

The Netherlands

Regulating GM crops in the Netherlands: precaution as societal–ethical evaluation

Piet Schenkelaars

Dutch regulators have generally made a sharp distinction between scientific–technical and societal–ethical aspects of regulating agri-biotechnology, but many developments have blurred or challenged that distinction. For field releases, risk assessment depended on agro-ecological norms regarding what plausible effects would be unacceptable. In the mid-1990s, stakeholder controversies continued over how to regulate genetically modified (GM) crops, as well as their food and feed use. Since the late 1990s, opposition by public-interest groups has led to new priorities for risk research, and tighter criteria for evidence. Involvement of non-governmental organisations, whether or not actively sought or appreciated by Dutch regulators, contributed to analytical rigour in risk assessment. Public debate also resulted in proposals for an integral societal–ethical evaluation framework (ISEEF) for biotechnology products, and market demands for the co-existence of GM, conventional and organic crops.

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UNLIKE THE USUAL environmental legislation, statutory frameworks for agri-biotechnology have not defined what counts as a harmful effect or an acceptable risk. No such norms were given in EC Directive 90/220 on deliberate releases into the environment of genetically modified organisms (GMOs). The Netherlands Competent Authority (CA), the Ministry of Environment, had to develop such criteria in the light of specific applications, drawing on advice from its expert Committee on Genetic Modification (COGEM).

Each favourable opinion on specific GMO releases had to be justified, given the political consensus on a precautionary approach to the uncertain risks of GMO releases. Although Dutch regulators officially spoke of 'risk assessment', in practice they moved towards flexible standards on the acceptability of environmental impacts. However, they avoided open discussion of these flexible standards, by arguing that the EC Directive allowed them to consider only scientific–technical safety aspects. Despite normative uncertainties, Dutch regulators thus made a sharp distinction between the scientific–technical and the societal–ethical aspects of regulating GMO releases in the mid-1990s. Meanwhile, industry and public-interest organisations used the new statutory regulation to legitimise or criticise specific developments, respectively (von Schomberg, 1996).

Uncertain risks of agri-biotechnology have remained a source of divergent views among regulators, innovators and public-interest organisations. This article examines the conflicts around further regulatory developments in the Netherlands. By drawing on social-science perspectives on precaution, this article will analyse whether and how:

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- different cause–effect models of risk/harm led to changes in the body of scientific knowledge, through new research priorities for “what is defined scientifically as problematic or not” (Wynne, 1992, page 120, 125) and;
- a deliberative process among stakeholders can highlight ambiguity or ignorance in risk assessment, so that “active stakeholder engagement in the appraisal process becomes a matter of analytical rigour” (Stirling, 1999, page 20).

The article draws on a study (SBC, 2004) conducted within the larger European research project, Precautionary Expertise for genetically modified (GM) crops (CTS, 2004).

Early risk assessment and decision-making

Since the first field trials in 1990, environmental risk research and risk assessment of releases of GM crops were closely linked by the Netherlands CA and the COGEM. They used the conventionally bred crop as baseline for judging the effects of the genetic modification. From its own ‘transgene-centred’ biosafety research conducted between 1991 and 1998 and the submission files from companies, the COGEM drew safety conclusions on a case-by-case basis. In particular, it judged that most commonly used antibiotic-resistance markers (ARMs), and transgenes for herbicide resistance (HR) and insect resistance (Bt) could be used safely in releases of GM crops.

Regulators thereby established an agro-ecological norm in environmental risk assessment, which separated agricultural and (semi-)natural environments. Outcrossing of ARMs or HR transgenes to wild relatives in (semi-)natural ecosystems would not confer them with a selective advantage in the absence of the corresponding antibiotic or herbicide and therefore would not affect population dynamics in these environments. Outcrossing of HR transgenes to weedy relatives in agricultural ecosystems was not considered an environmental risk but rather an agronomic problem that could be managed by mechanical control or application of another herbicide.

Furthermore, the potential transfer of ARMs from GM crop releases to micro-organisms in the soil or

the human/animal gut was judged a negligible risk to human health, given existing levels of antibiotic resistance in these environments. The risk of potential transfer of HR transgenes was also considered negligible, because it would not confer a selective advantage to microbes in the soil or the human/animal gut, given the absence of the herbicide in these environments.

For assessing GM Bt crops, the COGEM assumed that they would not affect non-target organisms because the Bt-toxin was highly specific. Moreover, the emergence of Bt-resistant insects was framed not as an environmental risk but rather as an agronomic problem, to be controlled with appropriate insect-resistance management measures.

There was an uncertain risk that outcrossing of other transgenes, for instance, for resistance to viruses or fungi, would confer a fitness increase to weedy or wild relatives. In such cases, the COGEM recommended risk-management measures, such as cutting of flowers, isolation distances and control of GM volunteer plants. The aim was to restrict uncertain risks of the field trial to the trial sites in agricultural fields.

Until 1999, the Netherlands was also the lead CA in the European Union (EU)-wide approval procedure for seven marketing applications of GM crops. Four of these applications also gained support from other EU member states, while three market applications were ultimately withdrawn by the applicants.

One of the latter cases concerned a GM high-amylopectin potato, developed by the Dutch potato starch co-operative Avebe, that contained the ARM NPTIII conferring resistance to the antibiotic amikacin. Whilst the Netherlands CA had determined that this ARM could be used safely, the EU-level Scientific Committee on Plants asked the company to supply additional information because amikacin was in clinical use. Avebe then decided to withdraw the application. Later it would respond by developing an ARM-free GM potato, for which the first field trials were conducted in 2003.

Contentious burden of evidence

Before 1999, opinions by the COGEM always contained a minority viewpoint from one of its members. This member, who worked part-time as senior researcher at universities and part-time for the environmental organisation Stichting Natuur en Milieu (SNM), consistently objected to the presence of ARMs in GM crops. He also criticised the majority for not considering potential risks of root saps from GM crops to soil ecosystems or potential risks of GM Bt crops to non-target organisms. He further argued that GM HR and Bt crops threaten sustainable agriculture; an issue that the majority considered beyond the COGEM’s remit.

After 2000, the COGEM’s expertise was expanded into new areas, including ecology, social

sciences and ethics, but its opinions no longer included a minority viewpoint. That member had given up his membership, because, in his view, the COGEM would never apply the precautionary principle appropriately.

For almost every permit for field trials with GM crops, the Government faced appeals at the highest administrative court, the Raad van Staate (RvS). These challenges came from the environmental organisations SNM and Greenpeace, the alternative consumer organisation AKB (now Goede Waar and Co) and, later, also the organic agriculture interest organisation Platform Biologica.

The official risk evaluation was challenged by pointing to molecular, agronomic and ecological uncertainties, whereby the risk-management measures were considered inadequate for limiting uncertain risks at the trial sites. Not surprisingly, their objections generally corresponded with the minority viewpoints within the COGEM. At the end of the 1990s, these organisations also started explicitly objecting that the precautionary principle had not been appropriately applied.

In most appeals, the RvS ruled that they did not sufficiently demonstrate that the official risk-evaluation and risk-management measures were inadequate and that the field trials would thus lead to unacceptable risks. Moreover, the legislation allowed the CA to consider only risks to human health and the environment. Yet, in one case dealing with an appeal against six permits, the RvS ruled in 2000 that the CA had not disclosed the trial sites with sufficient detail, so that regulatory decision-making had not been transparent to third parties. In another an appeal against four permits, the RvS ruled in 2004 that the CA had not shown that its environmental risk assessment was in accordance with the requirements of EC Directive 2001/18.

Notably, a study of 2003 on the precautionary principle commissioned by the Health Council, the expert body of the Minister of Public Health, questioned to what extent public-interest groups must demonstrate that there would be unacceptable risks. The CA now only had to show that the scientific risk assessment had been as thorough as possible and that its conclusions were scientifically objective, in order to base measures on 'sufficient' scientific knowledge. For public-interest groups it was difficult to provide 'conclusive' evidence that the CA's scientific evidence was 'insufficient' and that the field trials would lead to unacceptable risks.

Shifts in expert judgements

In 1999, the European Council of Ministers agreed that EC Directive 90/220 must be revised, for instance, by incorporating the precautionary principle and phasing out ARMs in GM crops. Whilst before 1999 the Netherlands CA had never referred to the precautionary principle, it was now explicitly

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invoked to justify a ban on ARMs in large-scale and commercial releases of GM crops.

According to the COGEM's (majority) case-by-case risk assessment, most ARMs could be safely used, but the CA now argued that many introductions of different GM crops with ARMs could cumulatively lead to an unwanted increase in existing levels of antibiotic-resistance in micro-organisms. As this accumulation could jeopardise the clinical use of the corresponding antibiotic, the precautionary principle was invoked to manage this uncertain risk by no longer allowing large-scale and commercial releases of GM crops with ARMs.

Obviously, consumer and environmental organisations welcomed this turn in regulatory policy on ARMs. By contrast, innovators expressed serious complaints, partly because they were suddenly confronted with a drastic change, about which regulators had neither consulted nor informed them. Since 90% of GM crops contained one or more ARMs at that time, the CA had to reject many permit applications for field releases. From 2000 to 2002, hardly any field trial was therefore conducted in the Netherlands. In 2001, a few innovators decided that they would no longer conduct field trials in the Netherlands, though their main reason was insufficient market demand for GM crops in Europe.

Moreover, expert discussions increased the burden of evidence to demonstrate the safety of GM insect-resistant Bt crops. Studies commissioned by the COGEM between 2000 and 2002 identified several existing knowledge gaps about effects of GM crops on soil ecosystems and multi-trophic effects on non-target organisms. The findings supported the minority viewpoint in earlier opinions by the COGEM and non-governmental organisations (NGO) criticisms.

Consequently, this new knowledge led the COGEM to reconsider its earlier judgement that there would be no non-target effects. Innovators seeking approval for commercialisation of GM Bt crops now had to supply more evidence of no effects. Also, as a consequence of NGO criticism, the baseline for

judging such effects became more stringent; in 2000, it was extended from the “conventionally bred crop” to “standing cultivation practices according to the latest scientific insights and molecular processes in the conventionally bred crop”.

After the new Directive 2001/18 entered into force in 2003, the European Commission restarted the approval procedure for 23 pending marketing applications for GM crops. Two applications, GM glyphosate-resistant oilseed rape GT73 and GM insect-resistant and glufosinate-resistant maize 1507, had been submitted in the Netherlands in 1998 and 2000, both for import and processing (not cultivation).

In both cases the evidence submitted by the companies was considered inadequate. For GM maize 1507, additional data had to be supplied on the toxicity and allergenicity assessment of the ‘novel’ protein encoded by the PAT transgene. For GM oilseed rape GT 73, extra evidence on the functioning of the GOX transgene had to be provided, even though earlier ‘transgene-centred’ biosafety research had suggested the safety of the PAT and GOX transgenes and the encoded proteins. Eventually the risks of import and processing both these GM crops were evaluated as negligible by the COGEM and the CA.

The COGEM provided advice on four other market applications submitted in other EU member states, which had reached a ‘positive’ initial assessment by their CAs. Yet, in all four cases, the companies were required to provide additional evidence. In two cases the COGEM ultimately saw no reason to object, whereas in the other two the COGEM eventually advised the Netherlands CA to object.

In the case of import and processing of GM Bt maize MON863xMON810, the COGEM reiterated its case-by-case judgement that potential risks of the ARMs present in the product were negligible. However, it reiterated the CA’s earlier decision to ban large-scale and commercial releases of GM crops with ARMs.

For GM maize Bt11, in the case of cultivation, the main reason to object was the lack of data on potential effects on non-target organisms, whereas the COGEM had earlier not expected such effects. In this case, the COGEM also identified theoretical flaws in the insect-resistance management plan proposed by the company, while noting that insect resistance concerns agronomic and not environmental risks. Post-market monitoring of the emergence of Bt-resistant insects should therefore not be imposed.

Notably, for all EU-level marketing applications of GM crops (or their uses) during 2003–2004, the Netherlands always voted in favour of authorisation. Only two other EU member states have always done so. For the cases in which the COGEM advised objection, that is, GM Bt maize MON863XMON810 and GM maize Bt11, it was not clear whether the Netherlands CA would vote according to that advice.

Finding consensual views on food safety

Food and feed safety research on GM crops were closely linked with regulatory decisions by relevant bodies in the Netherlands. These include: the CA for the EC Novel Food Regulation 258/97, the Ministry of Public Health, the expert body CVNV and the RIKILT, which is the state institute for the quality control of agricultural and horticultural products. For the food safety evaluation of a GM crop, the “history of safe use of the conventional crop” was used as the baseline. In the absence of EC regulations on the feed use of GM crops, a situation that lasted until 2003, the Ministry of Agriculture requested innovators to submit data for a feed safety assessment by the RIKILT on a voluntary basis. Most companies did so, in order not to jeopardise imports of feed ingredients derived from GM crops.

The food and feed safety assessors at the RIKILT were concerned about unintended changes in the metabolism of a GM plant as a result of genetic modification, which might have adverse effects on human or animal health. Several national research projects investigated those uncertainties in the mid-1990s. The main aim was to find methods of comparing the composition of a GM crop and its conventional counterpart.

While changes in levels of primary compounds (such as protein, fats and sugars) were quite easy to detect, unintended changes in levels of secondary metabolites required the development of new detection techniques. Yet the RIKILT viewed its new techniques only as forerunners of new tools that needed to be developed through further research into genomics, proteomics and metabolomics.

From 2000 to 2004, the RIKILT also ran the European research network Entransfood, which developed new test methods, in particular: a protocol for a sub-chronic 90-day animal test with the whole GM crop for the toxicity and allergenicity assessment; profiling techniques for the evaluation of unintended changes in the GM crop’s metabolism; and new analytical methods for the detection of ingredients of GM crops in foodstuffs.

From 1995 to 1998, the UK and German CAs had evaluated a series of refined products from GM crops as safe for human consumption on the basis of ‘substantial equivalence’, under the ‘simplified’ notification procedure of the Novel Food Regulation. This procedure caused disputes among EU member states, at a time when public concern about GM food was mounting all over Europe. So the Netherlands CA concluded it was better for innovators to use the authorisation procedure, which requires a risk assessment. All CAs would then have access to the submission file, while the full procedure might also increase public confidence.

In 2000, the CVNV closely linked national risk research and risk assessment by further tightening its data requirements for the compositional analysis of a GM crop compared to its non-GM counterpart, that

is, the substantial equivalence assessment. Not only changes in levels of macro- and micro-nutrients, inherent plant toxins and endo-allergens should be assessed, but also changes in levels of secondary plant metabolites, as they were considered characteristic of certain metabolic pathways in that crop, and because validated ‘omics’ tools were not yet available. Data should thereby be obtained through appropriately designed field trials. In addition, a sub-chronic 90-day animal-test with the whole GM crop was required, to supplement the ‘transgene-centred’ toxicity and allergenicity assessment.

The major Dutch consumer Consumentenbond (CB) and its think-tank Stichting Consument en Biotechnologie (C&B) appreciated that the CVNV had set much stricter requirements than had the German and UK CAs. This appreciation had its background in several technical studies commissioned by C&B since 1996. These studies often also served as input for national and European workshops for consumer groups, regulators and experts, which were organised by C&B together with CB or the European consumer organisation BEUC. BEUC joined the European research network Entransfood, while a study on substantial equivalence commissioned by C&B in 2001 was discussed at one of Entransfood’s workshops.

The Dutch regulators were praised for making their assessment reports publicly available, even though this disclosure was not legally required. However, the alternative consumer organisation Alternatieve Konsumenten Bond (AKB; later Goede Waar and Co) remained unsatisfied and argued that the food safety evaluation of GM crops should not be based on evidence supplied by the companies, while it questioned in particular the allergenicity assessment.

Between 1998 and 2001, innovators responded to these tighter requirements by submitting all their requests, in total seven, for the market authorisation of the food use of a GM crop in the Netherlands. They had hoped that this Dutch stringent but workable approach would contribute to consumer confidence in regulatory decision-making.

At the end of 2003, the CVNV had evaluated the food safety of GM sweet maize Bt11, GM maize GA21 and GM maize NK603 submitted between 1998 and 2000. In these three cases, the companies were asked to supply additional data on the compositional analysis of primary compounds in the GM crops, and on the levels of five secondary metabolites, which no other CA had so far required. Although for GM maize GA21 the company argued that this would not be relevant because “maize has a history of safe use”, the CVNV insisted the extra data was provided. For GM maize NK603, the results from a sub-chronic toxicity test with the whole GM crop had to be supplied. Eventually, the CVNV concluded that these three GM maize varieties were as safe for consumption as their conventional counterparts.

Following the CVNV’s advice, the Netherlands CA proposed a consent for the food use of these three GM maize varieties at the EU level. While the Dutch regulators had thus tightened several criteria for evidence and major Dutch consumer organisations had been satisfied beforehand, the available evidence was still criticised by several other CAs during the further course of the EU-wide approval process in 2003–2004. This criticism had several grounds: uncertainty about the EU-wide tightening of criteria for evidence; the absence of technical guidance to implement regulatory requirements for traceability and labelling of GM crops; and national political reasons.

Accounts of precaution in various arenas

Before 1999, regulatory decisions on releases of GM crops by the Netherlands CA never referred to the precautionary principle. After the agreement by the European Council of Ministers on the revision of EC Directive 90/220, the CA cited the precautionary principle in all its regulatory decisions as described by Rio Principle 15 of the 1992 UNCED conference:

“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

The CA added that the precautionary principle meant “not to set up a merely theoretical reasoning but to come to a reasonable substantiation whether certain effects can occur”.

For market approvals of GM crops under EC Directive 2001/18, the CA implicitly linked the precautionary principle with adequate evidence, to avoid uncertain risks. In the assessment reports on requests for market authorisation of the food use of GM crops submitted under the Novel Food Regulation 258/97, the CVNV drew no explicit link between the precautionary principle and any uncertain risk. Some

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company submissions also claimed that their risk assessments had been based on scientific analysis rather than assumptions. For the environmental risk assessment and food safety assessment, however, they initially supplied evidence that the CAs did not consider adequate. Companies therefore had to supply additional evidence before the expert bodies could complete their risk assessments.

Several major environmental and consumer organisations started invoking the precautionary principle in the mid-1990s as a further justification of their demand for a moratorium on releases of GM crops. On the one hand, they drew links between the precautionary principle and molecular, agronomic and ecological uncertainties, so as to justify further a moratorium because of uncertain risks. On the other hand, they invoked the precautionary principle as a justification for including what they considered other legitimate factors (OLFs) in regulatory decision-making; these included the usefulness and need of the GM crop, the availability and development of alternative solutions and/or ethical acceptability. The availability of alternative solutions, such as organic agriculture, was further linked to consumer freedom, farmer choice and financial liability for the presence of GM material in non-GM products above certain labelling thresholds.

Mainstream political parties became interested in GM foods as a result of mass-media attention to the controversy over the first imports of GM soy from North America in 1996. In 1999, this interest resulted in two Parliamentary resolutions asking the Government to declare its policy on biotechnology and to organise a broad public debate. This led the Government to issue a White Paper on biotechnology in 2000, in which the precautionary principle featured prominently, in particular to justify a ban on large-scale and commercial releases of GM crops with ARMs. Also, the Government announced the installation of the Commission on Biotechnology and Food (CBF) for the supervision of a broad public debate in 2001.

After a year of intense public and political discussions, the main result of the Parliamentary debate on the White Paper in 2002 was a resolution urging the Government to develop an integral societal–ethical evaluation framework (ISEEF) for biotechnology. A few months later this was followed by a discussion paper for an ISEEF commissioned by the COGEM. Although the importance of the precautionary principle was recognised, the proposed ISEEF did not link it with the scientific–technical risk assessment, nor did it elaborate how it should be applied within the societal–ethical evaluation.

The COGEM recommended that the CA make it mandatory for applicants of large-scale and commercial releases of GM crops to complete a ‘risk/usefulness’ form, to facilitate a dialogue among interested parties. However, both the CA and innovators immediately objected, since the European regulations did not allow for societal–ethical aspects,

such as usefulness/need or sustainability to be taken into account.

One year later, the discussion paper was followed by the COGEM’s societal–ethical signal on an ISEEF, which was sent to Parliament in November 2003, where it did not raise any comment. Parliament thus simply endorsed the COGEM’s ISEEF or took it for granted, probably because the mainstream media were then devoted hardly any attention to controversies over GM food. Neither the ISEEF nor the risk/usefulness form have so far been used in regulatory practice.

A few months after Parliament’s adoption of a resolution for an ISEEF in 2001, the Scientific Council for Government Policy (Dutch acronym WRR) published an extensive report on decision-making in biotechnology. The WRR recognised the importance of the precautionary principle in ethical evaluations, particularly in a risk-averse society. However, it criticised its disproportionate application to the environmental risk assessment of GM crops and its inconsistent application to the safety assessment of GM foods, because regulatory procedures should evaluate the risks of products, not the process of changing their genome. Weighing risks and benefits was considered complex because the risks are mainly of a public character in contrast to the private nature of most benefits.

The WRR proposed to found a virtual-knowledge institution, where public research institutions, companies and public-interest groups could make their information available for quality control and debate. In its response, the Government argued that the precautionary principle was applied in accordance with the COGEM’s ISEEF. The proposal for a virtual knowledge institution was rejected, since quality assurance of all available knowledge would not advance current public controversy, in which parties selectively or uncontrollably used scientific information.

Notably, in March 2005, the COGEM issued a call for tender to analyse the current and future role in risk governance of expert bodies, like itself. The call referred to the concept of ‘post-normal’ science, though without mentioning its source (Funtowicz and Ravetz, 1993). According to the call text, the COGEM’s role in risk governance is not only to diminish factual uncertainties but also to contain the outburst of controversy with opponents who keep pushing the risk debate into the area of scientific uncertainty.

This could be achieved by lowering the stakes of the debate through establishing commonly shared positive goals. Such a consensus would then enable an objective look at scientific uncertainties, while also allowing an expert body, such as the COGEM, to fulfil a broader role than simply reducing uncertainties about facts. Thus the COGEM sought to maintain its distinction between scientific–technical and societal–ethical aspects in risk assessment, while also trying to increase its social-science knowledge

for management of stakeholder controversies, which are considered a risk to further development of agricultural biotechnology.

Co-existence of GM and non-GM crops

As public-interest organisations and the major retail firms realised that farmer choice and segregation of GM and non-GM supplies were essential to ensure consumer choice, they jointly urged the Government in 1998 to implement a legally binding registration system for GM food/feed crops from ‘farm to fork’. Each operator in the agro-food chain would then have to provide transparency and guarantees to the next operator about whether genetic modification had been applied. The Government was further urged to establish legally binding threshold values for contamination of non-GM products (for instance, food, feed and seeds) by GM material, and the conditions for commercial cultivation and field trials with GM crops, aiming to minimise outcrossing of GM material to non-GM crops.

In 1998, these demands were also expressed at EU level, through a joint letter sent by CB, C&B and BEUC to the European Commission. There it took almost five years before most of these demands were largely met through two new EU regulations on GM food and feed and on traceability and labelling, which came into force in October 2003. That year, the European Commission also issued a recommendation on the so-called ‘co-existence’ of GM, conventional and organic crops. In essence, it was left to the member states to implement national co-existence measures.

In October 2003, the Netherlands Minister of Agriculture informed Parliament that market parties, for instance, the seed industry and farmers’ and organic-food interest organisations, had been given until April 2004 to develop ‘self-regulation’ of co-existence. Yet, almost every national and European study on co-existence or outcrossing had so far pointed to a lack of empirical data for many crop species.

Moreover, such data were also needed for establishing labelling thresholds for GM seeds in many non-GM seeds. While the European Commission had proposed labelling thresholds at the seed level, based on opinions by the Scientific Committee on Plants of 2001 and 2003, the COGEM pointed out in its societal–ethical signal of November 2003 that these thresholds lacked clear scientific substantiation, as there were several knowledge gaps. Notably, the COGEM had thus far never felt a need for such knowledge, but now it needed to commission research, to address a new societal–ethical issue: co-existence of GM and non-GM crops.

One year later, the COGEM issued its scientific–technical advice on co-existence with a series of crop-specific and agro-environment-specific suggestions for managing the economic risk of the adventitious

presence of GM material in non-GM crops. This enabled market parties in March 2005 to agree on technical co-existence measures, for instance, certain isolation distances between GM and non-GM crops.

In 2004, market parties fiercely disputed whether farmers growing GM crops should take confinement measures for co-existence or, rather, whether the responsibility should fall to the conventional and organic farmers. That year, a major insurance firm in the agricultural sector communicated that it was not prepared to insure the liability risk of non-GM produce contaminated by GM material. Given the many unknowns, it could not calculate the premium. Eventually, the agreement of March 2005 included setting up a compensation fund to cover economic damage resulting from GM contamination. Yet, individual organic farmers might not be prepared to contribute.

Conclusions

In conclusion, regulatory practices have become more precautionary in the Netherlands, partly in response to public controversy over agri-biotechnology. New research priorities have been set for what is defined as scientifically problematic, along the lines that Wynne (1992) characterised precaution in general. Such changes in risk research have included test methods for the composition of GM food and new knowledge on potential non-target effects of GM Bt crops. Moreover, involvement of NGOs in the appraisal process, whether or not actively sought or appreciated by Dutch regulators, has contributed to analytical rigour in risk assessment, along that lines that Stirling (1999) described as means of addressing scientific ambiguity and ignorance.

For the food/feed safety assessment of GM crops, Dutch regulators and the major consumer organisations developed consensual views on tightening the criteria for evidence. Whether this tightening was because of experts’ own concerns or a response to NGO criticism and the wider public debate is difficult to disentangle. Yet, even those tighter criteria did not satisfy other CAs in the EU-wide approval process, regarding the necessary information for three GM maize varieties for food use.

Within the Netherlands, the environmental risk assessment of GM crop releases remained a source of controversy. Contentious issues included: the criteria for evidence; and the role of the precautionary principle and the official agro-ecological norm, which conceptually separated agriculture from (semi-)natural environments. The engagement of environmental organisations contributed to analytical rigour in risk assessment. New research priorities were set, for instance, for obtaining knowledge on potential non-target effects of GM Bt crops. This in turn led the COGEM to reconsider its earlier risk assessments of GM Bt crop releases and to tighten its criteria for evidence of non-target effects. The

same goes for its earlier toxicity and allergenicity assessments of the herbicide-resistance genes PAT and GOX.

Regulatory procedures have also shifted the evaluation of antibiotic-resistance markers. Initially, expert advisors had accepted the safety of the most commonly used ARMs. Since the late 1990s, consumer and environmental NGOs consistently challenged the case-by-case safety judgements by the COGEM, especially regarding the presence of ARMs in GM crops. In the context of a wider public debate around 2000, the Minister of Environment invoked the precautionary principle for banning large-scale and commercial releases of GM crops with ARMs. The decision cited uncertain risks of cumulative effects of many releases, given that the cumulative transfer to pathogenic microbes could jeopardise the clinical efficacy of the corresponding antibiotic.

Also, the distinction between environmental and agronomic risks was continuously challenged, not only by minority viewpoints within the COGEM and environmental organisations, but also by regulators from several other EU member states. For example, for cultivation of GM Bt crops, several other CAs advocated mandatory post-market monitoring of GM Bt crops, especially because they framed the emergence of Bt-resistant insects as an environmental risk.

Furthermore, earlier judgements that outcrossing of ‘safe’ transgenes from GM crops to non-GM crops was not an environmental risk were challenged by the societal–ethical issue of consumer and farmer choice between GM and non-GM products. Also, this challenge contributed to new research for generating knowledge on how (trans)genes move through agricultural fields and nature.

In general, Dutch regulators still attempt to separate scientific–technical and societal–ethical aspects of risk assessment, yet the distinction has been blurred or challenged in several ways. Expert advice has had to adopt more explicit norms about which

potential effects would be unacceptable. Public debate on some issues, such as the potential contribution or threat of GM crops to sustainable agriculture, eventually led Dutch regulators to develop an integral societal–ethical evaluation framework and a voluntary risk/usefulness form to facilitate dialogue between innovators and other interested parties. In this way, Dutch regulators implicitly recognised what public-interest organisations viewed as other legitimate factors, although as issues to take into account in biotechnology policy, rather than as criteria for regulatory approval. They also have sought to increase their social-science knowledge for managing stakeholder roles in risk controversies.

References

- CEC, Commission of the European Communities (2000), “Communication from the Commission on the Precautionary Principle”, COM(2000) 1, Brussels, 2 February, available at <http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf>, last accessed 20 January 2003.
- CTS, Centre for Technology Strategy (Open University, UK) (2004), “Precautionary expertise for GM crops”, supported by grant from European Commission 5th Framework Programme Quality of Life and Management of Living Resources, project no QLRT-2001-00034, available at <<http://www.tecopen.ac.uk/cts/peg/index/htm>>, last accessed 12 March 2005.
- Funtowicz, S, and J Ravetz. (1993), “Science for the post-normal age”, *Futures*, 25(7), pages 327–336.
- SBC, Schenkelaars Biotechnology Consultancy (2004), “The Netherlands: precaution as societal–ethical evaluation”, national report for project ‘Precautionary expertise for GM crops’, supported by grant from European Commission 5th Framework Programme Quality of Life and Management of Living Resources, project no QLRT-2001-00034, available at <<http://www.sbcbiotech.nl>>, last accessed 25 April 2005.
- Stirling, A (1999), “On science and precaution in the management of technological risk”, SPRU, Brighton, UK, final report for EC Forward Studies Unit, available at <<ftp://ftp.jrc.es/pub/EURdoc/eur19056en.pdf>>, last accessed 9 April 2005.
- von Schomberg, R (1996), “Netherlands: deliberating biotechnology regulation”, *Science and Public Policy*, 23(3), June, pages 158–163.
- Wynne, B (1992), “Risk and social learning: reification to engagement”, in Krinsky and Golding (editors), *Social Theories of Risk* (Praeger, New York) pages 275–297.