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**INTERGOVERNMENTAL COMMITTEE FOR THE  
CARTAGENA PROTOCOL ON BIOSAFETY**

Third meeting  
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Item 4.1.1 of the provisional agenda\*

**LIABILITY AND REDRESS (ARTICLE 27)**

*Compilation of information on national, regional and international measures and agreements in the field of liability and redress for damage resulting from the transboundary movements of living modified organism*

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**AUSTRALIA**

[15 January 2002]

[SUBMISSION: ENGLISH]

**Australian Legislation dealing with liability and genetically modified organisms**

New legislation to regulate dealings with genetically modified organisms (GMOs) in Australia came into force on 21 June 2001, through the *Gene Technology Act*. The new scheme does six key things. It:

1. prohibits dealings with LMOs (eg. import, transport, research, manufacture, production, and propagation) in Australia, unless in accordance with the legislation. For example, all dealings which involve the intentional release of a LMO into the environment must be licensed;
2. establishes a process for assessing the risks to human health and the environment associated with dealings with LMOs, including opportunities for extensive public input;
3. establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation (including the issuing of licences);
4. establishes a scientific advisory committee, an ethics committee and a community consultative committee to provide advice to the Regulator;
5. provides for monitoring and enforcement of the legislation; and
6. creates a centralised, publicly available database of all LMOs and GM products approved in Australia (the Record of GMO and GM product dealings).

In developing the new scheme, a number of options were put forward for addressing the issue of liability. However, it was decided not to treat liability issues in this area any differently than the way they were treated in other related areas (such as contamination caused by pesticide spray drift, or flooding due to the breach of a dam). It was felt that this was preferable to enacting liability laws specific to gene technology.

As such, there are common law actions available for third parties in order to recover losses from damage caused by the transboundary movement of LMOs. In summary, a third party may have an action in negligence, trespass or nuisance. In addition, most Australian States and Territories have environment protection legislation in place which establishes a general duty not to undertake an activity that pollutes or might pollute the environment, or which causes, or is likely to cause, environmental harm. These pieces of legislation specifically allow persons to apply to the relevant court of tribunal for compensation.

However, a small number of mechanisms have been incorporated into the *Gene Technology Act 2000* to ensure compliance with conditions placed on a licence for dealing with a LMOs, and to ensure (where necessary) adequate compensation is available where the legislation is breached:

- Strict liability offences for dealing with a LMO in contravention of the *Gene Technology Act 2000*, or in breach of licence conditions have been included in the legislation. These offences carry a

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maximum penalty of A\$ 22,000 in the case of an individual and A\$ 110,000 in the case of a corporation.

- Offences for dealing with a LMO in contravention of the *Gene Technology Act 2000*, or in breach of licence conditions have also been included, which carry a maximum penalty of A\$ 220,000 and/or 5 years imprisonment for an individual, or A\$ 1.1 million in the case of a corporation.
- Extensive monitoring and investigation powers have been given to inspectors under the legislation, including powers of search and seizure.
- Where the Regulator incurs costs as a result of taking steps in order to avoid imminent risk of death, serious illness, serious injury or serious damage to the environment, the person who created the risk is liable for those costs.
- The Regulator may impose a licence condition on a person dealing with a LMO requiring them to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing.

In addition, Australia's *Quarantine Act 1908* also imposes possible fines and imprisonment terms on the importation of LMOs into Australia without an import permit.

## AUSTRIA

[11 January 2002]

[SUBMISSION: ENGLISH]

### Summary of provisions on liability of the Austrian Law on Genetic Engineering

The EU Directives 90/219/EEC and 90/220/EEC have been implemented by the Austrian Law on Genetic Engineering (in force since 1 January 1995 and amended 22 May 1998). In the amendment the following provisions on liability have been introduced:

- Personal injury and damage to property
- Damage to the environment
- Exclusion of liability
- Facility of evidence
- Access to information
- Insurance coverage
- Restoration of the environment

#### 1. Personal injury and damage to property

The notifier of a contained use or a deliberate release of LMOs is liable for compensation in the case of personal injury or damage to property that are due to the characteristics of the LMO resulting from the genetic modification. The notifier is also liable for damages that are due to the characteristics of the LMO

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resulting from the genetic modification in combination with other hazardous characteristics of the LMO and gives redress.

## 2. Damage to the environment

If the damage to property also constitutes a significant damage to the environment and if the restoration of the environment by the notifier is not advisable or the notifier is not prepared to do so, the person who suffered the damage obtains redress for the costs of the restoration, even if these costs are higher than the value of the property.

## 3. Exclusion of liability

Liability is excluded if the damage is caused (1) by military conflicts, civil wars, natural disasters, etc., (2) by third persons not involved in the contained use or a deliberate release of LMOs and intending to cause damage or (3) in compliance with legal provisions, instructions or coercive measures.

## 4. Facility of evidence

If depending on the case the LMO subject to the contained use or a deliberate release may cause damage, it is presumed that the damage is due to the characteristics of the LMO resulting from the genetic modification. To rebut the presumption the notifier demonstrates the likelihood that the damage is not due to the characteristics of the LMO resulting from the genetic modification (or in combination with other hazardous characteristics of the LMO).

## 5. Access to information

The notifier has to give information to the person who suffered the damage due to the characteristics of the LMO resulting from the genetic modification. In particular, this includes relevant information on the LMO, its characteristics and potential adverse effects. Note that also the person who suffered the damage has to furnish relevant information to the notifier regarding the nature and the extent of the damage.

Special provisions regulate proportionality and confidentiality of information.

## 6. Insurance coverage

The notifier takes adequate measures to settle claims for damages such as the conclusion of an insurance contract. Public liability insurances are required for the contained use in biosafety level 3 (large scale) and biosafety level 4 and for the deliberate release of LMOs.

Insurance sum of public liability insurances:

Biosafety level 3 (large scale) and deliberate release (small-scale): min. €712 194.-

Biosafety level 4 and deliberate release (large-scale): min. €4.069.679.-

## 7. Restoration of the environment

If the contained use or deliberate release of the LMO causes a significant damage to the environment due to the characteristics of the LMO resulting from the genetic modification, the competent authority instructs the notifier to restore the environment with a view to ensuring safety or to take preventive measures

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against further damage to the environment. In case of imminent danger the competent authority takes action (also if the notifier cannot be identified or is not in the position to take action). The notifier bears the cost of these actions.

**BELGIUM**[4 February 2002]  
[SUBMISSION: ENGLISH]

## 1. Introduction

At its second meeting, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP 2, Nairobi 1-10 October 2001) recommended that information gathering on the issue of liability and redress should continue. Parties were requested to submit information to the Executive Secretary on national, regional and international measures and agreements in the field of liability and redress for damage resulting from transboundary movements of living modified organisms (article 27)<sup>1\*</sup> and to express their views on elements of the terms of reference for the open-ended ad hoc group of legal and technical experts.

This paper aims at giving a general overview of existing Belgian and Flemish law and worked out proposals that might be applicable in cases of damage caused by the (transboundary) movements of LMOs. By doing this, the Belgian government would like to stimulate the debate on a process for the elaboration of international rules and procedures in the field of liability and redress, which will be held at ICCPs thirth meeting in The Hague (April 2002).

In Belgium, like most other countries, there is no special law concerning liability and redress for damage caused by GGOs. In the current legislation, there are several provisions implemented in various legal regimes, which could be applied in cases of damage resulting from (transboundary) movements of living modified organisms. To what extent does existing Belgian (liability) law cover environmental damages caused by GMOs?<sup>2‡</sup>

2. Civil liability<sup>3‡</sup>

Damage, which encompasses both “damage to the environment” as well as “damage through the environment”, is primary governed by provisions of civil liability law. Civil liability is based on the Civil Code, which makes a distinction between fault-based (subjective) and strict liability (objective).

## a. Fault based

The basic provisions of Belgian liability law are implemented in the Articles 1382-1383 of the Code Napoleon, which respectively state:

“Any act of man which causes damage to another, obliges the one by whose fault the damage occurred to compensate for this”

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<sup>1\*</sup> Article 27 of the Cartagena Protocol on Biosafety provides that: “The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking into account of the ongoing processes in international law on these matters, and shall endeavour this process within four years”

<sup>2‡</sup> See in general H. BOCKEN, “The Compensation of Ecological Damage in Belgium”, in *Harm to the Environment: The Right of Compensation and Assessment of Damages*, P. WETTERSTEIN (ed.), Oxford, Clarendon Press, 1997, 143-158.

<sup>3‡</sup> See McKENNA & CO, *Study of civil liability systems for remedying environmental damage*. Final report, Brussel, 1996, 391 p. and C. CLARKE, *Update comparative legal study*, 2001, 99p.

“A person is not only liable for the damage which he caused by its deed, but also for the damage which he caused by its negligence or imprudence”

The burden of proof is placed on the plaintiff (*actori incumbit probatio*), and the degree of proof is “judiciary certitude”, which means that the judge must be convinced by a high degree of probability. Hence, the victim must prove: (a) the damage, (b) the existence of a causation between this damage and an act of an omission of the defendant and (c) that the defendant acted faulty or negligently. Belgian law does not provide for a presumption of causation or a reversal of the burden of proof.

The concept of damage is quite broad in Belgian law. In principle, compensation may be granted for death, personal injury, impairment of the victim’s health, damage to moveable and immovable goods and for economic losses resulting from the damage. As a rule, damage has to be actual and has to stand firm. Only persons who are directly and personally affected are granted a right for action. Consequently, there is in principle no *locus standi* for actions related to the unowned environment (the so called “*res nullius*” and “*res communes*”), nor *stand trial* for damage that might occur in the future. There are, however, exceptions to this rule (see below).

With regard to the establishment of the causal link, Belgium applies the theory of the “equivalence of conditions”. An event is to be considered as the cause of the damage if it has contributed to the occurrence of the damage. A is a cause of B if, taking into account the concrete circumstances, B would not have occurred without A. All possible causes are judged on an equal basis. In reality, due to technical difficulties (e.g. it is impossible to identify the source of the pollution, it concerns historic pollution...) the causal link in environmental cases is often an insurmountable obstacle for the victim.

The defendant acted wrongfully, when he transgresses a provision laid down in a law or a regulation or when he did not exercise due care. Breach of even the slightest provision of environmental law constitutes a fault under Article 1382 C.C. If a person breaches an obligation laid down in national law or he did not behave with due diligence, he will be held liable for the damage. Belgian law imposes “joint and several” liability when actions of several operators gave rise to the same inseparable damage.

In order to put the victim in the position as if the damage did not occur, the tortfeasor will be placed under the obligation to restore or replace the damaged or lost asset (“compensation in natura”), whenever it is *de facto* not feasible to pay monetary compensation (“*herstel bij equivalent*”).

b. no-fault liability

From the beginning of the twentieth century the courts and the legislators have developed a number of strict liability rules, which might be applied to cases of (environmental) damage, caused by genetically modified organisms. Because it is often difficult to prove a fault or a negligence of the polluter, courts used Article 544 C.C. to develop the theory of “nuisance due to vicinity”. Article 544 states that ownership is the right to absolute use and enjoyment of goods as long as this use does not breach law or regulations. There is a kind of balance between neighbouring properties that has to be respected. If the landowner unreasonably disturbs the relationship between his property and the neighbouring properties, he must, even when he acted lawfully, compensate the victims and thus restore the balance. Fault is no longer required, the judge examines the conditions prevailing in a certain neighbourhood and decides then if an unreasonable disturbance took place.

In addition to the fault-based civil liability rules, several strict liabilities were introduced in the Belgian law. We only mention those of relevance to the subject of damage resulting from activities regarding GGOs. In all these cases the liability is channelled to a person who has a certain, legally defined bond with the damaging event.

Article 1384, par. 1 C.C. attributes liability to the custodian of a defective item for damage caused by the defect.

Article 1385 C.C. provides that: “The owner of an animal or the one whose making use of its services will be held liable for the damage caused by the animal while it was under custody or while it escaped or got lost”.

Custody implies the factual use and control of the object for one’s own account. Generally, the owner of the object or animal will be the custodian, but custody and property do not necessarily coincide. In the latter case, the custodian does not escape liability by proving he committed no fault. One could argue whether living modified organisms are animals or whether they have to be considered as products of the biotechnology industry.

A defect is an abnormal characteristic of the object, a deviation in the structure, its form, its parts... It varies depending on what one can normally expect from an object of the same type. However, the fact that an object is dangerous by its nature does not make it defective. The defect should be connected to the object itself, though it should not be inseparable from and inherent in it. The fact that the object occupies an abnormal place or undergoes a sudden change (e.g. an explosion, ice...) does not, in itself constitute a defect.

#### 1. Administrative statutes

Certainly worth mentioning are a number of federal laws and regional decrees which impose specifically strict liability rules for certain form of pollution (caused by certain activities). Contrary to civil liability, in order to ensure an effective clean up, administrative liability relies on compelling restoration orders given by public authorities and less on litigation.

- The Toxic Waste Act of 1974 holds the producer liable for damage caused by toxic waste, even when he has handed over the waste to processing operators.
- The Budgetary Law of 1976 requires the government and local authorities to reimburse from the owner of polluting substances, the costs of the intervention of the civil protection services or the fire brigades which have taken clean-up measures after a pollution incidents
- Of great importance is the Flemish Decree on Soil Sanitation of 1995. Liable is the operator of the activity whose ‘emissions’ resulted in “soil contamination that constitutes a serious risk”, provided the pollution isn’t historic (i.e. caused before 29 October 1995). If it concerns an activity, which requires a permit or an authorisation, liability will be channelled to the permit of authorisation holder. If this is not the case, liability is linked to the proprietor of the contaminated site as long as he is not able to prove that another person was exercising actual control on his land.

The defendant may be liable for the following costs:

- assessment of the contamination
- clean-up costs itself
- all possible damage caused by the above activities
- any restriction of use due to contamination

The objective of the clean up is the achievement of the “standard soil quality”, which has been elaborated by the Flemish government.

- Law of 20 January 1999 on the protection of the marine environment in the marine areas under Belgian jurisdiction

One of the objectives of this law is to safeguard the integrity and the biodiversity of the marine environment inter alia through measures to repair damage and environmental disruption “to its original condition as much as possible”. “Damage” is defined as “any damage, loss or prejudice suffered by an identifiable natural or legal person as a result of degradation of the marine environment, whatever its cause”, “environmental disruption (“milieuverstoring”) is “the negative impact on the marine environment, insofar it does not amount to damage”. The law specifically addresses biodiversity damage and damage to coastal habitats. Strictly liable will be the perpetrator, who, as a result of an accident or a breach of legislation, negatively affected the marine areas. The law installs a ban on the intentional introduction of genetically modified organisms and non-endemic species is prohibited. The victim suffering damage has a right to its repair, as does the state in the case of environmental disruption. Further, the liable party is required to reimburse the costs of remedial measures taken by others insofar these costs are not unreasonably high in the light of the results to be achieved for protection of the marine environment.

## CANADA

[31 January 2002]

[SUBMISSION: ENGLISH]

### **I. Introduction**

Canada is a federal state and jurisdiction over the environment is shared between the federal and provincial legislatures, each exercising exclusive jurisdiction over certain listed “heads” of power related to the environment, such as fisheries, criminal law, property and civil rights, etc. Territorial governments, operating under federal legislation, exercise legislative powers over essentially the same subject matters as the provinces. Aboriginal self-government agreements negotiated with aboriginal groups may also result in such groups taking on governmental responsibilities, including over matters related to the environment. Municipalities are the creation of the provincial level of government, which has jurisdiction to regulate or delegate regulation to municipalities over matters such as domestic sewage, water treatment and local land use.

The topic of civil liability is one which falls under provincial jurisdiction over property and civil rights, and includes the establishment of courts where civil claims are brought. Although at the federal level there is a Federal Court of Canada with both a trial and appellate division for particular types of cases, a lawsuit against a private actor for harm to the environment would typically appear in the provincial court system.

### **II. Liability and Redress rules applicable to damage from the transboundary movement of living modified organisms**

Except for the province of Quebec, which is a civil law jurisdiction, Canada has a common law system. This refers to a system of precedent-setting “judge-made law” which can be overruled or modified by provincial and federal legislatures through the enactment of legislation. Subsequent court interpretations of

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legislation also form part of the common law, which is continuously evolving. Under Quebec civil law, general rules are found in the Civil Code of Quebec.

With respect to liability and compensation, there are a number of possible legal actions under the common law that can be invoked to obtain compensation for damage. These include trespass, private nuisance, public nuisance, negligence, and strict liability for harm caused by the conduct of an abnormally dangerous activity conducted on the property of the defendant.

Damages and injunctive relief are available and anyone suffering loss or injury who is owed a duty of care has standing to sue. Unless imposed by statute, there are no ceilings to damage awards. Damages are determined by the courts on a case by case basis, depending on the facts of the case and any relevant case law precedents. Damages can include harm to persons and property and include economic loss. Plaintiffs have to prove their case on the balance of probabilities.

Under Quebec civil law, every person has a duty to abide by the rules of conduct which lie upon him, according to the circumstances, usage or law, so as not to cause injury to another, and therefore the type of fault involved may not have to amount to negligence. Similarly, a custodian of a thing must compensate for the damage caused by it, unless he can demonstrate having committed no wrong or acted reasonably in the circumstances, such as in the case of release of contaminants in the air, water or soil, emissions from an industrial process, and imprudent storage.

These are the remedies that would normally be available to a plaintiff, unless this has been changed or added to pursuant to statute.

### **III.a Statutory provisions—environmental protection statutes generally**

In addition to remedies provided for at common law and in the Civil Code of Quebec, federal and provincial statutes have been utilized in Canada to broaden the range of remedies available to protect the environment.

Canadian jurisdictions (federal, provinces and territories) have general environmental protection legislation which tends to address a wide range of environmental protection concerns, such as air, water, toxics, and hazardous wastes. Such legislation typically has a definition of the environment which is extremely broad.

Such general environmental legislation often contains provisions which provide for the Crown to have the right to recover certain government remediation costs. They may also provide for private civil actions for injunctive relief for persons suffering loss or damage as a result of conduct contrary to the statute.

It should also be noted that many such statutes also provide a civil type of remedy after conviction for an offence against the statute or the regulations made thereunder.

A more unusual provision found in different forms in several jurisdictions is a civil cause of action for a private individual to protect the environment more generally. This action usually has certain statutory conditions attached to it, and in some cases provides for compensation as a possible remedy, while in others it does not.

It should be noted that the foregoing have built upon the common law, improving but not eliminating access to those more traditional remedies. These enhancements to the common law through statute are tied into

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the legislative schemes regulating the environmental concern. To date stand-alone liability regimes have not typically been established for environmental damage.

### **IIIb. Statutory provisions—implementation of the Cartagena Protocol**

Canada signed the Biosafety Protocol in April 2001. In considering how we could implement the Protocol, there are a number of options available, including through amendments to existing legislation and regulations on LMOs. Currently several different departments and agencies are responsible for implementing legislation and regulations, depending on the LMO in question.

As one example, a number of LMOs are governed by the federal *Canadian Environmental Protection Act, 1999 (CEPA)*<sup>1</sup> § and its related regulations. *CEPA 1999* has augmented common law civil liability remedies and provides for civil-type remedies upon conviction for an offence in a number of ways.

#### *Provisions that augment civil liability remedies:*

- Section 22 creates the right to take an environment protection action against a person allegedly committing an offence under the Act where the Minister has failed to investigate the matter appropriately at the request of the person taking the action. Remedies are: declaratory orders; orders and interlocutory orders to refrain from offending the Act; orders and interlocutory orders to do anything that would prevent the continuation of the offence; orders to negotiate a correcting or mitigating plan and any appropriate relief (including costs), except damages.
- Section 39 of the Act provides that any person suffering or about to suffer loss or damage as result of a contravention of the Act or regulations thereunder may seek an injunction against the perpetrator. This is broader than tortious remedies as the grounds are offences to the Act, not simply common law torts.
- Section 40 of the Act creates a civil right of action for a person suffering or about to suffer loss or damage as result of a contravention of the Act or regulations thereunder for an amount equal to the loss or damage and proceedings costs.

#### *Civil-type remedy upon sentencing*

- Under section 291, after convicting an offender for an offence under the Act, the court may make an order:
  - prohibiting the offender from doing anything that continues or repeats the offence or directing the offender to take actions that would remedy or avoid harm to the environment;
  - directing the offender to prepare and implement a pollution prevention plan or environmental emergency plan;
  - directing the offender to carry out environmental effects monitoring or pay for such monitoring;
  - directing the offender to post any bond or pay any amount of money into court that will ensure compliance with any of its orders;

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<sup>1</sup> The Act can be accessed at [www.ec.gc.ca](http://www.ec.gc.ca).

- directing the offender to compensate the Minister of the Environment for the cost of remedial or preventive action taken as a result of the act or omission that constituted the offence;
  - directing that the amount of any fine be allocated on the basis of the harm or risk of harm caused by the commission of the offence;
  - directing the offender to pay an amount for the purposes of conducting research into the ecological use and disposal of the substance in respect of which the offence was committed or research relating to the manner of carrying out environmental effects monitoring;
  - directing the offender to pay, in the manner prescribed by the court, an amount to environmental, health or other groups to assist in their work in the community where the offence was committed;
  - directing the offender to pay an amount to an educational institution for scholarships for students enrolled in environmental studies.
- Under section 292, upon sentencing an offender for an offence under the Act, the court may order the offender to pay to the person aggrieved by the offence an amount by way of satisfaction or compensation for loss or damage to property as a result of the commission of the offence.

#### *Other remedies*

- Under section 311, the Minister may seek an injunction against a person that has done or is about to do or is likely to do any act or thing constituting or directed towards the commission of an offence to the Act ordering the person to refrain from doing so or to do any act or thing that would prevent the commission of the offence.
- Under various provisions of the Act (*eg.* ss. 98, 136, 170, 180, 203, 214, 240), the Crown may recover the costs it has incurred when remedying or mitigating damage resulting from an offence against the Act.

#### **IV. International Law**

In addition to the types of public international law regimes described in the Secretariat's paper for ICCP-2, we would suggest that information would be helpful from the Hague Conference on Private International Law. That body has two initiatives of relevance. First, work is underway on a Preliminary Draft Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters. While not focused on civil judgments related to environmental matters, such judgments would nevertheless fall within the scope of this work. Second, the Hague Conference is examining the question of a possible convention on civil liability resulting from transfrontier environmental damage, and has drafted a substantial paper in this regard, available on its website at [www.hcch.net](http://www.hcch.net). Information on how these initiatives could contribute to the work under the Protocol should be taken into account.

Private international law discussions regarding transboundary environmental damage under the Organization of American States could also be canvassed.

**CZECH REPUBLIC**[30 January 2002]  
[SUBMISSION: ENGLISH]***CURRENT SITUATION IN THE CZECH REPUBLIC***

The Czech Republic was one of the first countries that have ratified the Cartagena protocol on Biosafety. The instrument of ratification was deposited with the Secretary-General of the United Nations on October 8, 2001.

***Legislation***

The “Act No. 153/2000, on the Use of Genetically Modified Organisms and Products and Amendment of Some Related Acts” entered into force on January 1, 2001. The Act together with three implementing Decrees covers the contained use, deliberate release into the environment and placing on the market of GMOs and products containing or consisting of GMOs, including the export and import thereof. The main provisions of the Cartagena Protocol on Biosafety are included in the Act.

An Amendment to the Act on GMOs transposing the provisions of the EU *Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC* and the provisions of the Cartagena Protocol not transposed in the current legislation is under preparation in 2002. It should come into effect at the beginning of 2003.

According to the Act on GMOs all subjects using GMOs are obliged to submit a notification to the Ministry of the Environment before starting any activity concerning GMOs.

***State Administration***

The Ministry of the Environment is the Competent Authority on the use of GMOs and on biosafety issues in the Czech Republic. It co-operates with the Ministry of Health in respect of risks for human health and with the Ministry of Agriculture as the agricultural risks, animal health, crops and feed-stuffs are concerned. The Czech Commission for the Use of GMOs and Products was established as an advisory body to the Ministry of the Environment, to deal with various aspects of the use of GMOs and biosafety. The main Authority on state supervision of the use of GMOs is the Czech Environmental Inspection. It co-operates with other state supervision bodies in fulfilling this task, e.g. with Customs Offices.

***Information System***

The lists of approved GMOs and users are published periodically in the Official Journal of the Ministry of the Environment (in printed form) according to the law. These lists plus the relevant legislation, including the methodology of risk assessment, and the information on the use of GMOs are available to the public at the web-site of the Ministry of the Environment (address: [www.env.cz](http://www.env.cz)). This information is currently updated. The English version of the GMOs web pages is being prepared. The relevant information is also regularly provided to the international organisations, eg. OECD, for their databases and information system.

**DENMARK**

[20 December 2001]  
[SUBMISSION: ENGLISH]

**LIABILITY AND LMO'S**

Liability for damage caused by "LMO-activities" is regulated in Denmark by the Act on Compensation for Damage to the Environment Act No. 225 of 6 April 1994 (re. Annex) which is based on or reflects, explicitly or implicitly, the following main elements<sup>1\*\*</sup>:

1. The Act applies *i.a.* to pollution of air, water, soil and subsoil which means accidental or gradual impairment of the ecological balance, provided it exceeds what has to be tolerated due to the character of neighbourhood.
2. Pollution includes *i.a.* releases of substances (products) not generally present in the surroundings or if so, normally in lesser concentrations.
3. The liability is strict, joint and several, but not retroactive.
4. The liability is unlimited (with the exception of damage caused by activities carried out under compulsory government requirements).
5. A prior permit does not in general grant immunity from liability.
6. Compensationable damage must have been caused by the harmful feature of the activity.
7. Only activities, which are listed in the Annex of the Act, are included under the regime of strict liability. Among the activities listed is "enterprises, which are subject to the obligation to obtain an approval of the manufacturing of genetically modified organisms according to the Act on Environment and Genetechnology."
8. Liability is designated on the operator.
9. The Act upholds a requirement of causality (adequate causality).
10. The principle of full compensation for recognized economic losses proved to have been suffered by interest protected by the law is applicable, *i.e.* the claimant needs to establish that an interest of his protected by the law has been harmed.
11. Compensationable damage includes personal injury, property damage (including loss of use and revenues), other economic losses, and reasonable expenses to mitigate or prevent damage or costs of restoration of the environment. Damage must be assessable in economic terms.
12. Only private organizations recognized as having a "special grant" to the resource at issue, are (could be) admitted to claim, and in such cases only preventional costs.
13. Two limitation periods apply:

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<sup>1\*\*</sup> Based on *Marie-Louise Larsson: The Law of Environmental Damage. Liability and Reparation* (Kluwer Law International, The Hague and Nordstedts Juridik, Stockholm, 1999) p. 323-331.

- a first limit of 5 years from the day of knowledge (or should have had knowledge) of the damage, the tortfeasor, and his location,
- a second limit of an absolute maximum of 30 years counted from the time of the act having caused the damage.

## Annex

### **Act on Compensation for Damage to the Environment<sup>†††</sup>** **Act. No. 225 of 6 April 1994**

#### Part 1

##### *Scope of Act*

§ 1. The Act shall apply to damage caused by pollution of air, water, land or subsoil as part of commercial or public activity mentioned in the attachment to the Act.

*Subpara 2.* The Act shall also apply to disturbances by noise, vibration or the like.

§ 2. Damage according to this Act shall comprise

- 1) bodily injury and death,
- 2) property damage,
- 3) other losses and
- 4) reasonable expenses to prevention of damage or to re-establishment of the environment.

#### Part 2

##### *Liability for Damages*

§ 3. The one who is causing pollution while participating in a commercial or public activity, mentioned in the attachment, shall indemnify the loss resulting from this pollution.

*Subpara 2.* Liability according to subpara 1 shall not apply if the damage is due to the fact that the activity is displayed in accordance with invariable rules laid down by public authority.

§ 4. Compensation for bodily injury or to survivor in case of death may be reduced or cease if the claimant or deceased has wilfully contributed to the injury. Furthermore, compensation can be reduced and in special cases cease if by gross negligence the claimant or the deceased contributed to the injury.

*Subpara 2.* In other cases compensation can be reduced or cease if on purpose or by gross negligence the claimant contributed to the damage.

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<sup>†††</sup> Unofficial translation

Part 3

***Invariability of the Act***

§ 5. Agreements on deviation from the provisions of the Act entered into prior to an event shall be void if the deviation is to the prejudice of the claimant.

*Subpara 2.* The provision of subpara 1 shall not apply to agreements which are entered into between the responsible one and the State, a community or another public institution or with a business man who acts as part of his trade.

***Limitations***

§ 6. Compensation claim in accordance with the Act shall be statute-barred 5 years after the day when the claimant obtained or ought to have obtained knowledge of the damage, the person causing the damage and his place of residence. As regards interruption of and suspension of the Statue of Limitations provisions in § 2, subpara 2 and § 3 in the Act of 22 December 1908 shall apply.

*Subpara 2.* If Statute of Limitation has not occurred in accordance with the provision in subpara 1, the compensation claim shall not cease later than 30 years after the event that caused the damage. As regards interruption of the Statue of Limitation the provision in § 2, subpara 2 of the Act No. 274 of 22 December 1908 shall apply.

***Relation to ordinary rules on compensation***

§ 7. The Act shall no limit the claimant's opportunity for compensation according to the ordinary rules or outside contract or pursuant to provisions laid down in or pursuant to other legislation.

§ 8. The Act shall not apply to damage included in Act No. 332 of 19 June 1974 on Compensation for nuclear damage.

Part 4

***Commencement, etc.***

§ 9. The Act shall come into force on 1 July 1994 and shall apply to damage caused after the commencement date of this Act.

§ 10. The Act shall not extend to the Faroe Islands and Greenland, but may be bought into force for the Faroe Islands and Greenland by Royal Assent with such deviations as might be required in view of the special circumstances in these parts of the country.

## Attachment

Public and Commercial Activity comprised by the Act on Compensation for Damage to the Environment

- A. *Manufacture, processing, surface treatment of iron, steel, metal, wood and plastic.*
- B. *Processing of certain raw material, etc.*
- C. *Winning and treatment of mineral oil, mineral oil products, asphalt and natural gas.*
- D. *Manufacture of chemicals, glue, etc.*
- E. *Processing of vegetable raw materials, manufacture of feeding stuff and printing works.*
- F. *Processing of animal raw material.*
- G. *Generation of power and heat.*
- H. *Motor courses and airfields.*
- I. *Buildings with storage of livestock manure and fish farms.*
- J. *Other specially polluting activity.<sup>2</sup>*
- K. *Waste. Storage, deposit, treatment, destruction, recycling, etc.*

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<sup>2</sup> The enumeration of activities under section J includes i.a. :

« 2. Enterprises which are subject to the obligation to obtain an approval of the manufacturing of genetically modified organisms according to the Act on Environment and Genetechnology ».

## **EQUATORIAL GUINEA**

[11 January 2002]

[SUBMISSION: SPANISH]

### **4.1. Responsabilidad y compensación,**

#### **4.1.a Información sobre medidas y acuerdos nacionales, regionales e internacionales en la esfera de la responsabilidad y compensación por daños resultantes de movimientos transfronterizos de OVM (parr.2, recomendación 2/1)**

La información no puede ser ofrecida ya que a nivel nacional, no se dispone de alguna información sobre la existencia de medidas, acuerdos nacionales, regionales e internacionales, en esfera de responsabilidad y compensación por daños resultantes de movimientos transfronterizos de OVM.

## **EUROPEAN UNION**

[21 January 2002]

[SUBMISSION: ENGLISH]

This information, when available, has been submitted separately by EU Member States and the Commission.

Discussion is also going on within the European Community on the basis of a Commission proposal for a horizontal regulatory framework on Liability and Redress for environmental damages.

## **FIJI**

[19 December 2001]

[SUBMISSION : ENGLISH]

A new Public and Environmental Health Bill, 2001 to be introduced to Parliament in 2002 has provisions on importation or development of new organisms in containment, rapid assessment of the advice effects of GMO, prohibited organisms and regulations, which should protect human health and the environment. In the field of liability and redress for damage resulting from transboundary movements of LMO's, Fiji may need to enact other relevant legislation.

**FINLAND**

[29 January 2002]  
[SUBMISSION : ENGLISH]

**Provisions concerning liability and redress relating to genetically modified organisms and their use****1. Gene Technology Act (377/95)**

The Finnish Gene Technology Act is applied to the use, production, import, sale or other placing on the market of GMOs (or LMOs) and products containing them, as well as to the launch and operation of installations and premises intended for the handling of GMOs (section 2).

The Act contains certain provisions on liability and redress, or “compensation for loss” (section 36), whereby reference is made to other pieces of Finnish legislation:

- a) Compensation for damage to the environment arising as a consequence of operations referred to in this Act is subject to the provisions of the *Act on Compensation for Environmental Damage (737/94)*. (for details, see below)
- b) Compensation for loss caused by a product referred to in the Act to a person or to property intended for private use and consumption is subject to the provisions of the *Product Liability Act (694/90)*.
- c) Compensation for other loss caused by operations referred to in the Act is subject to the provisions of the *Damages Act (412/74)*.
- d) Liability for damages caused by GMO-operations shall be strict liability.

**2. Act on Compensation for Environmental Damage (737/94)****Scope**

According to the Environmental Damages Act, compensation shall be paid for a loss defined as environmental damage which is caused by activities carried out in a certain area and resulting in

- Pollution of water, air and soil
- Noise, vibration, radiation, light, heat or smell
- Other similar nuisance

Although the Act excludes losses for which compensation is provided for in another Act, it applies to environmental damage where compensation is due according to the Product Liability Act. Furthermore, it stipulates that the Damages Act shall also be applied to environmental damage, unless covered by the Environmental Damages Act itself.

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## **COMPENSATION FOR ENVIRONMENTAL DAMAGE**

Compensation shall be paid for “traditional” damage (bodily injury or material loss) in accordance with the provisions of the Damages Act (412/74).

As for environmental damage other than “traditional” damage described above, the Act stipulates that “reasonable compensation shall be paid”. In determining this, consideration should be given to the duration of the nuisance and to the loss itself, as well as to the chances of the person suffering the loss of avoiding or preventing it.

Compensation shall also be paid for the costs of measures needed to prevent environmental damage or to reinstate a damaged environment. The costs of the measures to be compensated should be reasonable in relation to the nuisance or threat thereof, and to the benefit gained by the measures.

However, compensation for environmental damage shall only be paid if a probable causal link between the activities and the loss is shown.

Furthermore, the Act calls for a certain toleration of the nuisance: compensation shall only be paid if toleration of the nuisance is deemed unreasonable. In assessing this, consideration must be given to local circumstances, regularity of the nuisance and other specific circumstances. However, the obligation to tolerate nuisance does not apply to loss inflicted deliberately or criminally, nor to bodily harm or material loss of no minor importance.

## **PERSONS LIABLE FOR COMPENSATION**

Even if the loss was not caused deliberately or through negligence (*i.e. strict liability*), liability for compensation lies with a person, whose activity has caused the environmental damage or who can otherwise be considered as the operator, or to whom the activity was assigned, providing that the assignee knew or should have known about the nuisance or its threat. If there are several actors, persons liable for compensation shall be jointly and severally liable for environmental damage caused by their activities as a whole.

## **SUMMARY: GMOS AND LIABILITY IN FINNISH LEGISLATION**

Section 36 of the Gene Technology Act establishes a very clear link with the Act on the Compensation for Environmental Damage. However, the interpretation and application of the provisions relating to liability and GMOs in these two Acts have never been tested in practice, since no cases or complaints concerning damage caused by GMOs have been brought before a Court of Justice.

**GERMANY**

[4 February 2002]  
[SUBMISSION: ENGLISH]

**Information on national measures and agreements in the field of liability and redress**

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Referring to recommendation 2/1. on liability and redress (Article 27) the German Federal Government provides to the Secretariat the following information on national regulations in the field of liability and redress for damage resulting from living modified organisms which are laid down in the German Genetic Engineering Act:

Entered into effect in January 1990, the German Genetic Engineering Act also incorporates provisions regulating liability (sections 32 to 37, see below excerpt from an unofficial translation).

Unlike German liability law in general, provisions regulating liability in the German Genetic Engineering Act foresee strict liability - i.e. liability does not depend on whether the party which is responsible for the genetic engineering operation is at fault or not, but instead focuses on the sheer risk posed by genetically modified organisms (so-called absolute or no-fault liability, see below, section 32 para 1).

In cases involving absolute liability, German law usually provides for caps to make up for this stricter form of liability and take into account the liable party's interest in economic predictability and insurability. Genetic engineering law, too, features such a cap that is currently set at 160 million deutsche marks (see section 33 below).

Moreover, the Federal Government can, by means of statutory ordinances, oblige the parties responsible for genetic engineering operations at containment levels 2 and 3 to provide for coverage against possible damage (in general by taking out a relevant insurance, see section 36 below). However, in the case of genetic engineering such an ordinance has not been issued as yet. Since, in practice, insurance companies have voiced some objections, it is planned to amend this provision to render it more concrete.

The German Federal Government has no information on damages to human beings or the environment which would be traced back to genetic engineering or genetically engineered organisms. Neither are there cases of liability caused by genetic engineering or genetically engineered organisms known to the German Federal Government.

### **Excerpt from the Genetic Engineering Law:**

#### *Section 32*

#### *Liability*

(1) Where any properties of an organism that result from genetic engineering operations cause the death of a person or injury to his/her health, or damage of property, the operator shall be obliged to give compensation for the damage ensuing therefrom.

(2) Where several operators are liable to compensate for the same damage, they shall be jointly and severally liable. With regard to the relationship of the liable parties to each other, the obligation to pay compensation and the extent of the compensation to be paid shall, unless otherwise provided for, depend on the extent to which the damage has been predominantly caused by one or the other party; for the rest, Sections 421 to 425 and 426 para (1) sentence 2 and para (2) of the Civil Code shall apply.

(3) Where negligence on the part of the injured party has helped to cause the injury, Section 254 of the Civil Code shall apply; in the event of property damage, the negligence of the party that has the actual control of the property involved shall be equivalent to the negligence of the injured party. The

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liability of the operator shall not be reduced if the damage was at the same time caused by the acts of a third party; para (2) sentence 2 shall apply accordingly.

(4) In case of death, compensation shall be made by reimbursing the costs of an attempted cure as well as the costs incurred by the pecuniary prejudice sustained by the deceased party as a result the suspension or reduction of his earning capacity or the resultant increase in his needs during his disease. The party liable for damages shall furthermore reimburse the funeral costs to the party who is responsible for defraying these expenses. If, at the time of injury, the deceased party maintained a relationship with a third party by virtue of which he was or could come under the legal obligation to support this third party and if the third party was deprived of the right to maintenance as a result of the death, the party liable for damages shall indemnify the third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of lifespan he would probably have had. Liability for damages shall also be enforced if, at the time of injury, the third party had been conceived but not yet born.

(5) In the case of injury to a person's body or health, compensation shall be given by reimbursing the costs of the treatment as well as the costs incurred by the pecuniary prejudice sustained by the injured party as a result of the temporary or permanent suspension or reduction of his earning capacity or the resultant increase in his needs.

(6) Compensation on account of the suspension or reduction of earning capacity and on account of increased need on the part of the injured party, as well as the compensation to be afforded a third party in accordance with para (4) sentences 3 and 4, shall be paid in the future by means of an annuity. The provisions of Section 843 paras (2) to (4) of the Civil Code shall apply mutatis mutandis.

(7) Where a material damage also implies a deterioration of nature or landscape, Section 251 para (2) of the Civil Code shall be applied, insofar as the injured party restores anything that would obtain if the deterioration had not occurred, subject to the proviso that the expenditure needed to restore the status quo ante are not incommensurate solely because of the fact that they considerably exceed the value of the object. The party causing the injury shall make an advance to cover the expenditure necessary, if the party entitled to damages so requires.

(8) As regards the limitation period, the provisions of the Civil Code governing torts shall apply accordingly.

### *Section 33*

#### *Maximum amount of liability*

Where a damage has been caused due to such properties of an organism as result from genetic engineering operations, the operator shall, in the case of Section 32, be liable to compensate the injured parties up to a maximum amount of one hundred and sixty million deutsch marks. Where the several amounts to be paid as compensation for one damage exceed the maximum amount specified in sentence 1, then the individual compensation shall be reduced pro-rata to the maximum total given.

### *Section 34*

#### *Presumed cause of damage*

(1) Where the damage was caused by genetically modified organisms, it shall be presumed to have been caused by such properties of these organisms as result from genetic engineering operations.

(2) This presumption shall be invalid if the damage is likely to have been caused by other properties of these organisms.

### *Section 35*

#### *The injured party's rights to be informed*

(1) Where the facts give reasonable grounds to presume that any personal injury or damage to property is due to genetic engineering operations performed by the operator, the latter shall be obliged to provide, at the injured party's request, information about the type of and steps involved in the genetic engineering operations performed in the genetic engineering installation or underlying a release, to the extent that this is necessary to establish whether there is basis for a claim under Section 32. Sections 259 to 261 of the Civil Code shall apply accordingly.

(2) Where the conditions of para (1) sentence 1 are fulfilled, the right to information shall also apply in relation to the authorities responsible for notifications, the granting of authorizations or supervision.

(3) The rights pursuant to paras (1) and (2) shall not apply if the legal provisions require these operations to be kept secret or secrecy is necessary due to an overriding interest of the operator or a third party.

### *Section 36*

#### *Coverage provision*

(1) The Federal Government shall establish by means of an ordinance adopted with the consent of the Bundesrat that anyone who operates a genetic engineering installation where genetic engineering operations at safety levels 2 to 4 are to be performed, or carries out releases, shall be obliged to provide for coverage for any damage or injury that may be caused by such properties of an organism as result from genetic engineering operations (provision for coverage). The regulation shall incorporate detailed provisions specifying the scope and amount of the provision for coverage as well as the agencies responsible for supervising the latter and their procedures and powers in supervising the provision for coverage.

(2) Provision for coverage may be made available, in particular, by means of

1. a third party insurance taken out with an insurance company authorized to conduct business within the area in which this Act applies or
2. an exemption or warranty obligation issued by the Federal Government or the government of a Land.

The ordinance under para (1) may also allow for other types of coverage to be authorized, particularly indemnity obligations or warranty obligations issued by credit institutions, insofar as they offer securities comparable to a provision for coverage under sentence 1.

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- (3) The following shall be exempt from the obligation to provide for coverage:
1. the Federal Republic of Germany,
  2. the Federal Laender
  3. legal entities under public law.

*Section 37*

*Liability under other legal provisions*

- (1) Where, as a result of the administration of a drug intended for human use which was distributed to the consumer within the area in which the German Drug Law applies and which is subject to compulsory marketing authorization or is exempted by ordinance from marketing authorization, a person is killed or the body or the health of a person is substantially injured, Sections 32 to 36 shall not apply.
- (2) The same shall apply where products containing or consisting of genetically modified organisms are placed on the market by virtue of an authorization under Section 16 para (2) or a licence or authorization under the legal provisions within the meaning of Section 2 No. 4 second part of the sentence. In this case, Section 1 para (2) No. 5 and Section 2 sentence 2 of the Product Liability Act shall not apply to the liability of the manufacturer who has been granted the marketing authorization or licence, if the product defect is due to genetic engineering operations.
- (3) Any liability based on other provisions shall not be affected.

**NORWAY**

[16 January 2002]  
[SUBMISSION: ENGLISH]

**National legislation within the field of liability and redress for damage resulting from genetically modified organisms**

**The Act relating to the Production and Use of Genetically Modified Organisms (the Gene Technology Act of 1993)** contains specific liability and redress rules. The Act applies to genetically modified living organisms, including substances and products that consist of or contain such organisms (GMOs). The Act states in Section 21 “Duty to prevent and limit damage” that when genetically modified organisms have entered the environment in conflict with the Act or decision pursuant thereto, the person responsible for the activity shall take reasonable measures to prevent or limit damage and inconvenience. The same applies if GMOs have been deliberately released into the environment in accordance with decisions pursuant to the Act, after which the use is shown to involve a greater risk to health or the environment than foreseen when the use was approved. Redress measures include compensation and restoration. The supervisory authority may order the person responsible to retrieve or take other measures

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to combat the organisms within a specified time, including measures to restore the environment to its previous state as far as possible. The implementation of measures pursuant to this provision may also take place on another person's property. According to the preparatory legislative work (Proposition No 8 to the Odelsting 1992-93 concerning the production and use of GMOs) the extent of the restoration will depend on the changes that have occurred in the environment, and will have to be assessed in each particular case. Restoration may be carried out by replanting of cultivated or wild plants, by release of fish or by building up a stock of wild animals. In a number of cases complete restoration will not be possible, or not within foreseeable future. Therefore the words "as far as possible" were included.

Section 23 of the same Act provides for strict liability in that the person responsible for an activity pursuant to the Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of GMOs into the environment. The duty to implement measures lies with "the person responsible for the activity", who is defined as the person who produces or uses the GMO within the meaning of the Act. "The person responsible" is a physical or legal person who operates the activity from which the GMOs are discharged. In general the person with the duty to provide information or to obtain approval under the Act may be subject to orders under the Act. It is also possible that there may be several persons responsible depending on the nature of the measures to be taken. For example, a transporter would be responsible for taking immediate measures if GMOs escape by accident during transport. However, it is normally the owner or the sender who has to pay for measures.

As regards redress measures, it follows from Section 23 of the Act that the provisions of Chapter 8 of the Pollution Control Act concerning compensation, apply insofar as they are appropriate. .

These provisions of the Pollution Control Act include:

- a) compensation for financial losses resulting from pollution damage
- b) compensation for damage, losses, nuisance or expenses incurred as a result of taking reasonable measures to prevent, limit, remove or mitigate pollution damage
- c) compensation for damage, loss or nuisance resulting from the fact that the pollution prevents or impedes the exercising of rights of common for commercial purposes
- d) compensation for pollution that hinders, impedes or limits the benefit of exercising rights of common for non-commercial purposes
- e) compensation for loss suffered by an employee because the pollution results in work stoppages etc.

Damage to biological diversity is not as such mentioned in the Pollution Control Act but may be addressed under the notion of damage which causes financial losses or prevents or impedes fights of common. According to the preparatory legislative work the term "damage" under the Gene Technology Act is also intended to apply to changes in the ecological environment that occur, for example, when a new organism supplants an indigenous species. The provisions of Section 23 in the Gene Technology Act will obviously have the greatest practical application in relation to illegal discharges or releases. The provisions of the Act which relate to requirements for approval, impact assessment etc. are all intended to prevent any damage to health or the environment from GMOs. However, even a lawful activity may have unforeseen consequences, and the compensation provisions cover such cases as well.

It should be noted that a claim for compensation may, irrespective of whether the claim is put forward by the pollution control authority, also be made by a private organisation or an association with a legal interest

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in the matter. If a private organisation or an association puts forward a claim for compensation, the compensation awarded shall nevertheless accrue to the pollution control authority. The pollution control authority will make further decisions on how the compensation awarded is to be used.

For further information see the enclosed Norwegian Gene Technology Act and Proposition No 8 to the Odelsting (1992-93).

## **The Act relating to the production and use of genetically modified organisms**

### **(Gene Technology Act)**

Act No. 38 of 2 April 1993

## **Chapter 1**

### **General provisions**

#### **SECTION 1 PURPOSE OF THE ACT**

The purpose of this Act is to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment.

#### **SECTION 2 TECHNICAL AREA OF APPLICATION OF THE ACT**

The Act applies to the production and use of genetically modified organisms. The provisions of the Act relating to genetically modified organisms also apply to substances and products that consist of or contain modified organisms.

Unless the genetically modified organisms are used as parent organisms, the Act does not apply to the production with the aid of cell technology of

- a) genetically modified plant cells when the same result can be obtained by means of traditional methods of cultivation, or
- b) animal cells in culture where the cell material has been obtained from different individuals of the same species and where the cells could have been produced by natural reproduction, and the use of such plant or animal cells.

#### **SECTION 3 THE TERRITORIAL AREA OF APPLICATION OF THE ACT**

The Act applies in the realm, including Svalbard and Jan Mayen. The Act also applies to the Norwegian dependencies in Antarctica, within Norway's economic zone and on the Norwegian part of the Continental Shelf.

#### **SECTION 3A DUTY TO REPORT WHEN ESTABLISHING GENE TECHNOLOGY ACTIVITY ABROAD**

The king may issue regulations imposing duty to report for norwegian persons or companies who establish gene technology activity abroad. Gene technology activity means activity as listed in para. 2 in this act.

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## **SECTION 4 DEFINITIONS**

In this Act the following terms mean:

- a) microorganisms: any cellular or non-cellular microbiological entity that is able to reproduce or transfer genetic material
- b) genetically modified organisms: microorganisms, plants and animals in which the genetic material has been altered by means of gene or cell technology
- c) gene technology: techniques that involve the isolation, characterization, modification and introduction into living cells or viruses of DNA
- d) cell technology: techniques for the production of living cells with new combinations of genetic material by the fusion of two or more cells.

## **Chapter 2**

### **Contained use**

## **SECTION 5 DEFINITION**

The term "contained use" means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other.

## **SECTION 6 SAFETY PRECAUTIONS IN CONTAINED USE**

Contained use shall take place in laboratories and installations that are approved pursuant to the second paragraph, and in accordance with good microbiological practice. The user shall ensure that the necessary safety precautions are taken to prevent adverse effects on health and the environment, including measures to limit the detrimental effects of the unintentional release of genetically modified organisms. Records shall be kept of all contained use of genetically modified organisms. Laboratories and other installations for contained use shall be approved by the King. The King may issue regulations concerning safety precautions for contained use and specifying the material details of the duty to keep records.

*The King may issue regulations granting exemptions from the provisions in this section for specified forms of teaching activities.*

## **SECTION 7 DUTY TO REPORT OR TO OBTAIN APPROVAL**

The contained use of genetically modified organisms shall be reported or approved in accordance with regulations issued by the King. The regulations may provide for exemptions to be granted for specified forms of teaching activities.

Irrespective of the regulations issued pursuant to the first paragraph, approval is required for the following forms of contained use:

- a) genetic modification of vertebrates resulting in hereditary genetic alterations, except for experiments that are approved pursuant to section 21, first paragraph, of the Prevention of Cruelty to Animals Act

- b) transfer of human genetic material to animals, plants or microorganisms which is not carried out in connection with research or experiments for the purpose of identifying the structure, characteristics and functions of DNA
- c) production and use of genetically modified organisms for placing on the market or other commercial use.

The King may issue regulations prescribing that the production mentioned in litra c shall instead be subject to the duty to report in the case of specified types or amounts of genetically modified organisms.

The provisions concerning the duty to report and the requirement for approval in accordance with this section do not apply to the production and use of hybrid animal cells for the production of monoclonal antibodies or for the isolation of chromosomes and chromosome fragments.

## **SECTION 8 IMPACT ASSESSMENT FOR CONTAINED USE**

The King may decide that a person or company applying for approval for contained use shall submit an impact assessment setting out the consequences of the unintentional release of genetically modified organisms. Section 11, second sentence of the first paragraph, and second paragraph, apply correspondingly.

### *Chapter 3*

#### **Deliberate release**

## **SECTION 9 DEFINITION**

The term "deliberate release" means any production end use of genetically modified organisms that is not considered to be contained use pursuant to section 5.

The following are among the activities that are considered to be deliberate release under the Act:

- a) deliberate release of genetically modified organisms for research purposes (field experiments)
- b) deliberate release of genetically modified organisms for commercial purposes, for remedial purposes and the like
- c) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation and the like, unless the facility in question is approved for contained use as part of an approved laboratory or other installation
- d) routine release of genetically modified organisms from contained use
- e) disposal of waste containing living genetically modified organisms
- f) placing on the market of a product consisting of or containing genetically modified organisms
- g) import of genetically modified organisms
- h) transport of genetically modified organisms.
- i) export of genetically modified organisms

## **SECTION 10 APPROVAL**

Deliberate release of genetically modified organisms may only occur subject to approval by the King.

Deliberate release pursuant to section 9 litrae a, b, c and f shall as a rule only be carried out step by step. A product may not be approved for placing on the market until it has been satisfactorily tested in natural

environments that will be affected by the intended use. Approval is not required for other deliberate release of a product that is approved for placing on the market pursuant to this provision.

Deliberate release of genetically modified organisms may only be approved when there is no risk of detrimental effects on health or the environment. In deciding whether or not to grant the application, significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

The King may issue regulations providing that deliberate release pursuant to section 9, litrae g and h, may take place without prior approval if certain specified conditions, including requirements for special packaging and marking of the products, have been fulfilled. The duty to report may be imposed instead.

The King may issue regulations providing that specified types of genetically modified organisms may be released in certain specified environments without approval pursuant to the first sentence of the first paragraph. Such release shall be subject to the duty to report instead.

Approval is not required for the placing on the market of a product that is approved for placing on the market in another EEA country pursuant to the rules laid down in Annex XX, Entry 25, of the EEA Agreement (Council Directive 90/220/EEC). The authorities responsible under the present Act, however, may still prohibit or limit such placing on the market if in their opinion it involves a risk to health or the environment or if the placing on the market is otherwise in conflict with the purpose of this Act.

## **SECTION 11 IMPACT ASSESSMENT**

Applications for approval of deliberate release pursuant to section 10 shall contain an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release. The King may issue regulations concerning inter alia the content of the assessment, and exemptions from the duty to submit an assessment.

The King may also require further information and investigations in addition to the impact assessment before a decision is made on the application.

### **Chapter 4 Implementation of the Act. Enforcement provisions**

## **SECTION 12 RELATION TO THE FREEDOM OF INFORMATION ACT**

The Freedom of Information Act applies to cases that are dealt with under the present Act. The following information shall, however, always be public, regardless of the duty of secrecy, unless it comes under section 6, subsection 1, of the Freedom of Information Act:

- a) the description of the genetically modified organism, the user's name and address, the purpose of the use and the location of use
- b) methods and plans for monitoring and emergency response
- c) assessments of the foreseeable consequences.

### **SECTION 13 PUBLIC CONSULTATION**

In cases where approval is required under the present Act, the competent authority may decide that a public consultation is to be carried out. Such consultation shall take place in good time before the decision on the case is made, The decision to carry out a public consultation shall be publicly announced.

### **SECTION 14 MARKING REQUIREMENT**

The King may issue regulations concerning the marking of products that consist of or contain genetically modified organisms.

### **SECTION 15 CONDITIONS OF APPROVAL**

Approval granted pursuant to section 6, second paragraph, section 7 or section 10 may be conditional. Conditions that may be stipulated are inter alia, the choice of the best technical procedure and other means of production from the point of view of health and the environment, a duty to take out insurance or provide security for liability pursuant to sections 21 and measures for preventing and limiting possible detrimental effects. The approval may be granted for a limited time.

### **SECTION 16 ALTERATION AND REVOCATION OF APPROVAL**

The conditions of approval may be altered by the King, and if necessary the approval may be revoked if:

- a) it turns out that the use concerned involves a greater risk to health and the environment than predicted when the use was approved, or
- b) new technology makes it possible to reduce the risk of detrimental effects on health or the environment, or
- c) such revocation follows from other existing rules relating to revocation.

### **SECTION 17 SUPERVISION**

The King decides who shall exercise supervision over the implementation of this Act and any decisions made pursuant thereto.

The King may issue regulations imposing (internkontroll og internkontrollsystemer) to ensure that duties established in this act is complied with.

### **SECTION 18 RIGHT OF INSPECTION**

The supervisory authority may inspect any place where the production and use of genetically modified organisms is being carried out. The supervisory authority may require to be shown documents and other material that may be pertinent to the performance of its function under the Act.

### **SECTION 19 DUTY TO PROVIDE INFORMATION**

Any person who produces and uses genetically modified organisms is obliged, at the request of the supervisory authority and regardless of the duty of secrecy, to provide the information necessary for the carrying out of the tasks of the supervisory authority under the Act. Information may also be required from other public authorities regardless of any existing duty of secrecy.

The supervisory authority shall be notified immediately in the event of accident or other unforeseen circumstances occurring in connection with the production and use of genetically modified organisms.

## **SECTION 20 ORDER TO CEASE ACTIVITY**

The supervisory authority may give orders for the immediate cessation of any activity that is in conflict with the Act or any decisions made pursuant thereto. The same applies if the production and use of genetically modified organisms in accordance with the Act or decisions made pursuant thereto are shown to involve the risk of detrimental effects on health or the environment. If necessary the order to cease activity may be implemented with the aid of the police.

## **SECTION 21 DUTY TO PREVENT AND LIMIT DAMAGE**

When genetically modified organisms have entered the environment in conflict with the Act or decisions pursuant thereto, the person responsible for the activity shall take reasonable measures to prevent or limit damage and inconvenience. The same applies if the genetically modified organisms have been deliberately released into the environment in accordance with decisions pursuant to the Act, after which the use is shown to involve a greater risk to health or the environment than foreseen when the use was approved. The supervisory authority may order the person responsible to retrieve or take other measures to combat the organisms within a specified time, including measures to restore the environment to its previous state as far as possible. The implementation of measures pursuant to this provision may also take place on another person's property.

If the orders given pursuant to the first paragraph are not carried out within the specified time, the supervisory authority may have the measures implemented at the expense of the person responsible. The same applies if the giving of the order pursuant to the first paragraph may mean that the implementation of the required measures is delayed. The expenses incurred by the supervisory authority are enforceable grounds for attachment of property.

## **SECTION 22 FEES**

The King may issue regulations concerning fees for the treatment of applications for approval pursuant to this Act or appurtenant regulations, and concerning supervisory measures implemented to ensure that the Act or decisions pursuant thereto are being complied with. Fees are enforceable grounds for attachment of property.

## **SECTION 23 COMPENSATION**

The person responsible for an activity pursuant to the present Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of genetically modified organisms into the environment.

Moreover the provisions of Chapter 8 of the Pollution Control Act concerning compensation for pollution damage apply insofar as they are appropriate. The supervisory authorities pursuant to the present Act take the place of the pollution authorities in section 58 of the Pollution Control Act. The person authorized to grant approval pursuant to the present Act takes the place of the pollution authority in section 63, second and third paragraphs, of the Pollution Control.

## **SECTION 24 COERCIVE FINE**

In the event of contravention of conditions, orders or prohibitions issued pursuant to this Act, the King may impose a coercive fine that accrues as long as the contravention is taking place. The coercive fine constitutes enforceable grounds for attachment of property.

## **SECTION 25 PENALTIES**

Any person who intentionally or negligently contravenes the provisions prescribed in or pursuant to this Act or decisions taken pursuant to these provisions shall be liable to fines or imprisonment for a term not exceeding one year.

In the event of especially aggravating circumstances, imprisonment for a term not exceeding four years may be imposed.

Attempts and complicity are a criminal offence. Contravention of the first paragraph is considered a misdemeanour.

## **Chapter 5**

### **The Norwegian Biotechnology Advisory Board**

## **SECTION 26 THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD**

The King shall appoint a board that shall express its views on matters covered by this Act and on other questions concerning biotechnology, on request or ex officio. The board's opinions are public unless otherwise required by the statutory duty of secrecy. Section 12 of this Act applies correspondingly to the board's opinions.

## **Chapter 6**

### *Concluding provisions*

## **SECTION 27 ENTRY INTO FORCE**

This Act enters into force on the date decided by the King. It may be decided that certain parts of the Act may enter into force at different times.

## **SECTION 28 TRANSITIONAL PROVISIONS**

For activities to which the present Act applies, which are already in progress when the Act enters into force, a report or application for approval pursuant to sections 6, 7 or 10 shall be submitted within a time limit determined by the King. Provided that the report or application has been submitted within this time limit, the activity may continue until the authorities have dealt with the report or the application according to the provisions prescribed in or pursuant to the Act.

## **SECTION 29 AMENDMENTS IN OTHER ACTS**

From the date decided by the King, the following amendments in other Acts will enter into force:

### **I**

Act No. 10 of 22 May 1902, the General Civil Penal Code, shall be amended as follows:

Section 153 a, first paragraph, shall read:

Imprisonment for a period term not exceeding 10 years may be imposed upon any person who manufactures, produces, stores or in other way obtains or keeps:

/...

1. bacteriological or other biological substances, genetically modified organisms, or toxins, irrespective of their origin or method of production, of such a type or in such quantities that they cannot legitimately be used for preventive, protective or other peaceful purposes; or
2. weapons, equipment or means of transport that are made for using substances, organisms or toxins as mentioned in subsection 1 for hostile purposes or in armed conflict.

## II

Act No. 73 of 20 December 1974 relating to the protection of animals shall be amended as follows:

The title of section 5 shall read: Breeding, supervision and care.

Section 5, new first paragraph, shall read:

It is prohibited to alter the genetic material of an animal with the aid of gene technology methods or by traditional breeding methods if

1. this makes the animal unable to carry out normal behaviour or affects physiological functions in an undesirable way
2. the animal is made to undergo unnecessary suffering
3. the alterations provoke general ethical reactions.

The present first paragraph becomes the new second paragraph.

Section 21, first paragraph, shall read:

No one may carry out biological experiments with animals without special permission. Permission may be granted if the purpose is to find out what kind of disease animals or humans are suffering from or if the purpose is to prevent or eliminate disease. Permission may also be given when the purpose is related to research, manufacture or testing of drugs, medications, preparations, toxins or the like for the use of humans, animals or plants.

## III

Act No. 79 of 11 June 1976 relating to product control shall be amended as follows:

Section 1 shall read:

Section 1. The scope of the Act

This Act is intended to prevent products from bringing about injuries to health or disturbances of the environment in the form of disturbances in ecosystems, pollution, waste or noise or the like.

Section 2, first paragraph, shall read:

This Act applies to the manufacture, including testing, import, placing on the market, use and other treatment of the product.

## IV

Act no. 4 of 4 February 1977 relating to worker protection and working environment shall be amended as follows:

/...

Section 7. subsection 3 b, shall read:

c) the undertaking shall obtain permission for the carrying out of hazardous work, including work with biological factors in the working environment.

Section 8, subsection 1d, shall read:

d) that pollution in the form of dust, smoke, gas, vapours, unpleasant odours, effects of biological factors and radiation is avoided unless it is known that the pollution cannot lead to undesirable effects upon employees.

In sections 11 and 18, the words "hazardous substances" and "hazardous substance" shall be amended to "hazardous substances, including toxic or hazardous biological material" and "hazardous substance, including toxic or hazardous biological material", respectively.

## V

Act No. 5 of 6 March 1981, relating to protection against pollution and relating to waste (the Pollution Control Act) shall be amended as follows:

Section 3, first paragraph, shall read:

The Act applies to pollution and waste in the external environment. As regards the deliberate release of genetically modified microorganisms and the disposal of same as waste in the environment, the Gene Technology Act applies

## VI

Act No. 66 of 19 November 1982 relating to the municipal health service shall be amended as follows:

Section 1-4, third paragraph, fourth item, shall read:

If the health service becomes aware of matters relating to the Working Environment Act, the Product Control Act, the Pollution Control Act or the Gene Technology Act, the health service shall inform the authorities concerned so that they may make a decision.

## ROMANIA

[14 January 2002]  
[SUBMISSION: ENGLISH]

- In Romania entered into force Governmental Ordinance no. 49/2000 regarding *The obtaining, testing, using, and commercialization of genetically modified organisms resulted by modern biotechnology, as well as the thereof products.*
- Between 13-15 September 2001 Romania organized a training workshop: "Handling requests for releases of GMOs into the environment"

**SLOVENIA**

[18 January 2002]

[SUBMISSION: ENGLISH]

**4.1. LIABILITY AND REDRESS (para 2, recomm.2/1))**

The first element of Art.27 of the Protocol impose the obligation on the COP/MOP to adopt the process for the appropriate elaboration of international rules and procedures in the field of liability and redress, and the preparation of this issue is part of mandate of the ICCP.

The second major element of Art.27 requires the future process on liability and redress to analyze and take due account of the ongoing process in international law on these matter.

The final element of Art.27 sets out a time-frame in which the process established shall endeavor to complete its work.

Regarding the ICCP recommendations that the Secretariat continues to gather and disseminate information on national, regional and international measures and agreements in the field of liability and redress, as well, to establish of an open-ended ad hoc group of legal and technical experts to carry out the process under Art.27, indicate some relation to the final form of the product of this entire process. Therewith the nature and final content of any future liability and redress regime shall be matter to be decided and resolved by the COP/MOP.

**SWITZERLAND**

[31 January 2002]

[SUBMISSION: ENGLISH/FRENCH]

**4.1 Liability and compensation**

Liability is one of the new issues currently addressed by the Swiss Parliament within the legislative project called "Genlex". Genlex has been initiated in 1996 by the Swiss Parliament to complement the existing provisions of the Federal Law relating to the Protection of the Environment (LPE) dealing with genetically modified organisms. In the Government proposal of March 2000 (available on Internet in French at <http://www.admin.ch/ch/f/ff/2000/2327.pdf>), the issue of liability is addressed in Article 59 al. 1bis, 2bis and 2 ter). During the course of 2001, the first Chamber of the Parliament, the State Council, has handled the Genlex project. One of its first decision was to establish a new Gene Technology Act that will integrate existing provisions of the LPE as well as the elements of Genlex. Chapter 5 of the draft Gene Technology Act specifically addresses liability. The Government proposal was modified by the State Council. The draft provisions, as adopted in first lecture, are publicly available in French in the minutes of the Parliament at: [http://www.parlament.ch/ab/frameset/d/s/4609/36513/d\\_s\\_4609\\_36513\\_36520.htm?DisplayTextOid=36522](http://www.parlament.ch/ab/frameset/d/s/4609/36513/d_s_4609_36513_36520.htm?DisplayTextOid=36522) (Art. 27 par 1,2 and 2bis) and [http://www.parlament.ch/ab/frameset/d/s/4608/32153/d\\_s\\_4608\\_32153\\_32157.htm?DisplayTextOid=32158](http://www.parlament.ch/ab/frameset/d/s/4608/32153/d_s_4608_32153_32157.htm?DisplayTextOid=32158) (Art. 27 par 3-6,art 28, art 29, art 30).

The draft Gene Technology Act will now be discussed by the second chamber of the Parliament, the National Council, during the course of 2002. Hence, the proposed liability regime is still subject to possible modifications.

The unofficial French text and English translation are enclosed to the present note as information documents (annex 1) to illustrate the status of the ongoing discussion on liability in Switzerland.

**Annex 1****Projet de loi fédérale sur le génie génétique**

La responsabilité est un des nouveaux éléments du projet Genlex actuellement traité par le Parlement fédéral. Genlex a été lancé en 1996 par le Parlement afin de compléter les dispositions existantes de la loi fédérale sur la protection de l'environnement (LPE) traitant des organismes génétiquement modifiés. Dans le projet du Conseil fédéral de mars 2000 (<http://www.admin.ch/ch/f/ff/2000/2327.pdf>), la responsabilité est traitée à l'article 59 al. 1bis, 2bis and 2 ter. Durant l'année 2001, la première chambre du Parlement, le Conseil des Etats a débattu le projet Genlex. Une de ses premières décisions a été de créer une nouvelle loi sur le génie génétique qui englobe les dispositions existantes de la LPE et les nouvelles propositions de Genlex. Le chapitre 5 de ce projet de loi sur le génie génétique traite spécifiquement de la responsabilité. La proposition du Conseil fédéral a été modifiée par le Conseil des Etats. Le texte officiel des dispositions adoptées en première lecture est disponible dans le bulletin du Parlement à l'adresse: [http://www.parlament.ch/ab/frameset/d/s/4609/36513/d\\_s\\_4609\\_36513\\_36520.htm?DisplayTextOid=36522](http://www.parlament.ch/ab/frameset/d/s/4609/36513/d_s_4609_36513_36520.htm?DisplayTextOid=36522) (Art. 27 par 1,2 et 2bis) et [http://www.parlament.ch/ab/frameset/d/s/4608/32153/d\\_s\\_4608\\_32153\\_32157.htm?DisplayTextOid=32158](http://www.parlament.ch/ab/frameset/d/s/4608/32153/d_s_4608_32153_32157.htm?DisplayTextOid=32158) (Art. 27 par 3-6,art 28, art 29, art 30).

/...

Le projet de loi sur le génie génétique va être débattu durant l'année 2002 par la 2<sup>me</sup> chambre du Parlement, le Conseil National. Les propositions concernant le régime de responsabilité sont ainsi susceptibles d'être modifiées.

Le texte ci-dessous est fourni en tant que version non-officielle afin d'illustrer l'état de la discussion en cours sur la question de la responsabilité liée à l'utilisation des OGM en Suisse.

## **Projet de Dispositions concernant la responsabilité selon la proposition du Conseil des Etats du 14.06 et du 26.09.2001 (Version non-officielle)**

### **Chapitre 1 Dispositions générales**

#### **Art. 5 Définitions**

##### *Al.6*

Par installation, on entend tout bâtiment, toute voie de communication ou toute autre installation fixe, ainsi que toute modification de terrain. Sont assimilés aux installations les outils, machines, véhicules, bateaux et aéronefs.

### **Chapitre 5: Responsabilité**

#### **Art. 27 Principes**

##### *Al.1*

Le détenteur d'entreprises ou d'installations qui utilisent des organismes génétiquement modifiés répond de tout dommage causé par cette utilisation et dû à la modification du matériel génétique de ces organismes.

##### *Al.2*

Le dommage causé doit être dû:

- a. aux nouvelles propriétés des organismes; ou
- b. à la reproduction ou à la modification des organismes; ou
- c. au transfert du matériel génétique modifié de ces organismes.

##### *Al.2bis*

Le détenteur ne répond pas du dommage causé par un effet indésirable d'organismes génétiquement modifiés qui ont été utilisés sur une personne à des fins médicales, lorsque la personne ou son représentant légal a consenti au traitement après avoir été informé de façon adéquate sur cet effet.

##### *Al.3*

Si un dommage est causé par des organismes génétiquement modifiés mis en circulation et utilisés comme matières auxiliaires dans l'agriculture ou la sylviculture, les dispositions suivantes sont applicables:

- a. seul répond du dommage le producteur au sens de l'article 2 de la loi du 18 juin 1993 sur la responsabilité du fait des produits, qui a le premier mis ces organismes en circulation;
- b. lorsque de tels organismes ont été importés, le producteur qui, le premier, les a mis en circulation à l'étranger et l'importateur répondent solidairement du dommage;
- c. le détenteur d'une entreprise ou d'une installation qui importe des organismes génétiquement modifiés pour ses besoins propres répond solidairement du dommage avec le producteur; et

- d. est réservé le droit de recours contre les personnes ayant utilisé ces organismes génétiquement modifiés de manière inadéquate ou ayant contribué de toute autre façon à la réalisation ou à l'aggravation du dommage.

*Al.4*

Est déchargé de la responsabilité celui qui apporte la preuve que le dommage est dû à un cas de force majeure ou à une faute grave commise par le lésé ou par un tiers.

*Al.5*

Les articles 42 à 47 et 49 à 53 du Code des obligations sont applicables.

*Al.6*

La Confédération, les cantons et les communes sont également responsables aux termes des alinéas 1er à 5.

**Art.28** Dommages causés à l'environnement

*Al.1*

Celui qui répond de l'utilisation d'organismes génétiquement modifiés doit également rembourser les frais nécessaires et adéquats des mesures prises pour remettre en état les composantes de l'environnement détruites ou détériorées, ou pour les remplacer par un équivalent.

*Al.2*

La collectivité publique compétente peut faire valoir un droit à la réparation si les composantes de l'environnement détruites ou détériorées ne font pas l'objet d'un droit réel, ou si l'ayant droit ne prend pas les mesures commandées par les circonstances.

**Art.29** Prescription

*Al.1*

Le droit à la réparation du dommage se prescrit par trois ans à compter du jour où le lésé a eu connaissance du dommage et de l'identité de la personne légalement responsable, et au plus tard par 30 ans à compter du jour où:

- a. l'événement dommageable s'est produit ou a cessé de se produire dans l'entreprise ou l'installation;  
ou
- b. les organismes génétiquement modifiés ont été mis en circulation pour la première fois.

*Al.2*

Le droit de recours se prescrit lui aussi selon l'alinéa 1er. Le délai de trois ans court à partir du jour où la réparation a été complètement exécutée et où l'identité du corresponsable est connue.

**Art.30** Garantie

Pour protéger les personnes lésées, le Conseil fédéral peut:

- a. prescrire que les détenteurs de certaines entreprises ou installations fournissent des garanties, sous forme d'une assurance ou d'une autre manière, pour couvrir leur responsabilité civile;
- b. fixer l'étendue et la durée de cette garantie ou déléguer cette tâche à l'autorité, qui statuera cas par cas;

/...

- c. obliger le garant à notifier à l'autorité d'exécution l'existence, la suspension et la cessation de la garantie;
- d. prévoir que la garantie ne sera suspendue ou ne cessera que 60 jours après la réception de la notification.

## **Annex I**

### **Draft Federal Law on Non-Human Gene Technology (Gene Technology Law)**

Liability is one of the new issues currently addressed by the Swiss Parliament within the legislative project called "Genlex". Genlex has been initiated in 1996 by the Swiss Parliament to complement the existing provisions of the Federal Law relating to the Protection of the Environment (LPE) dealing with genetically modified organisms. In the Government proposal of March 2000 (available on Internet in French at <http://www.admin.ch/ch/f/ff/2000/2327.pdf>), the issue of liability is addressed in Article 59 al. 1bis, 2bis and 2 ter). During the course of 2001, the first Chamber of the Parliament, the State Council, has handled the Genlex project. One of its first decision was to establish a new Gene Technology Act that will integrate existing provisions of the LPE as well as the elements of Genlex. Chapter 5 of the draft Gene Technology Act specifically addresses liability. The Government proposal was modified by the State Council. The draft provisions, as adopted in first lecture, are publicly available in French in the minutes of the Parliament at:

[http://www.parlament.ch/ab/frameSet/d/s/4609/36513/d\\_s\\_4609\\_36513\\_36520.htm?DisplayTextOid=36522](http://www.parlament.ch/ab/frameSet/d/s/4609/36513/d_s_4609_36513_36520.htm?DisplayTextOid=36522) (Art. 27 par 1,2 and 2bis) and

[http://www.parlament.ch/ab/frameSet/d/s/4608/32153/d\\_s\\_4608\\_32153\\_32157.htm?DisplayTextOid=32158](http://www.parlament.ch/ab/frameSet/d/s/4608/32153/d_s_4608_32153_32157.htm?DisplayTextOid=32158) (Art. 27 par 3-6, art 28, art 29, art 30).

The draft Gene Technology Act will now be discussed by the second chamber of the Parliament, the National Council, during the course of 2002. Hence, the proposed liability regime is still subject to possible modifications.

The text below is provided as an unofficial translation for information purposes to illustrate the status of the ongoing discussion on liability in Switzerland.

Draft provisions concerning liability, according to the proposal of the Council of States of 14.6. and 26.9.2001 (unofficial extract and translation)

### **Chapter 1: General Provisions**

#### **Art. 5 Definitions**

6. Installations are building, highways and other fixed installations as well as modifications of land. Installations are equal to appliances, machines, vehicles ships and aircrafts.

### **Chapter 5: Liability**

#### **Art. 27 Principles**

1. The owner of an installation that uses genetically modified organisms is liable for harm that may be caused during this handling due to the modification of the genetic material.

/...

2. In these cases, harm must have been caused because of
  - a. the new properties of the organisms; or
  - b. the reproduction or modification of the organisms; or
  - c. the transfer of the modified genetic material of the organisms.

*2bis* The owner is not liable for harm caused by an undesired effect of genetically modified organisms which have been used on a person for medical purposes, if the person or his/her legal representative, after being properly informed of this effect, has consented to the treatment.

3. If harm was caused by bringing genetically modified organisms onto the market for use as aids to agriculture or forestry, the following shall apply:
  - a. only the producer, in the sense of Article 2 of the Federal Law of 18 June 1993 on Product Liability, who first placed these organisms on the market, is liable;
  - b. if such organisms have been imported into the country, the producer who first placed them on the market abroad and the importer are jointly and severally liable;
  - c. the owner of a company or installation that imports such organisms for its own use is jointly and severally liable with the producer; and
  - d. recourse to persons who have handled such organisms improperly, or have otherwise contributed to the creation or worsening of the harm, is reserved.
4. A person who can prove that the harm was caused by an act of God or contributory negligence by the injured party or a third party, is free of liability.
5. Articles 42 to 47 and 49 to 53 of the Swiss Code of Obligations are applicable.
6. The Swiss Confederation, Cantons and communes are also liable under Paragraphs 1 to 5.

**Art. 28** Harm to the environment

1. A person who carries liability for the use of genetically modified organisms must also compensate the costs of necessary and appropriate measures that must be taken to restore destroyed or harmed components of the environment, or to replace them with components of equal value.
2. Proceedings for the recovery of damages shall be taken by the community responsible, as long as the destroyed or harmed environmental components are not the object of rights in rem, or the person entitled does not take the measures appropriate to the situation.

**Art. 29** Statute of limitations

1. Proceedings for the recovery of damages are subject to a limitation period of three years following the injured party recognising the harm and the person liable, and 30 years at the latest after:
  - a. the event that caused the harm occurred or came to an end within the company or installation; or
  - b. the genetically modified organisms were first placed on the market.
2. The right of appeal is also subject to a limitation period, according to Para. 1. The three-year limitation period commences as soon as the damages have been completely paid, and the person who shares liability is identified.

**Art. 30**      Guarantee

The Federal Council, to protect the injured party, may:

- a. require the proprietors of particular companies and installations to guarantee their liability through insurance or in another form;
- b. specify the extent and duration of the guarantee, or leave it to the authorities to determine for individual cases;
- c. require the person who guarantees liability to report the existence, suspension or cessation of the guarantee to the enforcement authority;
- d. require the guarantee to be suspended or ended only after 60 days following receipt of this report.

**UNITED STATES OF AMERICA**

[25 January 2002]  
[SUBMISSION: ENGLISH]

Pursuant to UNEP/CBD/ICCP/2/15 Annex, item 2/1, paragraph 2<sup>1</sup> on liability and redress and the Secretariat's November 7, 2001 notification to governments, the U.S. hereby makes this submission.

Currently, U.S. regulation of the products of biotechnology is primarily shared between three federal agencies: the Food and Drug Administration, the U.S. Department of Agriculture, and the Environmental Protection Agency. Relying on existing laws, these agencies establish requirements pertaining to the production and use of such products, and allocate liability for the failure to comply with these requirements.

However, the U.S. has not established any federal measures or agreements specifically tailored to address whether compensation would be available for environmental damage resulting from transboundary movements of living modified organisms (LMOs). Nor is the U.S. aware of any individual state measures intended to specifically allocate liability for such damage. Instead, such damage would be addressed under the existing federal legal regimes, and/or state tort legal systems. Under tort law, a court assesses damage and assigns responsibility after due consideration of the individual facts of the case, in light of concepts such as the extent of any duty of care the parties have towards each other, causation, foreseeability, actual harm and the overall dangerous nature of the activity. We believe that these concepts are generally applicable in allocating liability. Moreover, tort law is well developed in the U.S legal system and we are not aware of any special measures that would be necessary to tailor this system to address a case involving harm resulting from transboundary movements of LMOs.

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<sup>1</sup>Paragraph 2 of item 2/1 requests Parties, Governments and relevant international organizations to provide the Executive Secretary with information on national, regional and international measures and agreements in the field of

liability and redress for damage resulting from transboundary movements of living modified organisms by no later than three months prior to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

VIET NAM

[16 January 2002]

[SUBMISSION: ENGLISH]

**4.1. Information on national, regional and international measures and agreements in the field of liability and redress for damage resulting from transboundary movements of LMOs:**

In environment law approved by Vietnam Government in 1994, there is only one article relating to the liability and redress for damage of natural resources in general. Specific measures and agreements in the field of liability and redress relating to transboundary movements of LMOs is not yet.

In Law on Environmental Protection, there is article 19 which states that: *“The importation and exportation of technologies, machinery, equipment, biological or chemical products, toxic substances, radioactives materials, various species of animals, plants, gene sources and microorganisms relating to the protection of the environment must be to approval by the sectorial management agency concerned and the State management agency for environmental protection.*

*The Governmnet shall stipulate a schedule for each domain and each category reffered to in this article.”*

Vietnamese Government intends not to constrain the developments of modern biological technology, and permits the importation of technologies and new GMOs that have positive impacts on economic development and environmental protection. However, those activities must be strictly controlled in order to prevent risks to human and environmental well-being as stipulated in the protocol. The controlling operations focus on not only trans-boundary movements but also domestic research and development activities.

However, so far investigations and assessments of GMOs importation and use for living and producing purposes have not been carried out yet. Capacity of controlling bodies has not been evaluated yet and their responsibilities have not been clarified. Plan for implementation of the protocol and regulation has not been prepared yet, etc.

In conclusion, participation in the programme for developing "National Biosafety Framework" initiated by UNEP- GEF is vital and appropriate to help Vietnam in developing the controlling system and completing legal documents.

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