Should EU Legislation Be Updated?

Scientific developments throw new light on the process and product approaches

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Netherlands Commission on Genetic Modification (COGEM)
COGEM has the duty to advise the government on the risks of genetically modified organisms and to report on the ethical and social aspects of genetic modification (Environmental Management Act §2.3).

Summary

The EU legislation on genetically modified organisms (GMOs) is no longer in step with scientific developments in plant biotechnology. As a result it is no longer clear what should be considered to be GMOs and this has led to an uneven playing field for the European plant breeding industry compared with their colleagues in North America. It also undermines consumer choice and strains the government's credibility. This situation calls for a rethink of the European legislation.

In Europe a decision was made to introduce a specific regulation for GMOs in order to guarantee human and environmental safety. The reasoning behind this was that genetic modification can be used to create organisms with new characteristics that have never before existed in the environment, and would therefore involve inherent risks. The principles underlying the EU legislation are set out in Directive 2001/18.

The EU legislation is referred to as a process-based legislation because the reason for passing it in the first place is the method of production – the process. The United States, Canada and some other countries have chosen to place GMOs under the general legislation. In these cases the characteristics of an organism – the product – are the subject of the legislation. These characteristics are the reason for implementing the legislation (product-based legislation), regardless of the techniques used and the way in which the organism is produced. 'Process' therefore stands for the technique used to make the crop, in this case genetic modification. 'Product' stands for the crop and its characteristics.

Although from the start the difference between the principles underlying the legislation in the United States and the EU has been the subject of considerable debate, the actual consequences were limited. Until recently the use of genetic modification always resulted in a plant with a newly acquired character. In addition, the different legislative bases of the regulatory systems do not influence the method of assessing the implications for human and environmental safety. Safety assessment is always based on the characteristics of the product, regardless of the reason for carrying out the assessment in the first place.

However, new techniques in plant biotechnology have made it possible to use genetic modification in the development process without the final products (crops) having any new combinations of genetic material, making them indistinguishable from, or the same as, conventional plant breeding products. In principle, these crops fall under the EU GMO legislation. In other parts of the world, such as the US, these crops are considered to be conventional plant breeding products. This has consequences for the position of trade and industry, and also for consumer choice and government credibility.

In Europe these new crops are subject to an exacting and costly assessment regime, but not in the US, which creates an 'uneven playing field' for companies. Foreign companies can use these techniques and market the products outside Europe without having to invest heavily in GMO authorisation procedures; European companies do have to incur these costs. Moreover, this undermines consumer choice. If these products are imported into the EU they are not identifiable as GM products because they cannot be distinguished from conventional plant breeding products. Although under EU regulations these products have

to be labelled as GMOs, there is little chance of this actually happening when they are imported because in the producing country they are not classified or registered as GMOs, and therefore cannot be identified as such. The EU has made consumer choice the cornerstone of its policy and so failure to label these products can damage the credibility of the government. This problem raises questions about the basis of the European GMO legislation.

In response to the earlier COGEM report on this topic, 'New Techniques in Biotechnology' (CGM/061024-02), a European working group was established at the instigation of the Dutch government with the task of investigating a number of new techniques and determining whether the products of these techniques should fall under the GMO legislation. We point out that an approach in which decisions on whether a technique or product falls under the GMO legislation are made on an ad hoc basis is probably inadequate. New techniques are continually being developed and in each case new appraisals will have to be made and fresh decisions taken. Such decisions will be contingent on the prevailing scientific insights and the political and social climate, which erodes the core values of consistency and continuity of policy. Neither do EU decisions on whether a specific technique does or does not lead to the production of GMOs under EU legislation resolve the problems arising from the different regulatory approach in countries like the US and Canada.

A radical recasting of the EU GMO legislation from a process-based to a product-based system would seem to offer prospects for overcoming the problems of new techniques and their applications, as well as the trade-related issues. There would then be no need to appraise each new technique separately because the production method would no longer be relevant. In addition, the main trading blocks in the world would be working with a similar sets of regulations. However, a change to a product-based GMO legislation in the EU would run up against two complications.

First, it would be more difficult to guarantee consumer choice because labelling of GMOs is closely linked to the process approach. Under a product-based approach GMOs are not considered to be a separate category and are thus not registered as such. Under a process-based regulatory approach GMOs are considered to be a separate category, are registered as such and can therefore be labelled appropriately.

Consumer choice is the cornerstone of both Dutch and EU policies. This means that some form of registration is required to meet the demands of those consumers who wish to avoid GMOs altogether. This in turn raises the question of definitions: what is a GMO? A possible solution is to label 'GMO-free products'. The question is whether reversing the labelling requirements will be an acceptable solution for those who wish to avoid being exposed to GMO products.

Second, the process-based approach is firmly established in Europe and the regulations can only be changed with the approval of a qualified majority of EU countries. It is doubtful whether majority support can be found in Europe for such a change in the legislation.

A possible alternative solution to the dilemma thrown up the workings of the legislation and the emergence of new scientific applications may be found in the Cartagena Protocol on Biosafety. The Cartagena Protocol has been in force since 2003 and has been signed by 153 countries, including the EU member states. In the protocol a GMO, or 'living modified organism' in the words of the protocol, is defined as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'.

In the EU the Cartagena Protocol is implemented by EU Regulation 1946/2003. This regulation states that the definition of a GMO in the Cartagena Protocol means a genetically modified organism as defined in Directive 2001/18, despite the fact that Directive 2001/18 states that a GMO is an organism 'in which the genetic material has been altered'. Regulation 1946/2003 therefore equates 'altered' with 'a novel combination'. This means that there is room to interpret EU Regulation 2001/18 differently from the way it is currently interpreted, and in a way which makes the 'new combination' of genetic material the key issue. Plants developed using new biotechnological techniques but which do not contain a new combination of genetic material, such as 'reverse breeding' products, would then not fall within the scope of the EU GMO legislation. This has a number of advantages. Only plants or crops with new characteristics, and which are therefore identifiable and traceable, would then fall under the GMO legislation. Human and environmental safety would still be safeguarded, but it would be easier to verify the labelling of products. On the other hand, it would mean that consumers that reject the use of techniques involving genetic modification would be obliged to turn to 'organic products'. Only products with an 'organic' label would then be guaranteed not to contain any material derived from biotechnological breeding techniques.

Another advantage is that the EU legislation would not have to be amended, just interpreted differently. In addition, the greater emphasis on the fact that the plants or crops must possess new characteristics would make the EU regulations more compatible with 'product-based' legislation, helping to create a level playing field for European companies and avoid trade conflicts.

COGEM concludes that it would be worth raising the potential opportunities for bridging the differences outlined above within the EU.

Contents

1. Introduction

The EU legislation on genetically modified organisms (GMOs) is no longer in step with scientific developments in plant biotechnology.[1] Some modern biotechnological techniques generate products (crops) that cannot be distinguished from the products of conventional plant breeding. The only difference is the way they have been produced. In the EU these crops fall under the GMO regulations, but in other countries, like the US and Canada, these products or crops are not considered to be GMOs. This has consequences for the position of European trade and industry, and also for consumer choice and government credibility.

In Europe these crops obtained using new techniques fall under the exacting and costly GMO assessment regime, but not in the US. This creates an uneven playing field for companies. Foreign companies can use these techniques and market the products outside Europe without having to make heavy investments in GMO authorisation procedures, whereas European companies have to pay these costs, which vary from 7 to 10 million euros per crop ('event').[2] If these products are imported into the EU they are not identifiable because they cannot be distinguished from conventional plant breeding products. Although under EU regulations these products have to be labelled as GMOs, there is little chance of this actually happening when they are imported because in the producing country they are not classified or registered as GMOs, and therefore cannot be identified as such. European governments cannot monitor and verify whether the labelling obligation is met.

This problem raises questions about the principles underlying the European GMO legislation. The regulations governing genetically modified organisms in different regions of the world are based on different principles. During the research for this report COGEM organised an international symposium on 2 October 2008 in The Hague. The title of this symposium – The New GMO Debate: A Clash Between legislations – was deliberately somewhat provocative. COGEM realises that in the early years of genetic modification and the establishment of the legislation there was a discussion between American and European regulators, and the relevant issues are examined in this report. However, this discussion was partly theoretical. In the day-to-day work of assessing and authorising GMOs the differences between the principles underlying the regulatory systems have not led to any serious problems. However, current scientific developments have reawakened the conflict between the different approaches, this time with palpable consequences.

This report explores the history and contexts of the dominant regulatory systems in the world and describes their consequences for human and environmental safety and for consumer choice. From this a number of options are derived for bridging the gap that has arisen between the different GMO regulatory systems and between the EU GMO legislation and scientific developments.

It should be noted here that these issues and this report relate specifically to plant biotechnology. However, the same problems will affect other sectors in the not too distant future, an example being vaccines. The production of vaccines using genetic modification

techniques also sometimes leads to the same products as those obtained from conventional techniques. The former fall under the GMO regulations, but the latter do not.

2. Legislation

The legal basis for the regulation of GMOs in the EU differs from that in countries like the United States and Canada. The European countries have chosen to establish special regulations for GMOs, which is consistent with the 'process approach'. The reason for regulation is not the existence of an altered or new characteristic of an organism, but the way in which the organism has been obtained. If the genetic material has been altered in a way that is 'not natural', the organism falls under restrictive legislation and a safety assessment must be carried out. The idea behind this is that altering the hereditary material in an 'unnatural way' carries inherent risks that are expressed in the resulting organism (product).

Various other countries, such as the US, have chosen to regulate GMOs under their existing general legislation. Regulation is triggered when an organism possesses an altered characteristic. In this approach it is the product, the crop, rather than the way it has been made that is the issue. This approach is referred to as the 'product approach' or 'product-based'.[a]

Having said that, the fact that the principles underlying the legislation in the EU and in the US and Canada are different does not mean that the risk assessment of GMOs or GM crops in the EU is completely different from that in the US or Canada. We shall look into this in more detail later in this report.

2.1 GMO legislation in the EU

The EU has one of the most extensive GMO regulatory systems in the world[3] and it is not possible in this report to go into all the aspects of the EU GMO legislation. Only the aspects of relevance for this report will be covered.

The GMO regulations in the EU are set down in various directives and regulations. There are directives on activities with GMOs in laboratories and similar facilities (contained use), on labelling and traceability, on food safety, etc.

The key documents relating to the subject of this report are EU Directive 2001/18 'on the deliberate release into the environment of genetically modified organisms'[4] and its predecessor, Council Directive 90/220/EEC.[5] Directive 2001/18 is not an environmental directive, unlike Directive 98/81/EC on contained use, its main purpose being the harmonisation of the internal market. This means that when national governments implement the directive in their national legislation they may not deviate from its provisions (i.e. they may not relax them or tighten them up). They may, though, take their own legislative systems into account. When transposing environmental directives, EU countries may impose stricter rules (but not laxer rules). All EU regulations must be adopted directly into national legislation without regard to any specific national laws.

[a] 'Process' stands for the methods or techniques used to produce the crop plant, in this case genetic modification; 'product' stands for the crop and its characteristics. Both terms, therefore, have nothing to do with the way in which the crop is cultivated or with the food products manufactured from the crop.

Market authorisation (for import, sales, cultivation) of a GMO is an EU responsibility. The licensing procedure is centralised and licences apply to the whole territory of the EU. At the moment, market authorisation of GM crops usually follows the procedure set out in EU Regulation 1829/2003 ('on genetically modified food and feed').[6] However, EU Directive 2001/18 is decisive for determining what is a GMO in the EU. This means that an EU country cannot decide independently what is or is not a GMO.

In EU Directive 2001/18 and its predecessor Directive 90/220 a GMO is defined as:

> *'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.'*

In addition, Annexes 1A and 1B[4] list a number of techniques through which genetic modification occurs or does not occur and techniques which are excluded from the Directive, such as mutagenesis. These annexes are intended for the purposes of 'clarification' and to ensure that techniques that have been in use for several years are not suddenly classified as leading to the production of GMOs. Existing crops developed using one of these techniques, for example mutagenesis induced by radiation or chemical mutagens, were therefore not retroactively subjected to the authorisation procedures for GMOs.

2.2 Biotechnology legislation in the United States

In contrast to the EU, the US has no specific legislation on the introduction of GM crops. In 1986 it was decided that no specific GMO regulations were needed, but that the existing general legislation, such as the regulations on food safety and pesticides, were sufficient. Subsequent decisions have further reinforced this position. The principle is that GMOs do not form a new category and do not carry any unique risks.[7,8,9]

As stated above, this approach is generally referred to as the 'product approach'. The reason for regulation and possible safety assessment is not the method or process by which an organism is produced, but the characteristics of the organism itself.

Given the lack of any specific GMO regulations, GM crops are assessed by several organisations: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).[8] Their powers are complementary and sometimes overlap. The USDA has jurisdiction over the cultivation of GM crops; the EPA is involved because of its responsibility for regulating pesticides[10] (with respect to the insertion of bacterial toxins active against certain insect species), the regulations on 'new substances'[11] and the general environmental legislation;[12,13] and the FDA is responsible for food safety.[13] In the US, food safety assessments are not required by law, but are conducted on a voluntary basis. So far all GM crops produced have been assessed for food safety by the FDA, despite the voluntary nature of these assessments.

In recent years there has been a clear tendency in the US to tighten up the regulation of GMOs. Over the years a growing number of reasons have been found for regulating some GM crops, many of which appear to be somewhat contrived. For example, at an early stage it was decided to make GM crops that contain the 35S promoter of the cauliflower mosaic virus (at that time almost all GM plants) subject to the regulations on plant diseases because these plants have a regulator gene derived from a plant virus. This makes the Animal and Plant Health Inspection Service (APHIS) of the USDA responsible for the safety assessment and authorisation of field trials, transport and importation of GMOs. APHIS is the agency that evaluates whether a GM crop is safe and can be authorised. In 2008 APHIS began a revision of the regulations on GM crops[14] and in 2009 it started a project to set up a quality management system for field experiments.

A consequence of the gradual expansion of the regulations is that a growing number of specific elements for GMOs are being incorporated within the general legislation. In the past the American authorities consistently used the term 'biotechnology' to include genetic modification as well as other modern techniques like marker assisted selection. These days American regulations also use the phrase 'genetically engineered'. Some people argue that the general legislation in the US now contains so many GMO-specific elements that it can no longer be considered to be product-based.[15,16]

2.3 Product or process: History and context of EU versus US legislation

The difference between the legal basis of the regulations in the EU and the US cannot be seen in isolation from the public opposition to GMOs and GM crops in Europe. However, the specific nature of the EU legislation is also in part a product of the history of the creation of the EU and the establishment of EU institutions. [17]

The first concerns about GMOs, and the risks to human health in particular, were raised by the researchers themselves. This led to the famous Asilomar Conference in 1975, which resulted in the introduction of voluntary restrictions and safety measures for working with GMOs.[18] These voluntary measures were the catalyst for government intervention (especially in Europe) and the later legislation. In the years following Asilomar there was a growing feeling within the scientific community that the risks had been overestimated. At that time developments in the field of regulation, safety requirements and such like in Europe and the US were running more or less in parallel, partly because Europe tended to follow developments in the US. The main reference work was the US National Institutes of Health (NIH) guidelines for research involving recombinant DNA techniques. The differences only emerged during the 1980s.

The environmental movement gained ground during the 1970s and several environmental groups focused their attention on GMOs. Critical scientists and consumer organisations also raised questions about the developments in this field. In response, the OECD established the Ad Hoc Group of Government Experts on Safety and Regulations in Biotechnology. Their recommendations[19] were published in 1986 and became the new international guidelines (replacing the NIH guidelines). The OECD introduced the 'case-by-case' and 'step-by-step' principles, which remain the guiding principles today. Shortly

after, the EU presented proposals for Directives 90/219 (contained use) and 90/220 (release into the environment).

The 1986 OECD document refers to various definitions of GMOs, such as those used in the US and the UK, but this seems to reflect a search for the best scientific definition. However, in the OECD's follow-up document[20] from 1992 the definition seems to have acquired political overtones, encompassing different approaches. It explicitly states that the scope of the term 'genetic modification' can vary from country to country and from agency to agency:

> *'The term "Genetically modified organism" is employed here in a broad sense. Its scope may evolve over time with the progress of science and technology, and vary from country to country and agency to agency, depending on the various responsibilities and purposes involved.'*

The OECD document takes a line that balances between the EU and the US approaches. It states that experiments with GMOs are actually the same as 'normal' experiments by breeders with conventional new plants, in line with the US standpoint. On the other hand, it establishes various specific safety requirements in line with the EU standpoint.

During the 1980s the EU and the US moved in different directions. The reasons for this lie in the political and cultural differences between the two, as explained in the extensive analysis by Jasanoff.[17]

In the US there was also opposition to experiments with GMOs in the environment. At various times in the 1980s Jeremy Rifkin's Foundation on Economic Trends and others instituted legal proceedings against experiments with GMOs and patenting GMOs. These actions led to more transparent safety assessments and authorisation procedures, making them less the preserve of a closed circle of scientific colleagues. Meanwhile, scientists became increasingly convinced that the risks of GMOs were negligible and no different from those associated with other organisms. In the American tradition, the government adopted a rather noncommittal stance and the main responsibility remained with the scientific community. In the US, in contrast to Europe, more is regulated via litigation (holding companies liable for their actions) and less by government legislation and supervision. In addition, there was and is much less public opposition in the US than in Europe.

In 1989 the US National Research Council[21] stated that:

1) *the product of genetic modification and selection constitutes the primary basis for decision…and not the process by which the product was obtained*
2) *although knowledge about the process used to produce a genetically modified organism is important…the nature of the process is not useful for determining the amount of oversight*

3) *organisms modified by modern molecular and cellular methods are governed by the same physical and biological laws as are organisms produced by classical methods*

This report essentially brought the discussion in the US to a close.

When considering the differences between the US and the EU, Jasanoff states that we should not lose sight of the influence of the constitutional house of the EU itself. The organisational structure and mandate of the EU and its institutions is controversial, or in any case subject to debate at any moment. One of the important 'justifications' for the further expansion of European institutions is to strengthen the European economy and its competitiveness with other countries, such as the US. Having embraced science as a subject for possible EU policy, the EU identified biotechnology at an early stage of its development as a key sector for innovation and has taken measures to stimulate its development. Biotechnology was seen as a field for which the EU could develop policy.[17]

The position of the EU was determined by several different factors. The European Commission (EC) was of the opinion that biotechnology offered major opportunities for innovation and economic growth. It also believed that biotechnology should be promoted, but there were social objections to genetic modification and so measures to regain the confidence of the European public were also needed. Strict regulations were considered necessary to instil confidence in the safety of biotechnology among the European public and the European institutions. They were also necessary to satisfy the national governments that anticipated political problems.

In Europe, Germany and the United Kingdom, among others, were in favour of a process approach.[17] They felt that the process of genetic modification carried intrinsic risks. Within the EC, the Directorate-General for Research (DG XII) was in favour of the American approach, while the Directorate-General for Environment (DG XI) was in favour of the process approach. The final outcome of the political deliberations and the 'power struggle' between the different directorates and other organs with an interest in biotechnology, the individual member states and the EU, was that the EU chose to adopt the process approach. This struggle began at the start of the 1980s and ended at the beginning of the 1990s with Directive 90/220.

Other, sometimes pragmatic, arguments had an influence on the decision on the type of legislation to adopt. Some member states, including the Netherlands, held the opinion that the regulations should not be spread out over several directives. Their argument was that as further knowledge was acquired the regulations would be relaxed or amended and that amending one or just a few directives specific for GMOs would be easier than amending various directives or laws falling under the jurisdiction of different EU DGs.

One of the consequences of the choice for a process approach was that in any case DG XI alone would be responsible for the legislation. Under a product-based approach various DGs would have been responsible (as in the US).

By the end of the 1990s Directive 90/220 had to be replaced. In 1999 the public opposition to GM crops and food prompted various EU member states (Denmark, Greece,

France, Italy and Luxembourg) to announce that they would block the authorisation of GM crops,[22] which led to the '*de facto* moratorium'. For various reasons, both opponents and proponents of the authorisation of GM crops criticised Directive 90/220 as unworkable, undemocratic and confusing. COGEM cannot go into all the arguments and discussions here, but the fact that the legislation was specific to GMOs was not an issue. The process approach was well established.

The *de facto* moratorium could only be lifted after Regulation 1829/2003 (safety assessment of food and feed consisting of or produced from GMOs) and Regulation 1830/2003/EC (concerning the traceability and labelling of GMO products) had been adopted. Regulation 1829/2003 reinforced the process approach: food and feed have to be assessed in the same way as GMOs and do not fall under the regular assessment frameworks.

Meanwhile, the US, Canada and Argentina had launched dispute proceedings against the EU at the World Trade Organization (WTO). They demanded that the EU authorise GM crops because its moratorium amounted to unfair trade restrictions. The EC anticipated legal problems if the *de facto* moratorium was not lifted.[23] In 2006 the WTO did indeed decide against the EU, but by then the moratorium had been lifted.[24]

Although import permits for GM products have been issued again in the EU since 2003, the procedures are still lengthy. The member states remain divided and voting on permits delivers no qualified majority for or against, and so the EC has to take the decisions. In practice, this means that the EC comes to positive decisions on import licences based on the recommendations of the EFSA (Regulation 1829/2003). To date, no decisions have been taken on new applications for cultivation permits. For all practical purposes, the moratorium on new cultivation permits is still in place.

2.3.1 Differences and similarities between the EU and US – a transatlantic discussion

Numerous publications have appeared on the differences between the EU and US legislation and the resulting trade conflicts.[17,25,26,27] One of the constants in these analyses is the description of the EU and US legislation as 'process-based' and 'product-based' respectively.

In some publications the process-based approach is stated as being incompatible with the WTO regulations. This trade legislation states that 'like' products cannot be refused, regardless of the way in which or by whom they are made. It should be noted that the EU did not lose the WTO case because its regulations are based on the process approach, but because it did not follow its own procedures.[24]

In addition to the different legal bases of the regulations, other related elements in the transatlantic discussion play a significant role: the 'precautionary principle', 'sound science' and 'substantial equivalence'.

The US claims that its regulation of GM crops is based on 'sound science', in contrast to the 'biopolitics' pursued by the EU. Independent scientific assessment and quantitative measurability are paramount. This claim of a grounding in 'sound science' is questionable. It appears to be based on the idea that 'science' implies a uniform opinion, but this fails to

address the dynamic character of science and the essential element of scientific debate (challenging hypotheses, etc.). Murphy et al. (2006)[9] point out that in the past this attitude has led to (or has strayed into) heavy criticism of scientific publications that corroborate the attention given to risks, whereas publications that paint a positive picture of GM crops despite possible scientific failings are accepted almost without question. An example of this is the research into the potential adverse effects of Bt maize on 'non-target organisms' (or organisms other than the pest insects the maize is resistant to). Initially, the American authorities considered it unnecessary to test for such potential effects and research indicating the existence of possible effects was brought into discredit. Only later, and following the example of the EU, did the EPA decide that testing for potential effects on non-target organisms should be included in the risk assessment carried out as part of the licensing procedure.[9]

We should also note that in the event of a scientific consensus, the scientific facts will always be disputed in the public debate. The COGEM report 'Farm Scale Evaluations Evaluated'[28] examines in detail the role that science can play in socially contentious innovations.

'Substantial equivalence' is interpreted differently in the EU and the US. This is the question of the degree to which products are 'like'. 'Substantial equivalence' has been adopted as the cornerstone of food safety assessment in various international treaties. However, in the EU 'substantial equivalence' is used in risk assessment as a method for comparing the GM product with the conventional starting product or analogous material.[29] In the American system, 'substantial equivalence' appears to be used in the way that was originally intended by the OECD.[29,30] If a GM or other product is the same as the conventional product, a risk assessment is not needed.

The EU defends its policy by pointing to the precautionary principle, but the US takes exception to this, saying it is a specious argument designed to frustrate the authorisation of GM crops.[31] The differences between the EU and US appear to be not as great as they seem at first sight if we take a closer look at the way the precautionary principle is applied in the EU and how current US authorisation procedures are carried out. In both cases a risk assessment is carried out before a GM crop can be authorised. In both the US and the EU the environmental risk assessment contains the same elements, such as a characterisation of the crop, the probability of effects on non-target organisms, the likelihood of and consequences of escape, and the chances of outcrossing with wild relatives.

2.4 The Canadian legislation

The international literature on GMO regulations concentrates on the differences between the main trading blocks, the US and the EU. This ignores the diverse forms of GMO regulations found in some other countries. For the purposes of this report it is interesting to take a look at the legislation in Canada.

The Canadian legislation is strictly 'product-based'.[32] For example, there are regulations specifically for GM crops and GM food. The risks to human health and the environment are assessed under generic legislation, the Food and Drugs Act (food safety) and the Environmental Protection Act.

The current legislation took shape at the end of the 1980s. In 1988 the former Canadian Agricultural Research Council organised a number of stakeholder meetings on the revision of the Canadian Environmental protection Act. Two important outcomes of these meetings were the following recommendations:

- *'Those plants which possess characteristics or traits sufficiently different from the same or similar species should require an assessment of risk'*
- *'The product, not the process should be regulated'*

The government adopted these recommendations. In the regulations the term 'plants with novel traits' is abbreviated to PNTs. Depending on the way they are produced, all PNTs have to be tested for human and environmental safety, which means that conventional breeding products and crops obtained using classical (chemical or radiation) mutagenesis also have to be tested for safety if they contain new characteristics that were not previously present in the environment.

A good example of the implications of this regulation relates to herbicide tolerance, one of the most frequently introduced characteristics in GM crops. Herbicide tolerance can also be obtained in other ways. For example, it can be introduced into oilseed rape via:

- conventional plant breeding: atrazine tolerance
- mutagenesis: imidazolinone tolerance
- genetic modification: glyphosate tolerance

In Canada all three herbicide intolerant crops are covered by the legislation. They have to be assessed for environmental safety because they are products with the same new characteristic: tolerance to a herbicide.

In the EU only the crop obtained via genetic modification requires a licence; plants obtained through the use of chemical mutagenesis or radiation mutagenesis are exempt. If use is made of site-directed mutagenesis, in which a short DNA fragment (oligonucleotide) is involved, the plant does then fall under the GMO regulations. Conventional breeding products never fall under the EU GMO legislation.

In the US only genetically modified crops fall under the legislation. Crops produced by means of (classical or site-directed) mutagenesis and conventional breeding products are not regulated.[16]

From this we can conclude that Canada is one of the few countries in the world that employs a truly product-based set of regulations. The US approach seems to be more pragmatic with a view to minimising the number of specific regulations for GM crops and to enable their regulation under the general legislation.

A Plant with a Novel Trait is a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using rDNA technology, mutagenesis, or conventional breeding techniques and have some potential to impact weediness, gene flow, plant pest potential, non-target organisms, or biodiversity.
The PNT definition is aligned with other products and commodities including food, feed, microorganisms, animals, fish, etc.

2.5 Assessment and authorisation of GM crops

The methods for assessing the human and environmental safety of GMOs and GM crops in the various countries are more or less the same. Risk assessment methods are independent of the grounds for carrying out a risk assessment in the first place. As we have seen, risk assessments are always based on the characteristics of the product. Does the GM crop or GM product have characteristics that present a potential threat? To answer this question it is necessary to describe the crop and the introduced characteristics. The potential impacts of the crop on other organisms have to be identified and the likelihood of escape and weediness assessed. If the crop can outcross with wild relatives or cultivated plants, an assessment must be made of any potentially adverse impacts on human health and the environment. In addition, for food crops the food and feed safety should also be investigated. With respect to food and feed safety, international agreements on testing and assessment methods[33] have been drawn up by the Codex Alimentarius Commission.[34]

It should be noted that risk assessments always refer to a baseline of known and accepted risks. There are no absolute zero risks. Any risks must therefore exceed a certain threshold value or baseline before the crop or product in question can be given a negative safety assessment. The baseline for GM crops is standard agricultural practice or conventional breeding products.

As mentioned above the current authorisation procedures in the US and the EU do not differ much. In the past the differences were greater because the US took a more relaxed approach to authorisation and tended towards the view that GM crops do not have to be assessed because they are ‘substantially equivalent’ to conventional breeding products. The US and EU requirements appear to be converging, partly because each has been exerting an influence on the other. The US is meeting some of the European demands because of the trade interests. Moreover, American opponents of GM crops have called upon European researchers to strengthen their case and have used their publications as evidence to push for the tightening of the requirements in the US.[9] To a certain extent the US is moving towards the position taken by the EU.

The fact that the assessment and authorisation requirements for new GM crops in the EU and the US are not that different is also apparent from a study commissioned by COGEM

into the costs of authorisation in the US and the EU.[2] The costs of authorising a new GM crop in the EU are about 25% higher than in the US and on average amount to 6.8 million euros. Although this is still a considerable amount, the difference is not as great as many would expect. The difference in cost is almost entirely due to the larger amount of data required by the EU assessment agencies for each part of the assessment dossier, and not to any extra elements in the risk assessment. Nevertheless, the European obligation to make a specific detection method available and have it validated by the European Joint Research Centre leads to higher costs.

An important difference between the US and the EU is the time taken to complete the licensing procedure. The average time taken to complete the process in the US is about 18 months, whereas it takes about 47 months in the EU. However, this is independent of the assessment methodology and may have to do with the procedures chosen by the EU, in which all the member states are involved.[35] A consequence of the differences in the time taken to process an application and issue a licence is that GM crops that are not yet authorised for import into the EU are already being cultivated in countries outside the EU. This 'asynchronous' authorisation generates considerable problems for importers of GM products, such as the livestock feed industry.[36] On the one hand there is a chance of mixing with not yet authorised products in bulk cargo imports. Such mixing can lead to rejection of the whole consignment. On the other hand, it also leads to increased costs for importers because they are obliged to turn to the products authorised in the EU and are not able to access the full range of products on the world market.[37] In recent years, for example, a supplement has been levied on the price of conventional maize and soy, which rose to as much as 30%.

Another difference that is directly related to the different principles underlying the regulations is the length of the authorisation procedures. In the EU licences are issued for ten years, after which the holders must apply for an extension. Now that the first licences have come up for renewal, it appears that new dossiers have to be submitted, which of course involves additional costs. In the US the crops are deregulated and no permit is required, which means that no licence renewal is required.

3. Pros and cons of the different approaches

3.1 Does the process approach provide consumer choice?

A process approach to GMO legislation seems to be compatible with the government's desire to guarantee consumer choice, which is a cornerstone of current Dutch and EU policy.[6,38] This legislation serves consumers who want to remain free of products containing genetically modified ingredients. Such products fall within the scope of the GMO legislation and have to be labelled as GM products.

This is hardly possible under product-based legislation. Under such legislation products are assessed on the basis of their characteristics and there are only general 'safety regulations' which make no distinction between production methods.

A disadvantage of process-based GMO regulations is that they always fail to keep pace with the latest scientific developments. Biotechnology is a rapidly evolving discipline. As new techniques are continually being developed, the limits of what should be considered to be genetic modification are becoming blurred. In a process approach, however, it is essential to be able to state in the regulations what genetic modification is and which processes or techniques lead to GMOs.

The problem is that the legal description of the techniques that lead to the production of GMOs in EU Directive 2001/18 no longer reflects the scientific state of the art. In the past the use of genetic modification always led to an identifiable GM product. New DNA sequences were inserted into the genome of the resulting GM plant and the plant obtained new characteristics as a result. With current techniques, genetic modification can also be used as an interim step, without altering the genetic make-up of the final product, the plant. In addition, genetic modification 'tools' can be used in conventional techniques to gain time or other advantages. Because use is made of these tools, the products of such techniques currently fall under the GMO legislation,[39] although they are not identifiable as such or possess characteristics not present in wild type plants (see text boxes).

In response to the earlier COGEM report on this topic, 'New Techniques in Biotechnology',[1] a European working group was established, at the instigation of the Dutch government, with the task of investigating a number of new techniques and determining whether the products of these techniques should fall under the GMO legislation. A disadvantage of this approach is that for each technique, scientific application or product a new decision has to be made on whether it should or should not fall under the GMO legislation. Such decisions will be contingent on the prevailing scientific insights and the political and social climate. In this process a balance will have to be found between the scientific facts, the room for legal discretion permitted by the Directive and the political leeway for decision-making. The fact that new decisions have to be made for each new technique or scientific application, the outcome of which cannot be predicted, puts the core values of consistency and policy continuity in jeopardy.

Reverse breeding This technique is used to obtain the parent plants of a plant with specific desired characteristics. As the production of gametes (meiosis) in the plant can involve a variety of recombinations, the original parent plant can seldom be obtained through self-fertilisation and back-crossing. The following technique was devised to circumvent this problem. A gene is inserted into the plant that blocks recombination during meiosis. As a result, recombination no longer takes place during self-fertilisation and several of the progeny will be exact replicas of the parent plants. By inserting just a single copy of the gene or transgene only half the progeny will be genetically modified. These are discarded and only the non-GM plants are selected for further use. These plants contain no genetic modification and are identical to the desired parent plants.

The memorandum by the Netherlands Ministry of Housing, Spatial Planning and the Environment (VROM) on new techniques in plant biotechnology[39] states that the Dutch government sees possibilities for excluding the products of reverse breeding from Directive 2001/18, but not from the labelling obligation:
'In reverse breeding, nucleic acid molecules prepared outside the organism are introduced into the cell. According to Annex 1A article 2 of Directive 2001/18/EC, this technique leads to the production of GMOs that require a permit because of "the direct introduction into an organism of heritable material prepared outside the organism". The goal of reverse breeding is to obtain a plant that is genetically identical to the starting organism. The transgene does not express a characteristic in the product, but functions as a tool for suppressing recombination. It therefore cannot be found in the end product, which has an identical gene combination to the crop from which the breeding was started. These products therefore involve no additional risks to human health and the environment resulting from genetic modification. When the GMO regulations were drawn up no account was taken of the logical consequences of a technique such as this. This situation means that when assessing a specific case VROM could conclude, provisionally, that the products of a reverse breeding process are not GMOs. However, the outcome of such an assessment depends on the precise activities involved in the specific case and applies only in the Netherlands. In the European context, the Netherlands sees possibilities for exempting these techniques from the provisions of Directive 2001/18/EG (but not from Directive 1829/2003/EC), although the Netherlands will take the arguments for and against exemption that have been put forward by the various member states fully into account before coming to a final judgement. Nevertheless, any decision at the European level will in all cases be the decisive consideration for the Netherlands, even if this means that the products of reverse breeding will always be judged to be GMOs and therefore require a permit.'

Moreover, an important advantage of the process approach – guaranteeing consumer choice – may be put at risk. In other parts of the world, such as North America, products falling under EU legislation are not considered to be GMOs. If these products are imported into the EU they are not identifiable because they are very hard or impossible to distinguish from conventional plant breeding products. The question is whether these products will be labelled as GMOs when they are imported into the EU, because in the producing country they are not classified or registered as GMOs and therefore cannot be identified as such. This means that the government cannot guarantee that each product that falls under the GMO legislation will actually be labelled as such. This undermines consumer choice and therefore the credibility of the government.

It must be emphasised that the pros and cons of a process-based or product-based approach are not related to any potential safety aspects. The actual risk assessment carried out for the authorisation of a product is always based on the characteristics of a crop, independent of the reasons why the risk assessment is considered necessary.

3.2 Does the product approach provide certainty?

Site-directed mutagenesis Annex 1B of Directive 2001/18 explicitly excludes mutagenesis – inducing mutations in the genome of a plant using radiation or chemicals (mutagens) – from the Directive. Mutagenesis has been used extensively in the past (and still is). The disadvantage of this technique is that numerous alterations, such as deletions, point mutations and recombinations, are made at random sites in the genome. After the plant with the desired mutation (change in characteristic) has been identified, a lengthy process of back crossing must then be performed to remove all the undesired and adverse mutations. The availability of information on gene sequences has allowed plant biologists to pinpoint with greater accuracy where they want to induce mutations, which has allowed them to devise the following solution to this disadvantage. Targeted mutations can be made by coupling the mutagens to a short strand of DNA (oligonucleotide) which has the same sequence as the area in the genome where the mutation is wanted. The oligonucleotide 'sticks' to the complementary DNA strand and the mutagens do their work. In its advisory report 'New Techniques in Plant Biotechnology' COGEM states that this technique is safer than 'traditional mutagenesis' because it does not involve numerous random mutations or other effects. The mechanism of action of traditional and site-directed mutagenesis is the same as in both cases the mutation is caused by radiation or chemical mutagens. The oligonucleotide serves as a 'site-finder'. For this reason COGEM has argued for not classifying such plants as GMOs.

However, in its memorandum, VROM states:[39]
Annex 1B of Directive 2001/18/EC is significant with regard to the use of oligonucleotides coupled to mutagens. It lists two techniques, including mutagenesis, that are excluded from the Directive. However, the header to the Annex states that they are excluded on the condition that they do not involve the use of other recombinant nucleic acid molecules or genetically modified organisms. According to Directive 2001/18/EC, therefore, mutagenesis that involves the use of oligonucleotides, where oligonucleotides prepared outside the organism are introduced into the cell, is a technique that leads to a GMO that requires a permit.'

Legislation based on a product approach seems to be more responsive to scientific developments and better suited to the safety assessment. After all, the crops are assessed for their characteristics independently of the way in which these have been obtained. These types of regulations also seem better able to accommodate new scientific applications. The process is not defined and therefore each new technique does not have to be assessed to determine whether it falls within or outside the scope of the regulations.

However, product-based regulations also have their problems. These revolve around answering the following questions: what is a 'new characteristic' and which agency is responsible for any necessary risk assessments?

In the US, for example, three government agencies are involved in the risk assessment and authorisation of GM crops: the USDA, the EPA and the FDA. This is a direct consequence of the fact that there are no specific GMO regulations. Without these, various regulations apply and different authorities are responsible. The disadvantage of this is that responsibilities and competences sometimes overlap, and sometimes it is unclear whether a certain application is the responsibility of one of the three agencies. A potential risk is that an application that should have been assessed for its environmental and food safety

Cisgenesis Cisgenesis is currently attracting considerable interest. The Dutch House of Representatives, among others, have pressed for cisgenesis to be excluded from the GMO regulations.[44] It should be noted that cisgenesis is a form of genetic modification. It is a process in which characteristics are introduced into a plant by means of genetic modification. As the genes inserted into the plant are taken from the same species or from a crossable relative, in principle the characteristics could also have been obtained by conventional breeding.

The advantage of cisgenesis over conventional breeding is that the process is considerably faster. Conventional breeding is a difficult and time-consuming process, especially in polyloid crops such as potatoes and strawberries; it sometimes takes decades to create a new crop with the desired characteristics. Using cisgenesis the required gene (in combination with its natural regulatory signal) is directly introduced into the genetic material. This avoids also introducing various undesired genes ('linkage drag') which then have to be removed by multiple backcrossing, as in conventional breeding. Sometimes this is almost impossible because the genes in question are linked due to their location next to each other.

The advantage of cisgenesis over transgenesis is that no genes from unrelated organisms are transferred. This satisfies the ethical argument that species boundaries should not be crossed. The environmental safety risks are also smaller than in transgenesis. COGEM has previously stated that the environmental safety risks of cisgenesis correspond with those of conventional breeding. [45]

From the environmental safety point of view there are good arguments for giving cisgenic plants, or cisgenesis, a separate status and excluding them wholly or in part from the GMO regulations. However, cisgenesis falls mainly outside the scope of this report, given that it is a form of genetic modification. The question is not whether cisgenic plants are GMOs, but whether these special GMOs should be excluded from the regulations.

falls through the net of the general legislation. In Canada, too, several authorities are involved in the assessment (Canadian Food Inspection Agency, Health Canada, and Environment Canada). The Plant Biosafety Office of the Canadian Food Inspection Agency is responsible for environmental safety and feed safety, while Health Canada assesses food safety.

The main problem with product-based regulations is determining what should be considered to be a 'new characteristic'.[32] This problem is most acute in the case of GM crops with transferred characters that have previously been assessed ('follow-on products') and 'conventional' breeding products. When should breeders submit their crops for assessment, and what is a new characteristic?[40]

In Canada a PNT is defined as follows:

> *'A PNT is a plant containing a trait not present in plants of the same species already existing as stable, cultivated populations in Canada or a trait that is present at a level significantly outside the range of that trait in that plant species in Canada.'*

This means that characteristics that were already present in plants before the legislation came into force (1988) cannot lead to PNTs. Such breeding products (or GMOs) fall outside the legislation. In practice, in Canada almost no conventional breeding products fall under the legislation. The Canadian government tries to establish whether a crop falls

under the regulations at an early stage through the use of guidelines and consultation with crop developers.

4. How to bridge the gap

At the moment the EU faces a number of dilemmas and challenges regarding GM crops. Within the EU there is public and political opposition to GM food and the cultivation of GM crops. This does not alter the fact that the EU livestock sector imports large amounts of GM soy and GM maize from South America and the US. Some of the GM crops grown in the exporting countries have not yet been authorised in the EU because the EU authorisation procedures for GM products are much slower than in the exporting countries ('asynchronous authorisation').[35] On the one hand, this leads to problems for the livestock feed sector, which cannot import all the products they need.[36,37] On the other hand, it leads to problems resulting from the mixing of products not yet authorised in the EU with conventional or authorised GM products in bulk consignments.

The advancement of scientific knowledge and the development of new techniques and applications generate a further problem: the nature of the legislation. The principles underlying the GMO legislation in the EU and a few of its key trading partners, such as the US and Canada, are different. The EU's choice of specific GMO legislation and the decision by the US and Canada to include GMOs in the general legislation was a matter of debate right from the start. However, current developments in plant biotechnology are such that this difference is now giving rise to the problems affecting business interests, consumer choice and government credibility described in this report.

A number of options are available to address these dilemmas, varying from radical changes to the current legislation to retaining the current regulations as they stand and simply accepting the shortcomings.

At the instigation of the Dutch government, the EU decided to appoint a working group to review several techniques and determine whether the products of these techniques should fall under the EU GMO legislation or not. In mid 2009 this working group is due to make recommendations to the competent authorities in the field of GMOs. For the time being it seems likely that their advice will be to alter the current regulations as little as possible and to look for ways of accommodating new scientific developments within the current legislative framework.

COGEM applauds the stance adopted by the working group. However, COGEM points out that an approach in which decisions on whether a technique or product falls under the GMO legislation are made on an ad hoc basis does have its drawbacks. New techniques are continually being developed and in each case a new appraisal will have to be made and a new decision taken.

Moreover, it is not easy to reconcile scientific reality with legal and policy realities. An example of this is 'site-directed' mutagenesis. From a scientific viewpoint the mechanism of action of classical, exempted mutagenesis the same as that of site-directed mutagenesis. Neither can the end products be distinguished from each other. However, according to the Ministry of Housing, Spatial Planning and the Environment (VROM)[39] there are probably no legal possibilities to exclude site-directed mutagenesis from the GMO regulations because use is made of 'recombinant nucleic acid molecules'.

Further, there is a risk that this will lead to a lack of consistency in the decision-making on new techniques. Developers of new techniques would then have little or no confidence that their applications will or will not fall under the GMO regulations, with the risk that companies and scientists will abandon the development of new and possibly promising techniques.

Neither will taking a decision on whether a certain technique does or does not lead to the production of GMOs under current EU legislation resolve the problems associated with the different approaches taken by the regulations in countries like the US and Canada, such as unidentifiable imports and an uneven playing field for companies. For this reason, COGEM argues for the inclusion of the regulations – and the principles underlying the legislation in particular – in the discussion on EU policy for GMOs.

Calls have been made from various quarters to recast the EU legislation on GMOs to take a product-based approach.[41] At first sight, such a revision would seem to offer good prospects for overcoming the problems associated with new techniques and applications. There would be no need to consider each new application, while human and environmental safety can be guaranteed just as well under product-based regulations as under the current process-based regulations. The trade issues could also be resolved, given that the two main agricultural trading blocks would then have similar legislative frameworks.

Nevertheless, there would still be differences in the implementation of the legislation between the EU and the US. For example, the EU would still require a compulsory food safety assessment. Neither would the problem of asynchronous authorisation be resolved because the time taken to authorise products does not depend on the basis of the legislation, but is related to the procedures followed in the EU and the public and political opposition in the EU countries.[35]

However, a change to a product-based GMO legislation in the EU would run up against two complications. First, it would be more difficult to guarantee consumer choice. Under generic regulations, GMOs would be treated in the same way as conventional products. As Canada and the US do not require GMOs to be labelled, some form of registration would be required to meet the demands of those consumers who wish to avoid GMOs altogether. The question of definitions – what is a GMO? – would then probably play just as important a role as under the current regulations. A solution might be to reverse the labelling requirement and only label products that meet certain requirements as ‘GMO free’. The question is, will reversing the labelling requirements will be an acceptable solution for those who wish to avoid being exposed to GMO products? This requires further study.

Second, the process approach is firmly established in Europe – as evidenced by the historical development of EU legislation. The regulations can only be changed with the approval of a qualified majority of EU countries. A complicating factor is that in many EU countries there is political and public opposition to the use of genetic modification in agriculture. Revising the GMO regulations in the way described above will be seen by some as amounting to a relaxation of the legislation.

Another option for bridging the gap between the EU legislation, new scientific applications and contrasting legislative systems may lie in the Cartagena Protocol on

Biosafety,[15] a supplement to the Convention on Biological Diversity.[42] The Convention regulates the transboundary movement of GMOs exported with the aim of introducing them into the environment. When GMOs are exported from the EU the same risk assessment data are required as prescribed in Directive 2001/18. The Cartagena Protocol has been in force since 2003 and has been signed by 153 countries, including the EU member states. It is implemented in the EU by Regulation 1946/2003.[43]

The Cartagena Protocol contains a definition of what a GMO, or a 'living modified organism' (LMO) is:

> *(g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;*
> *(i) 'Modern biotechnology' means the application of:*
> *a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (dna) and direct injection of nucleic acid into cells or organelles, or*
> *b. Fusion of cells beyond the taxonomic family,*
> *That overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

In Directive 2001/18 a GMO is described as an organism 'in which the genetic material has been altered'. The Cartagena Protocol states that GMO must have 'a new combination of genetic material'. EU Regulation 1946/2003 states that both definitions are equivalent.[b] This means that the phrase 'a new combination of genetic material' is interpreted in the same way as 'altered genetic material'.

This appears to mean that the EU legislation can be interpreted differently from the way it is currently interpreted.[39] As a result, new techniques that do not lead to a new combination of genetic material, such as reverse breeding, would not fall under the EU GMO regulations. In other words, products (crops) of new biotechnological techniques that cannot be distinguished genetically from conventional products (because they do not contain a new combination of genetic material) do not have to be considered to be GMOs.

COGEM observes that on the basis of the Cartagena Protocol there may be room for a different interpretation of the EU GMO regulations. This could resolve a number of the problems described in this report. We suggest that it would be useful to investigate this line of reasoning within the EU.

The question remaining is to what extent the Cartagena Protocol can help to bridge the gap between the different sets of regulations. The US has not signed the Cartagena Protocol. Canada has signed, but not ratified it. However, both countries were involved in the negotiations on the text of the Protocol. COGEM concludes, therefore, that the Cartagena Protocol could provide a common basis for building a consensus.

[b] Regulation 146/2003, Article 3, *Definitions* (2) 'genetically modified organism', or 'GMO', means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC.

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