and European regulations are often also

intended to have effects in the rest of the world. For example, regulations intended to protect an individual country from the entry of unwanted products can form a trade barrier for other countries. There can also be side effects with unintended consequences. For example, EU import restrictions can in developing countries influence the choice as to whether or not to engage in GM agriculture. This could possibly result in the stagnation in GM agriculture in these countries. The intended result could be the promotion of a GM-free food chain. The unintentional effect could be the non-realization of possible advantages in the areas of economy or sustainability. In this way, the great deal of attention that is paid to individual (national or European) values and interests can conflict with other values, such as worldwide solidarity and justice.

Preferable, according to COGEM, is a policy approach in which the international dimension is also taken into account, and in which choices are made on the basis of all the relevant arguments.

Because of its cross-border nature, the globalization of genetic engineering requires international interaction and harmonization. The Cartagena Protocol on Biosafety (CPB) aims at providing this. Society, technology and regulations do not develop independently of one another; they develop within a process of mutual influence or co-creation. Furthermore, regulation in developing economies is for the greater part not yet operational. ‘Capacity-building’ in this area is furthered by international bodies such as the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF). Methods that seek to implement regulation that has been developed elsewhere, however, appear to achieve little success. On the other hand, an approach in which laws and regulatory systems relating to genetic engineering are developed within the context of local policy, as pursued by Dutch development policy, certainly is effective. This approach merits the support of and application by international organizations such as the EU and the UN.

The cross-border nature of GM agriculture also carries with it the effect that undesirable situations, such as the unintended mixing of different batches of grain, etc., acquire a supranational scale. If the EU is to maintain for its citizens its guarantees of safety and freedom of choice in their current form, this will then require an increasing degree of control and inspection. The growing volume and assortment of GM products and the increase thereof in commercial channels will, for technical and financial reasons, make the control and inspection of imported products in the Netherlands and the EU increasingly difficult for governmental authorities to carry out. Here too, unidentifiable GMOs would be difficult to trace.

This could ultimately have consequences for consumer confidence and government credibility.

In relation to the import of GM agricultural products into the EU, COGEM urges that the government adopts a more pro-active and communicative policy approach, as a supplement to the current defensive policy of control and exclusion at the border. By means of entering actively into collaborative projects, for example, the government can try to exercise influence from the inception of the innovational process in countries that have different values without forcing its own opinions upon them. In this way, common values and manageable enforcement at the EU border can be anticipated.

From the point of view of cost control and transparency, a system of worldwide reporting to a single international agency is functional, according to COGEM. This organization is a proponent of a strengthened and harmonizing role for the 'Biosafety Clearing-House' (BCH) as a worldwide registration system, in which the description of detection methods also requires attention. A good, watertight and functional worldwide registration of commercial market approvals and field trials is, *inter alia*, a necessary precondition so that local controls can be carried out to ascertain the presence of unapproved GMOs. This applies both to government and to industry. Within this framework, a better international attunement of dossier qualifications for approval in different countries can be functional for producers and developers from the aspect of cost control and for the benefit of increased transparency.

# 1 Genetic engineering developments

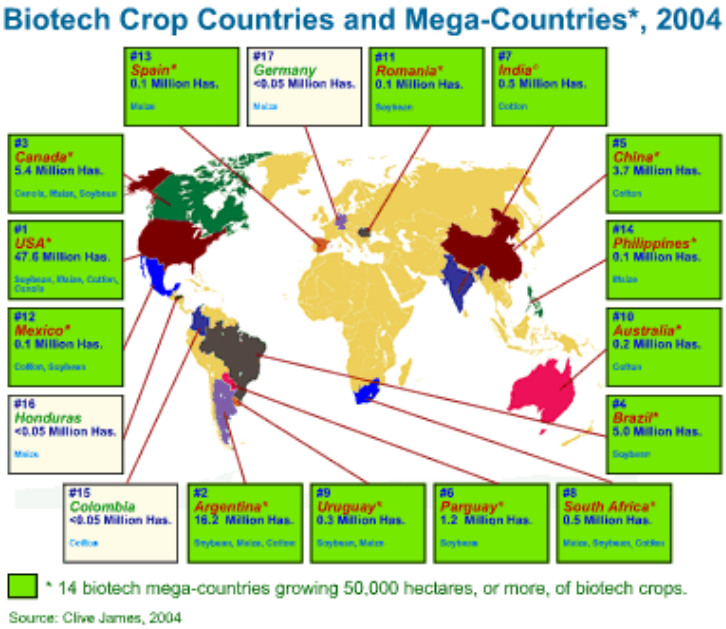


*Figure 1: Countries and regions where GM agriculture was being carried out in 2004.*

## 1.1 Worldwide production of and trade in GM crops

The current trend of globalization - worldwide intensification of the interchange of people, goods, money and information - has important consequences for the spread of genetic engineering and its products. This applies to all areas of the application of genetic engineering. In this report, the focus is centred on agriculture involving genetically modified (GM) crops and the resultant products. Currently, GM crops are being grown on more than 80 million hectares worldwide.[i,ii]

At the moment, GM agriculture is being carried out on only a very small scale in Europe and Africa. In contrast, GM crops are being grown on a large scale in America, and GM agriculture is burgeoning in the Asiatic countries. The figure shown above, an extract from a report of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) on the Global Status of Commercialized Biotech/GM Crops, provides data on the worldwide cultivation of GM crops.[iii]

In their study on the worldwide impact of GM agriculture, *GM crops: the global socio-economic and environmental impact - the first nine years 1996 – 2004*, Brookes and Barfoot sketch the almost fivefold increase in the

**Table 1: The worldwide acreage of GM crops ($10^3$ ha), per country (1996-2004)**[iv]

| | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 |
|---|---|---|---|---|---|---|---|---|---|
| Country | ha | ha | ha | ha | ha | ha | ha | ha | ha |
| U.S.A. | 1,449 | 7,460 | 19,259 | 26,252 | 28,245 | 33,024 | 37,528 | 40,723 | 44,788 |
| Canada | 139 | 648 | 2,161 | 3,529 | 3,331 | 3,212 | 3,254 | 4,427 | 5,074 |
| Argentina | 37 | 1,756 | 4,818 | 6,844 | 9,605 | 11,775 | 13,587 | 14,895 | 15,883 |
| Brazil | 0 | 100 | 500 | 1,180 | 1,300 | 1,311 | 1,742 | 3,000 | 5,000 |
| China | 0 | 34 | 261 | 654 | 1,216 | 2,174 | 2,100 | 2,800 | 3,700 |
| Paraguay | 0 | 0 | 0 | 58 | 94 | 338 | 477 | 737 | 1,200 |
| Australia | 40 | 58 | 100 | 133 | 185 | 204 | 162 | 165 | 248 |
| South Africa | 0 | 0 | 0.08 | 0.75 | 93 | 150 | 214 | 301 | 528 |
| India | 0 | 0 | 0 | 0 | 0 | 0 | 44 | 100 | 500 |
| Other countries* | 0.9 | 15 | 62 | 71 | 94 | 112 | 136 | 209 | 527 |
| **Total** | **1,666** | **10,071** | **27,161** | **38,722** | **44,163** | **52,300** | **59,245** | **67,357** | **77,448** |

* The other countries are: Romania, Mexico, Spain, the Philippines and Uruguay.

cultivation of GM crops (table 1). These crops are not intended solely for the home markets. They are traded and shipped internationally.

At present, the cultivation of GM crops is mainly limited to herbicide-tolerant and insect-resistant maize, soy, cotton and rape. However, an inventory of world-wide field trials that is currently being carried out by COGEM shows that the cultivation of other crops with these and other properties could be anticipated in the near future. At the moment, thousands of trials under field conditions are being carried out worldwide on tens of different crops with innumerable different properties. These GM plants vary from petunias with a modified bloom colour, frost-tolerant potatoes, vaccine-producing alfalfa, to coffee with a reduced caffeine content.

## 1.2 Genetic engineering is a new key technology

Genetic engineering is a recent form of biotechnology. In agriculture too, it brings about a wide range of changes in comparison with the traditional and conventional practices. Genetic engineering is a key technology that is leading to a wide range of new products, new roles and new responsibilities, and therefore also to changing working methods and practices.[v] However, the far-reaching and innovative character of genetic engineering also means that this technology can bring with it undesirable effects: new risks for mankind and the environment. In order to guarantee our safety, governments have developed a wide range and variety of measures and laws. In addition to the effects these are intended to have within the governments' own territories, these measures will also influence the flows of

commerce and consequently also countries beyond their national borders. These effects are sometimes intentional, for example in the case of trade barriers, but also sometimes unintentional. As a result of economic globalization, EU regulations can influence the opportunities for economic development in developing countries, and technological innovations in Asia can confront the maintenance of GMO-free chains in Europe with unanticipated problems. This issue was the reason behind COGEM organizing a workshop and drawing up an advisory report. The report examines the nature of the above-mentioned unintended side effects, together with the opportunities for dealing with them.

# 2 Governmental policy

## 2.1 Government and values

It is the task of governments to protect their citizens. It is for this reason that nations are striving to achieve a form of regulation that will control the possible risks associated with genetic engineering. In addition to safety, governments also have a duty to protect other values that may or may not relate to genetic engineering, such as sustainability, freedom of choice, biodiversity, the integrity of the organism, the dignity of human life, justice and solidarity.[vi] With regard to GM agriculture, this is translated in the Netherlands in particular and Europe as a whole into a policy in which, in addition to the safety of food and the environment, the coexistence of different types of agriculture is taken care of and the freedom of choice of consumers and growers guaranteed.

## 2.2 National and supranational policy

Governmental policy has, in the first instance, a national or community scale, based on the nation's sovereignty in its own territory and on its own norms and values. The societal rules that apply within a society develop in a continually evolving 'civil society'.[1,vii] In the course of time, these rules are made concrete in the form of legislation and regulation. Accordingly, laws and regulations fit in with the economic, socio-cultural and political climate that is prevalent in a society.

The globalization of genetic engineering, which, of course, displays region-specific characteristics in the area of the development and application of knowledge, means that adequate regulation demands a supranational dimension. The effects of the introductions of GMOs, after all, transcend national borders. Harmonizing with the national 'civil society' is then no longer a matter of course,

[1] Use is made in this report of the concept civil society in the description made by the Centre for Civil Society (CCS) of the London School of Economics and Political Science. This definition reads: *Civil society refers to the arena of uncoerced collective action around shared interests, purposes and values. In theory, its institutional forms are distinct from those of the state, family and market, though in practice, the boundaries between state, civil society, family and market are often complex, blurred and negotiated. Civil society commonly embraces a diversity of spaces, actors and institutional forms, varying in their degree of formality, autonomy and power. Civil societies are often populated by organisations such as registered charities, development non-governmental organisations, community groups, women's organisations, faith-based organisations, professional associations, trades unions, self-help groups, social movements, business associations, coalitions and advocacy groups.* However, the CCS also recognizes that the idea of civil society has both now and in the past aroused debate, and that many definitions for this exist. The reasons for the CCS to employ the above-mentioned definition, are that the multiformity of the concept comes to the fore in it, and that it is both empirically and analytically useable.[7]

since this relates to a number of societies. International interaction and attunement is essential for global laws and regulations in the area of genetic engineering.

## 2.3 Worldwide effects of regulations

The cross-border nature of (the trade in) GM agricultural products means that national and European regulations have effects in the rest of the world. These effects can be of an economic nature. Strict regulatory requirements, which emanate from the concern for mankind and the environment, societal resistance and other nationally shared ethical principles, can mean for other countries a barrier to their own commercial development of GM crops, whether this effect is intentional or not. In addition, European regulations can lead to the adoption of western assessment regimes in other countries. This is not of necessity an intended effect. It can be a consequence of the standards set on imports, such as those laid down by the EU, which affects a country's trading position. It can also be a psychological effect: if they are so cautious in the countries where the technology was first developed, then maybe we should follow their example.

Europe is an important market for agricultural products that are produced worldwide. The European consumer's resistance to GM food products is for some producers in other parts of the world a major barrier to cultivating GM crops. The very limited extent of consumer acceptance has led to regulations that are far more restrictive than in most of the other parts of the world. This has also played a role in the past in the institution of the European *de facto* moratorium, which resulted in the blocking of the approval of new GM products. This moratorium has had a clear influence on some countries' preparedness to produce GM crops, given that their market was limited to countries outside the EU. Strict regulatory requirements, to some extent directed at guaranteeing the freedom of choice of European citizens, and the consequent high costs of gaining approval and certification, can also form an obstacle to a changeover to the cultivation of GM crop. An unintended consequence of this is that the freedom of choice of the (often non-European) producer is limited.

The fact that in Africa, for example, genetic engineering is applied to agriculture in only a minor scale, as is apparent from figure 1, is, apart from social, cultural and geographic factors, also ascribed to the restrictive attitudes of the EU states with regard to GM crops.[viii] It should be mentioned here that on the one hand some of the stakeholders are of the opinion that GM agriculture has much to offer to developing countries, such as resistance to plagues and insects (reduction in the use of pesticides), harvest increase and drought tolerance. On the other hand, other stakeholders believe that GM agriculture has, on the contrary, very little to offer to developing countries, and will only increase their degree of dependence. GM

agriculture is a form of industrialized farming, which for the greater part is not attuned with the economic balances and socio-cultural beliefs in the countries concerned. In current applications of genetic engineering in agriculture, the focus lies, with an eye to the world market, on bulk crops and uniformity. If countries where small-scale agriculture is predominant were to adopt the current western production model, the loss of local agrarian know-how and increasing genetic erosion as the result of the disappearance of locally adapted varieties could be a consequence. The stakeholders who point out such adverse aspects of GM agriculture are therefore in favour of a different approach to or direction of development for agriculture, supported by a different form of biotechnology. COGEM takes no position on this, but points out that the producers and citizens of developing countries should have both the right and the opportunity to make their own assessment or choice in the matter, just as is the case in the EU.

In Latin America the influence of opinions from within the EU appears to be much smaller. Here, it is rather the United States that forms the frame of reference. GM crops are cultivated on a large scale in Latin America on the basis of technology that has principally been developed in the United States.

In Asian countries such as China and India, the dependence on other countries is much less, thanks to their own large internal markets. In a number of Asian countries, to some extent because of recent political developments, a major development of their own knowledge and technology has been set in motion, with their own GM crops and accompanying regulatory regimes being the result. In some instances they are ahead of developments in Europe.

As a consequence of the rapid development of genetic engineering in America and Asia, and of globalization, Europe will be confronted increasingly by GM crops – and their resultant products – that have been developed elsewhere.

## 2.4 The current international regulations on genetic engineering

The global scale of genetic engineering and the cross-border nature of the trade in GM crops make it necessary to have regulations that take these factors into account, i.e. regulations that are of a supranational dimension. The Cartagena Protocol on Biosafety (CPB) is an answer to this.[ix,x] But other forms of international regulation that could be related to genetic engineering, for example on food safety, such as the Codex Alimentarius, and on commerce, such as the conventions within the framework of the World Trade Organization (WTO), are of importance to the global spread of GM agriculture. The CPB forms a supplementary agreement to the UN Biodiversity convention, which was adopted in January 2000 and which has in the meantime been ratified by 127 countries, including the Netherlands. In accordance with the principle of precaution, it is the intention of

the CPB to protect biodiversity against the possible risks of GMOs that have been produced by the use of biotechnology. At the same time, the risks to human health are also taken into consideration.[xi]

The CPB addresses itself to cross-border movements. It makes provisions for procedures for the supply of information by an exporting party to an importing party, in order that the latter can make a well-considered decision about the possible import of GMOs. Further, it is the intention of the CPB to promote the exchange of information about GMOs and regulations, via a so-called ‘Biosafety Clearing-House’, and to help countries in the implementation of regulatory systems that contribute to the objectives of the CPB.

# 3 Tensions appearing

## 3.1 Regulation is 'foreign' to many developing economies

Many countries have ratified the CPB. In some countries, GM agriculture has expanded enormously, while in others it scarcely exists. Not all countries are equally well prepared for the implementation of the CPB or similar regulations. The building up of knowledge and expertise (capacity-building) in this area is supported within the framework of the CPB. At the same time, help is offered to countries in their design of a National Biosafety Framework (NBF)[xii] by the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF). The result of these efforts is that a process of regulation transfer is set in motion. However, this is not always successful.

As has been indicated earlier, regulation should fit in with the local civil society, the societal rules. Technology and society develop in a process of co-evolution. The societal context determines how a technology develops and in turn, in the course of time technology changes the societal context. In the process of evolution of the ever-changing society, the rules applicable within that society are also adapted. Eventually these are crystallized in laws and regulation. Accordingly, laws and regulations fit in with the socio-cultural and political climate prevalent in a society. At the same time they are in tune with the level of development of technology. If such a process of development is ignored, this can then lead to problems.

Making expertise and money available, and offering structures for a regulatory framework, such as the so-called UNEP-GEF Toolkit is, for example, often ineffective.[xiii] In many instances it leads to the institution of a complex and extensive system of regulation that does not tie in with the local needs and capacity. After all, many of the countries involved have virtually nothing to do with the cross-border movement of GMOs, or do not have at their disposal the means to maintain an administrative system such as an NBF.

Help in capacity-building should be adapted to suit the regional resources and needs, and should also take into account the local parties involved. To this end, in the EU and in international bodies more attention must be requested for an approach such as that brought into practice in Dutch international co-operation, in which help is offered for the development of regulatory regimes that fit within the context of local policy. Conversely, top-down methods, in which regulatory systems that have been developed elsewhere are implemented from above, do not warrant support. In such approaches, the co-evolution of technology and society

are ignored and the social, normative codes (scripts) that are linked with genetic engineering are simply imposed.

### 3.2 Will enforcement of the European regulations remain affordable?

The cross-border nature of (the trade in) GM agricultural products also means that unwanted situations, such as unintentional hybridization and contamination, can reach a supranational scale. As a result of the increase in acreage, increasingly greater amounts of GM crops are being traded and transported throughout the world. There is always a chance that, within this process, mixing with other batches occurs. Currently, there is in the EU a zero limit for mixtures involving GMOs that are not approved for the EU market. Further, for approved GMOs there are threshold values for mixing with non-GM products. If the EU is to fulfil to its citizens its guarantees of safety and freedom of choice in the form in which these are now laid down in the regulations, this will demand an increasing extent of inspection and control. Depending on the intensity thereof, and the extent of collaboration therein between producers and importers, the costs to the government can rise considerably. This will apply especially to the Netherlands, as this country is a major crossroads for the importation and transit of agricultural products. Because of the high costs involved, it is possible that the practicability of inspection and control might be at issue. This too is one of the potential unintended effects of the current regulation to which the COGEM wishes to draw attention.

### 3.3 Will enforcement of the European regulations remain technically possible?

In technologically highly developed countries that are not inconvenienced by barriers such as those created by EU policy, developments are certainly not at a standstill. New applications and types of GMOs not earlier produced are constantly coming into being. This is also true for GM agriculture. This means that seeds and crops will be produced with properties that are not known here, that have not been reported earlier, and that have not been assessed in the context of genetic modification. The above-mentioned control and inspection will therefore become problematic not only from the point of view of the costs involved; the detection of unknown GMOs will also be extremely difficult. This could result in any hybridization remaining unnoticed in the first instance, only coming to light at a later stage. Such circumstances could give rise to societal doubts as to the quality and purity of food products, for example, ultimately having consequences for the government’s credibility.

# 4 Suggestions for policy

## 4.1 An alternative for the current European policy position

Current EU policy is essentially of a defensive nature. It is directed primarily at closing the European borders to GMOs that have been produced elsewhere and have not been tested against environmental or foodstuff safety standards. As has been stated earlier, in the long term the maintenance of this policy of protectionism will be both costly and technically difficult to achieve. These circumstances will increase the call for a different type of policy response. Entering into dialogue with other nations and asking them to consider European opinions and values (without imposing these upon them) will serve to facilitate an active collaboration in earlier phases of the development process and the chain of production. This will offer Europe as a partner an earlier opportunity to exert influence in the process of innovation, and to gain insight into developments. A reversal from the current, essentially defensive approach consisting of control at the border, towards a more pro-active and communicative attitude, is therefore worthy of recommendation.

## 4.2 Strengthening a bottom-up approach for developing countries from within international organs

As expounded in section 3.1, it has become apparent that, in development co-operation, greater attention should be paid to the local needs, and that top-down imposed approaches are of little effect. Increased attention to a bottom-up approach by the EU and VN is required, in the same way that this has a prominent place in the Dutch approach to development co-operation.

## 4.3 Increasing global standardization and transparency

According to the COGEM, a system of worldwide reporting to a single international organization is functional from the point of view of cost management and detection. Registration with an international organization, as is provided for by the ‘Biosafety Clearing-House’ (BCH), is beneficial to the international interchange of information. In view of the fact that the availability of a detection method is a precondition of registration, the BCH also plays an important facilitative role in the control of local, non-approved GMOs and of hybridization. However, if the BCH is to be able to play its role in a satisfactory way, it is necessary that there is worldwide agreement on both the manner of reporting and the type of national approval to be registered. At present it is only compulsory to register risk analyses

and approval decisions that emanate from procedures under the CPB, i.e. in the case of cross-border movement. This means that information about field trials generally does not have to be registered and that the system is limited principally to commercial market approvals. COGEM points out that field trials should also be registered if the BCH is to be able to fulfil adequately its role as provider of information. Further harmonization of the manner of registration is also a necessary precondition for the BCH to function well. COGEM therefore supports the activities of the different organizations and working groups that, within the framework of BCH, strive for further harmonization.

COGEM also points out that worldwide standardization of dossiers brings with it both cost savings for the producer and transparency for the citizen. The OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology has set itself the objective of contributing to this. Progress has been made in this area, for example, in the form of consensus documents on environmental risk analysis and on specific plants. Standardization demands that in the foreseeable future the differences in political and societal views on risk analysis and risk management be overcome.

With respect to the standardization of information, it is important that in the streamlining, regional environmental differences, biogeographical diversity, consumption patterns and the like are taken into account. Decision-making on granting approval made on the basis of the standardized information shall, therefore, continue to retain a national or regional character.

# 5 Advice from associate organizations

## 5.1 EKAH

It is not only the COGEM that has occupied itself with the ethical and societal aspects of genetic engineering in relation to the North-South issue. In the autumn of 2004, the Swiss counterpart of COGEM's subcommittee Eethics and Societal Aaspects, the *Eidgenössige Ethikkommission für die Biotechnologie im Ausserhumanbereich* or EKAH [Swiss Ethics Committee on Non-Human Gene Technology], published a report on this subject entitled *Gentechnik und Entwicklungsländer* [Gene Technology and Developing Countries].[xiv] Based on the findings that the proponents of genetic engineering acclaim its application in developing and semi-industrialized countries as being the solution to the problem of hunger, whilst on the other hand its detractors point out its negative consequences for these countries, this report's intention is to describe the universal ethical basic principles on the grounds of which the implications of genetic engineering should be judged. Particularly at issue is justice at a global level, according to the EKAH. With regard to genetic engineering, this is further elaborated in four fundamental principles: The right to (adequate and healthy) food; The right to sovereign, autonomous choice of food; The obligation to provide a sustainable lifestyle and to protect biodiversity for the benefit of future generations; The right to societal peace. On the basis of these four principles, the EKAH presents in its report an analysis of the arguments for and against the application of genetic engineering in developing and semi-industrialized countries.

The EKAH also makes recommendations to the Swiss government on advisable forms of development assistance. It prefers financial help to help in the form of goods. It supports current Swiss policy, in which sovereignty over food is respected and, according to the EKAH, traditional rights such as 'farmers privilege' and 'breeders privilege' must be guaranteed. Moreover, EKAH believes that biodiversity should be protected, particularly in so-called 'centres of origin' and, in addition to advocating 'capacity-building', is also a proponent of measures that promote cultural diversity, such as micro-credits and 'fair trade' projects. Lastly, the EKAH points out the importance of dialogue with religious communities in areas in which new technologies are to be applied and of the desirability of the participation of the local community in this. In its report *Gentechnik und Entwicklungsländer* the EKAH addresses the consequences of certain developments in genetic engineering and the policy that it would be advisable for the government to pursue. The criterion for this is a universal ideal of worldwide

justice. The focus in the report is centred on the Swiss policy on development aid. Concrete elaborations of policy or of the intended and unintended effects of policy in the developing countries concerned, or via the repercussions thereof in Switzerland, are not taken into consideration in the report.

## 5.2 Nuffield Council

In December 2003, the British Nuffield Council on Bioethics, which draws the attention of policy-makers to the ethical issues that arise in connection with medical science and biotechnology, published a discussion paper, *The use of genetically modified crops in developing countries*, which was a follow-up to a 1999 report entitled *Genetically modified crops: ethical and social issues*, in which making GM crops available to developing countries was viewed as being highly desirable.[xv,xvi] The same body recently wrote a letter to the G8 on the same theme.

## 5.3 Other international organizations

The Food and Agriculture Organization of the United Nations (FAO) has also issued a number of publications on the application of genetic engineering, both on the necessity of preserving biodiversity and the conservation of genetic resources and on the benefits of gene technology for the poorest countries.[xvii,xviii] In 2005 a World Health Organization (WHO) study was published in which attention was devoted to the worldwide impact of modern biotechnology.[xix] Themes examined included, *inter alia*, the inherent risks of biotechnology, but also 'capacity-building' and societal, economic and ethical aspects of GMO-based food. Within the framework of the Codex Alimentarius Commission of the FAO and the WHO, an *ad hoc* intergovernmental task force is involved specifically in considering food that is derived from modern biotechnology.[xx]

In addition, various international organizations such as the earlier-mentioned UNEP are carrying out studies into the problems associated with the globalization of the regulations concerning biotechnology.

# 6 Conclusions

1. Because of the cross-border nature of (the trade in) GM agricultural products, individual national and European regulations have consequences that affect countries in the rest of the world. They can form a barrier to the ability of countries outside the EU to exercise freedom of choice with respect to their acceptance or non-acceptance of GM agriculture. Stagnation in GM agriculture and the non-realization of any possible advantages in the areas of economy or sustainability can be the (unintended) consequence of this. The large amount of attention that is paid to individual national or European interests and values can thus be in conflict with other values, such as global solidarity and justice. This international dimension should therefore be taken into account in the development of new policies.

2. In America and Asia, the development and cultivation of GM crops is expanding enormously. As a result, the pressure on the EU regulatory system is becoming increasingly great. In the absence of watertight regulatory systems or because of the effects of other values and ideologies in prevalent in other parts of the world, the control and inspection of GMO-free products will become problematic for the government, if only from the aspect of cost. Also from the point of view of detection, it will be exceptionally difficult to trace unidentifiable GMOs. Inadequate enforcement could ultimately have consequences for consumer confidence and for the government's credibility.

3. COGEM points out, from the point of view of cost management and transparency, the advisability of a further strengthening of the Biosafety Clearing-House (BCH), including the description of detection methods, as a worldwide system of harmonized registration. Moreover, a harmonized registration system can be instrumental in ensuring that GMOs for which no detection method is available do not turn up in the worldwide commercial channels.

4. COGEM advocates that, with respect to the import of agricultural products into the EU, the government adopts a more pro-active and communicative policy approach. In countries where other values and ideologies are prevalent, by actively engaging in collaborative projects in the beginning stages of the process of innovation, the Dutch government can endeavour to exercise influence without either imposing its opinions on the other country or sacrificing its own views. In this way, effective enforcement of the EU regulations can also be anticipated.

5. Technology and society shape each other in a process of co-evolution. When this is misunderstood during the transfer of regulatory concepts, and scripts are imposed, inefficient solutions are the result. The approach pursued in Dutch development policy, in which the context of local policy is furthered in the development of regulatory structures, is worthy of imitation. This approach could be brought to the attention of international organizations such as the EU and the VN, where it could also be supported.

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