AFRICAN CENTRE FOR BIOSAFETY

IMPLEMENTATION OF SECTION 78 OF THE NATIONAL ENVIRONMENTAL MANAGEMENT BIODIVERSITY ACT: KEY ISSUES AND CHALLENGES

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TABLE OF CONTENTS

TERMS OF REFERENCE

I have been asked to furnish the National Department of Environmental Affairs and Tourism (DEAT) with an opinion regarding the implementation of section 78 of the National Environmental Management Biodiversity Act (NEMBA), once the said NEMBA comes into effect on the 1 September 2004.

This opinion focuses on the key policy issues to assist the DEAT to better understand the environmental risks and regulatory challenges posed in the area of genetic engineering research and commercialisation.

This opinion examines issues concerning the environmental assessment of GMOs released into the environment, and therefore does not address the many serious problems associated with the evaluation of risks currently undertaken in South Africa regarding the release and marketing of GMOs, nor with the decision-making process itself.

In this opinion, the terms genetic engineering, genetic modification and transgenics are used interchangeably.

OVERVIEW

The implementation of section 78 of NEMBA will pose innumerable challenges for DEAT, precisely because environmental risks are most easily assessed after damage has already occurred, yet environmental assessments are useful for decision-making only when the risks are assessed before damage occurs. Furthermore, the absence of independent monitoring and testing (in the fields) in South Africa, has made it difficult to reliably assess the degree of environmental risks posed by transgenic crops already released into the South African environment over the past 15 years![1] However, section 11(1)(b) of NEMBA creates a peremptory duty for the South African National Biodiversity Institute (SANBI) to "monitor and report regularly to the Minister on the impacts of any genetically modified organism that has been released into the environment, including the impact on non-target organisms, ecological processes, indigenous biological resources and the biological diversity of species used for agriculture."

Thus, the implementation of section 78 of NEMBA is linked to these monitoring and reporting functions of SANBI, as it is during the environmental assessment phase, that what should be monitored will be identified. Monitoring is in turn, linked to possible direct, indirect, immediate or delayed effects identified in the risk assessment. At the same time, monitoring should also include general surveillance (routine observations) to detect possible unforeseen adverse effects that were not predicted in the environmental assessment.

Crucially, however, section 78 of NEMBA is inextricably linked to the regulations to be promulgated under section 24(5) of the National Environmental Management Act, 107

[1] The first transgenic plant crop released into the South African environment, Bt cotton, was sanctioned by the apartheid government in 1989, on the advice of the now defunct, South African Committee on Genetic Experimentation (SAGENE).

of 1998 (NEMA) using powers that are created in NEMA by the National Environmental Management Act, No 8 of 2004. The draft Environmental Impact Assessment Regulations published in terms of Notice 764 *Government Gazette* 26503 of 25 June 2004, however, completely ignores GMOs. In fact, it is the writer's belief that these Regulations were never intended to apply to GMOs, thereby rendering the implementation of section 78 of NEMBA difficult, if not impossible.

IMPERATIVES UNDERPINNING SECTION 78

Currently, the Executive Council established in terms of section 3 of the Genetically Modified Organisms Act No. 15 of 1997 ("GMO Act") acting in consultation with the Advisory Committee established in terms of section 10 of the said Act, is responsible for conducting biosafety assessments (evaluations) of genetically modified organisms (GMOs). These institutions have to date, applied the "substantial equivalence" principle, which relies on the concept of "familiarity" with conventional varieties of especially genetically engineered crop plants, to judge whether a transgenic plant requires a full environmental assessment.

The principle assumes the validity of the simple linear model of "precise" single gene modifications that do not significantly alter other plant processes. This may explain why, to date, not a single environmental assessment has ever been conducted in South Africa in respect of GMOs released into the environment.

Section 78 of NEMBA, however, recognises that unanticipated changes can be induced by expression of a novel gene (and indeed parts of the genetic construct), and that phenotypic consequences need to be assessed empirically across time and environments. Section 78 thus creates the opportunity for the development of an environmental assessment system that moves away from the assumption of "precise" genetic engineering to a knowledge-based precise analysis of the resulting GMO.[2]It thus holds the potential for DEAT to contribute significantly towards more scientifically rigorous environmental science in the decision-making processes concerning research and commercialisation of GMOs.

Furthermore, section 78 creates an important opportunity for DEAT to address the serious shortcomings inherent in the current requirements for risk assessment. These have been and are still contested by public interest groups in South Africa. Currently, an Applicant who wishes to release GMOs into the environment is required to furnish the Executive Council only with the information required in terms of Guidelines published by the National Department of Agriculture, Genetically Modified Organisms, Revised Procedures.[3]It is on the basis of this information, that a risk evaluation or assessment (desk top only) is carried out, of the potential risks posed by the GMO in question. These guidelines (*Application for General Release; Application for Intentional Release*) do not constitute an adequate framework for conducting an initial environmental assessment and it is therefore not possible, on the basis of these guidelines, for proper and reliable conclusions to be drawn on the potential environmental impact the release into the environment, GMOs are likely to pose. (See for example, objections to GM releases and marketing applications, www.biosafetyafrica.net; www.biowatch.org.za).

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[2] See, Barret, S et al., Elements of Precaution: Recommendation for Regulation of Food Biotechnology in Canada. The Royal Society of Canada, Ottawa, Canada.

[3] http://www.nda.agric.za/docs/geneticresources/geneticcontrol.htm

However, section 78 does have serious shortcomings, not least of which is that environmental assessments of GM releases are not automatic or mandatory, and that not all GMOs released into the environment are subject to environmental assessments.

DETAILED DISCUSSION OF SECTION 78 OF NEMBA

The implementation of NEMBA must take place within a precautionary environmental regulatory context/approach to GMOs. An approach well established in international and South African environmental law, and which requires that the DEAT take into account and respond to the following:

(a) Significant gaps in knowledge (the science is small and inconclusive);
(b) The fact that some risks posed by GMOs are unique, thus requiring specially tailored biosafety regulations; and
(c) Major risks posed by GMOs[4] already identified in the peer reviewed scientific literature.

The DEAT may also take into account current international precedents/examples, and three such examples are discussed briefly in Annex I.

Bearing this in mind, the implications of the various key components of section 78 of NEMBA are discussed below.

For ease of reference, the section is reproduced here, in its entirety:

(own underlining)

NEMBA does not define "genetically modified organism" but the GMO Act does, and this definition is sufficiently wide[5] to include current and well as future scientific developments:

[4] Here, reference is being made to the so- called "first generation" of GMOs namely, transgenic crops that have been growing in the South African environment since 1989.
[5] "genetically modified organism" means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and "genetic modification" shall have a corresponding meaning.

(i) Plants

- Current transgenic plants-crops (and grasses) with transgenic resistance to certain herbicides, insects, or diseases;
- Future transgenic plants engineered for introduction into rangelands, forests, landscaping, nutrition, pharmacology, biological control, production of industrial chemicals, and bioremediation, and these may include the following;
    1. Plants engineered to tolerate abiotic stresses such as salinity, drought, or freezing, biotic stresses, such as pathogens, and anthropogenic stresses, such as heavy metal contamination;
    2. Transgenic tree plantations[6];
    3. Transgenic plants that produce pharmacologically active proteins[7], vitamins, industrial polymers, and those that are engineered to "improve" the quality of animal feed;
    4. Transgenic food plants engineered to reduce allergenicity.
    5. Transgenic food plants engineered to produce edible vaccines (those that are eaten directly, e.g. in fruit).

(ii) Viruses, Microorganisms and Algae

- Most genetic modification of viruses intended for environmental release has focused on baculovirsuses although to date, work has taken place under contained conditions or in small-scale field tests-no baculoviruses have been released commercially;
- Transgenic microorganisms are being developed for bioremediation of toxic compounds and for removing excess carbon dioxide from the atmosphere;
- Experimental field test of microorganisms intended for release into the environment include bacteria with visual markets, biosensors of toxic chemicals, insecticidal properties and reduced virulence.
- GM virus vaccines.

(iii) Animals

Animals have been genetically engineered to grow faster, resist diseases, tolerate cold, produce organs for transplants, or produce biologically active, therapeutic proteins. Much of this research is still exploratory, however, fast growing salmon that will increase production of farm- raised fish are currently being considered for commercial release in

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[6] Targeted traits include herbicide tolerance, pest resistance, abiotic stress tolerance, modified fibre, quality and quality and altered growth and reproductive development. Trees have also been engineered to bioremediate mercury pollution. Ecological risks include transgene escape and introgression into wild gene pools and the impact of transgenic products on ecological processes. See, K. van Frankenhuyzen and T. Beardmore "Current status and environmental impact of transgenic forest trees" Can. J. For. Res. : 1163-1180 (2004).

[7] See, Research and pharmaceuticals: EU 'pharming' solutions to major diseases, European Commission, Press Release http://europa.eu.int/rapid/pressReleasesAction.do?reference. South African scientists from the CSIR are part of an European-South African consortium, Pharmaplant, to develop GM pharmaceutical crop plants, using maize and tobacco, to produce pharmaceuticals to combat TB, AIDS and rabies. Open field trials are part of the experimental plan, and a number of test sites in South Africa have already been identified. Testing is expected to commence by 2006.

[8] See further, I. Findinier Animal Biotechnologies: state of the art, risks and perspectives, April-June2003, Food and Agriculture Organisation.

the United States and genetically engineered tilapia has been also been released in Cuba. Genetically engineered zebrafish produced for aquarium trade have also been commercially released in the U.S.

This category will also include genetically engineered insects. Scientists are modifying insects for a number of purposes, including to address agricultural problems. A major area of research involves genetically engineering of insects to make them less effective as vectors of animals and human diseases, such as malaria and Chagas' disease. Additionally, some research is being carried out to genetically modify the microbes associated with the gut of reproductive systems of pest insects. This type of genetic modification is called "paratransgenesis", because although the insect itself has not been modified, its microbial inhabitants have been.

Subsection (3) has limited the release into the environment contemplated in subsection (1) of section 78 to "trial release" and "general release", in order to typically capture open field trials and commercial releases. The definition of "trial release[9]" read together with the definition of "contained use"[10] in section 1 of the GMO Act, appears to exclude several activities that are in fact, environmental releases of GMOs. The following environmental releases are arguably excluded from the purview of section 78(1):

- Storage (at mills and silos) and transport of whole kernels of GM grain imported for use as food, feed and processing;
- Placing on the market;
- Greenhouse experiments;
- Liquid and solid wastes of transgenic livestock contained in the laboratory or greenhouses;
- Liquid and solid wastes of laboratories creating transgenic organisms in the laboratory or greenhouses;
- Xenotransplantation using transgenic animal organs;
- Gene therapy involving animals.
- GE vaccines used in the treatment of animals and humans (i.e. the direct use).

It is regrettable that section 78 has repeated the flawed definitions of the GMO Act.

(i) Discretionary powers

Although seemingly wide discretionary powers have been vested in the Minister in section 78 by the wording " If the Minister has reason to believe…may pose a risk to any

[9] "trial release" means the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organism is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment." (own underlining).

[10] "contained use" means any activity in which organisms are genetically modified or in which such genetically modified organisms are cultivated, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers are used to limit contact thereof with the environment"

indigenous species or the environment" it is implied that the exercise of these powers should be:

- Science based;
- Applied on a case-by-case basis, rather than automatically generalising results from one case to the next ("release of ***a*** genetically modified organism"); and
- Taking into account the triad-the transgene, the organism, and the environment into which the proposed release would occur.

In regard to the exercise of decision-making powers that are science based, it is increasingly being recognised by international bodies that science and the criteria defining rational uses of science in regulation and policy have to take into account, public concerns for reasons of scientific robustness and democratic legitimacy. In this regard, the GM Science Review in the United Kingdom has concluded "the provision of robust scientific advice to policy making, depends not only on the involvement of a wide range of specialists disciplines, but also on in-depth critical engagement with public values and concerns."[11]

(ii) "indigenous species"

Indigenous species[12] has been especially identified because of the spreading of gene transfer to indigenous species e.g. wild relatives. An important case in this regard, is the unintentional contamination of GM maize in Mexico, a centre of origin of maize.[13] GM cotton has been growing in South Africa in open fields since 1989, and GM cotton seeds are commercially sold on the South African market, despite that a wild relative of cotton grows in South Africa *Gossypium triphullum*. In fact, the US Environmental Protection Agency has banned the growing of GM cotton in Hawaii and Florida because wild and feral populations of cotton relatives are known to grow there.[14]

(iii) "environment"

"environment**"** is not defined in NEMBA, because it has been sufficiently defined in NEMA, and is generally accepted to connote an adequately wide definition (wide enough to allow the DEAT to interface with the monitoring and reporting functions of SANBI.)

(iv) Specific Recommendations

As a General Principle**, the** DEAT should require environmental assessments for all GMOs being released into the environment. Significant gaps in knowledge warrant a cautious and risk averse environmental regulatory approach for GMOs. **However, this may not be enough to convince either DEAT itself, nor the other stakeholders. Hence, the following is additionally proposed:**

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[11] GM Science Review Panel, *GM Science Review An open review of the science relevant to GM crops and food based on interests and concerns of the pubic* (Second Report, January 2004), http://www.gmscience debate.org.uk./report/default.htm#second

[12] defined in NEMBA, means a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity"

[13] Quist D. and Chapela I. H. 2001. Nature Vol. 296.

[14] http://www.epa.gov/pesticides/biopesticides/regtools/biotech-reg-prod.htm

(a) That the DEAT establish a set of guiding principles for those instances, where environmental assessments will routinely be required. In this regard, the DEAT may want to consider the following recommendations by the Ecological Society of America[15]:

- Where there is little prior experience with the trait and host combination (e.g. GMOs with new genetic constructs/transgenes, multiple transgenes, transgenic animals, transgenic pharmaceutical crops, GM trees etc.)
- Where GMOs may proliferate and persist without human intervention;
- Where genetic exchange is possible between a transformed organism and non-domesticated organism, especially for instance, where there are wild/weedy relatives (e.g. cotton); and
- Where the trait confers an advantage to the GMO over native species in a given environment.

(b) That the DEAT carefully consider the scientific literature[16]that has already identified possible risks to the environment arising from GMOs already introduced into the environment, with a view to formulating policy guidance for such risks. A non-exhaustive list of these risks is set out below. These risks have been thoroughly debated in the scientific literature and many of them have been verified by research in some species and environments.

- The spreading of genes through hybridisation between GMOs and closely related domesticated or wild species.
- Population growth, spreading and invasion of GMOs into natural ecosystems.
- Increased competition from GMOs or their hybrids with natural species.
- The spreading of genes through horizontal gene transfer from plants to microorganisms in the environment, including microorganisms in the guts of insects and animals.
- Development of herbicide resistant weeds.
- Development of insects resistant to insecticides.
- Effects on non-target organisms, including soil biota.[17]
- Secondary environmental effects as a consequence of changed agriculture practises e.g. new use of insecticides, herbicides, fertilisers etc.

A consequence of these possible risks may be: population decrease or extinction of species in natural ecosystems, or unforeseen/unintended negative impacts for agriculture.

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[15] Ecological Society of America Position Paper "Genetically engineered organisms and the environment: Current status and recommendations" submitted to the ESA Governing Board, November 21, 2003.

[16] Keeler K.H. 1985 (Exhibit NOR-77); Crawley, M.J., 1988. Meeting report: COGENE/SCOPE at Lake Como. Special combined issue: Trends Biotechnology & Trends Ecology, E vol 3. 2-3; Ellestrand N.C. 1988. Special combined issue: Trends Biotechnology & Trends Ecology, E vol 3. 30-32; Tidje J.M (and 6 others) 1989. Ecology. Vol 70, No 2; Williamson M. 1989. Special combined issue: Trends Biotechnology & Trends Ecology, E vol 3. 32-35; McNally R. 1994. The Ecologist, Vol 24, No. 6 Nov/Dec, 207-212; Doyle J.D, Stotzky G, McClung G, Hendricks C.1995. Advances in Applied Microbiology, Vol. 40, 237-287; The Royal Society of Canada. 2001. Elements of Precaution: Recommendations for the regulation of food biotechnology in Canada. An expert panel report on the future of food biotechnology prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada (ISBN 0-920064-71-x) Snow A.A. *et al.,* 2004; "Genetically engineered organisms and the environment: Current status and recommendations" ESA position paper

[17] See for example, D.A.Andow and A Hilbeck "Science-Based Risk Assessment for Nontarget Effects of Transgenic Crops" where they propose an ecological risk-assessment model for non-target organisms.

Whether these **impacts** will indeed occur is difficult to predict *a prior*, and will depend on the species and genetic modification in question, the receiving environment or the farming and agro-ecosystem in use.

Hence, it is crucial for DEAT to consider the extent to which there is scientific certainty and consensus on the issue at hand. The greater the uncertainty and the less consensus in the scientific knowledge, the broader the range of regulation, the NDA and industry, would be persuaded to accept.

This component of section 78 gives rise to a number of problems, anomalies and uncertainties.

If the Minister is of the belief for instance, that the release of a GMO may pose risks to the environment, and therefore, an environmental assessment is required to be conducted in terms of Chapter 5 of NEMA, then such intended release, will in terms of section 78, be deemed to be a listed activity in terms of Chapter 5 of NEMA. Environmental assessments of listed activities is to be regulated through a series of Regulations to be promulgated in terms of section 24(5) of NEMA, using powers that have been created by Act No. 8 of 2004.

It stands to reason therefore, that such Regulations must be drafted in a way, so that section 78 is itself operationlised. However, the draft Regulations issued under government notice 764 in *Government Gazette*26503 of 25 June 2004, have been drafted in a way that completely ignores section 78 of NEMBA. **As it currently stands, these Regulations do not apply to GMOs**. This means that section 78 has potentially been rendered unimplementable.

It is incumbent upon DEAT to devise appropriate mechanisms for the conducting of the environmental assessment contemplated in section 78 of NEMBA.

In order for these Regulations to apply to GMOs, **GMOs must either be listed in an appropriate schedule to the said Regulations or Regulation 5 must be amended to make specific reference to GMOs .**[18]

Furthermore, a discreet set of provisions must be drafted for GMOs (for both the initial environmental assessment and the full environmental impact assessment.) Regulation 15 dealing with the contents of initial assessment reports for instance, (assuming it were to apply to GMOs), whilst containing a number of important elements (social impacts, cultural impacts etc) is not appropriate for GMOs. See, in this regard Annex I below

[18] Regulation 5 should be amended to read as follows " Any person who intends undertaking an activity listed in Schedules 3 or 4 or in an area identified in Schedule 1
must submit…"

dealing with Directive 2001/18/EC[19]as an example of what an initial environmental assessment enquiry should cover.

GMOs present unique threats to the environment, and require specially tailored measures for its regulation. Appropriate provisions are required to bring about legal certainty for interested and affected parties. A flexible approach to the drafting of such guidelines should be adopted, because as a general rule, it is unrealistic to envisage a uniform environmental assessment system that could assess the environmental risks posed by particular GM varieties (in the case of GM crop plants for instance) in all, or even many environments in South Africa. No single environmental assessment can incorporate all the known or potential risks that GMOs pose, as uses, functions, and volumes vary widely among plants, animals, microorganisms and receiving environments. At the same time, such Regulations should be forward-looking and make allowances for the evolving nature of environmental assessment of GMOs, as well as future technological developments.

Furthermore, the public notification mechanism set out in Regulation 7 (assuming it were to apply to GMOs) merely repeats the flawed mechanisms in the GMO Act and its Regulations/fails to address the serious concerns raised repeated raised by public interest groups. (See numerous objections to GM releases published on www.biosafetyafrica.net). The assessment process generally must be much more transparent and rigorous than is currently provided for. A framework for environmental GM regulation requires that public officials, natural and social scientists, and interested and affected parties are involved throughout the process, and that learning and feedback be part of the whole analysis and deliberation process.

It is acknowledged that Schedule 1, "identification of geographic areas in which specified activities require environmental authorisation" is potentially an important mechanism for the declaration of GM free zones in the future. It is recommended that the DEAT keep this in mind and solicit public inputs into the process of such identification.

The turn around time, from the date of submission of the application, to the date of final decision by the Executive Council is extremely short, between 6 and 8 weeks. DEAT will have to establish adequate mechanisms to process applications, make a decision, and communicate this decision to the EC within a rather narrow time frame, taking into the average of applications the DEAT may deal with per month, as well as the flood of applications that may be submitted near planting seasons/anticipated favourable weather conditions. This will require co-ordination between the DEAT, the NDA and the EC.

[19] Directive 2001/EC/18 of the European Parliament and Counsel 12 March 2001 on the deliberate release into the environment of a genetically modified organisms, Official Journal of the European Communities

CONCLUSION

While section 78 of NEMBA creates many opportunities for the environmental regulation of GMOs that are released into the South African environment, it is not an ideal regulatory tool for controlling the environmental risks posed by GMOs. It does not create legal certainty, and is speculative regarding the environmental assessment of GMOs. It will also facilitate devices by industry to get around the discretion conferred on the Minister. This scenario is compounded by the draft Proposed Regulations under section 24(5) of NEMA, which fail to address GMOs. Even if these Regulations were to be amended to address GMOs, these will not cure, the shortcomings inherent in section 78 of NEMBA. Several recommendations have been made to amend the said Regulations in order that these may apply to GMOs and thus create an opportunity for environmental assessments to be conducted for those few GM releases that the DEAT may want to subject to environmental assessments.

ANNEX I

UNITED STATES

The Pew Initiative on Food and Biotechnology in the United States published a report in April 2004, outlining in great detail, how the agencies in the United States-the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have regulated GM crops, animals and foods. In summary, neither of these agencies have any affirmative postmarket/release testing, assessment, monitoring, inspection or compliance programmes. In fact, the FDA merely oversees a voluntary system under which corporations submit their own safety test procedures for their products, often based on incomplete data.

However, recently, the USDA's Agriculture's Animal Plant and Health Inspection Service (APHIS) adopted a different approach in respect of a petition[20]filed by Monsanto for the approval to commercialise (deregulate) creeping bentgrass (*Agrostis stolonifera*), genetically modified to tolerate Monsanto's Roundup, a glysophate herbicide. The GM bentgrass has been under development since 1998 and field tested in a number of states in the US. APHIS opened a 60-day period for public comment and after receiving some 450 comments, it compiled a preliminary environmental risk assessment which formed the basis for the drafting of a document under the National Environmental Policy Act, to assess the potential environmental impacts of a decision to approve the GM grass for commercial growing. In other words, the first environmental assessments for GMOs will be conducted in the US in the near future, and should be monitored by DEAT.

BRAZIL

Brazil passed RESOLUÇÃO Nº 305, on the 12 June 2002, requiring mandatory environmental impact assessments before GMOs could be released into the environment.[21]However, as long ago as 1998, GM soya was smuggled into Brazil from Argentina and grown illegally in Brazil, primarily in Rio Grande do Sul. Owing to pressure from Monsanto, the State Government of Rio Grande do Sul and farmers who had illegally planted the GM soya, the newly elected Federal Government, on the 26th March 2003, passed Provision Measure (PM) 113, and allowed the commercial use of the illegally grown GM soya in food, feed for the domestic and international market until 2004.

This case reflects the disdain large multinational seed and agrochemical companies have, for developing countries' biosafety polices and laws, that they will even stoop to subversion.

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[20] The petition was filed by Monsanto and the Scotts Company see http://www.aphis.usda.gov/brs/aphisdocs/03_10401p.pdf

[21] Dispõe sobre Licenciamento Ambiental, Estudo de Impacto Ambiental e Relatório de Impacto no Meio Ambiente de atividades e empreendimentos com Organismos Geneticamente Modificados e seus derivados.

Resolucion No305 has been utterly undermined, and it remains to be seen, what the Brazilian authorities will do to restore some credibility to the rule of law in that country.

EUROPEAN UNION

The European Union has the most comprehensive and evolved biosafety regime in the world. Contrary to public perceptions, this regime is not being challenged by the US, Argentina and Canada before the World Trade Organisation (WTO). What is being challenged in the WTO, is the individual bans imposed by 6 member states of the EU, regarding specific GMOs, and the *de facto* moratorium, namely, the five year delay in approving GMOs. This *de facto* moratorium has been ended 2 months ago, when the European Commission took a decision to allow the import into the EU, of Syngenta's GM maize, event Bt11 as food, feed and processing.

DEAT may find Directive 2001/18/EC[22] governing deliberate releases of GMOs into the environment, which came into effect on the 17 August 2003 instructive when considering drafting discreet guidelines or regulations for environmental assessments. Annex III sets out "Principles for the environmental risk assessment". The Principles deal with the following:

A. Objective –(The objective of an e.r.a, on a case-by-case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release may have.)
B. General Principles (based on the precautionary principle)
C. Methodology (C1. Characteristics of GMOs and releases; C2 Steps in the e.r.a)
D. Conclusions on the potential environmental impact from the release (D.1 In the case of GMOs other than higher plants; D.2 In the case of GM higher plants)

On the basis of an e.r.a carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in D1 and D2 are to be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release of a GMO.

[22] Directive 2001/EC/18 of the European Parliament and Counsel 12 March 2001 on the deliberate release into the environment of a genetically modified organisms, Official Journal of the European Communities