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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).

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 labeling 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 authorizing 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…

…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***

… **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

… 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.

…**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.

… ‘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.

…Literatuur

31 Kogan L (2003) “EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy That Ignores Sound Science,” The National Foreign Trade Council Inc.