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OPEN-ENDED AD HOC WORKING GROUP OF
LEGAL AND TECHNICAL EXPERTS ON
LIABILITY AND REDRESS IN THE CONTEXT OF
THE CARTAGENA PROTOCOL ON BIOSAFETY

Second meeting

Montreal, 20-24 February 2006

Item 3 of the provisional agenda*

**FINANCIAL SECURITY TO COVER LIABILITY RESULTING FROM
TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS**

Note by the Executive Secretary

I. INTRODUCTION

1. The Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety (the “Working Group”, hereinafter) held its first meeting from 25 to 27 May 2005 in Montreal. At that meeting, the Working Group considered and further developed scenarios of damage resulting from transboundary movements of living modified organisms (LMOs), options, approaches and issues for further consideration relating to liability and redress, that were initially identified by a technical group of experts that met earlier to undertake preparatory work for the first meeting of the Working Group.

2. The Working Group also concluded that it needs further information in several areas that it considered were pertinent to accomplish its tasks specified in its terms of reference. In that regard, it requested, among other things, the Secretariat to gather information on financial security to cover liability resulting from transboundary movements of living modified organisms, including information from Parties and other Governments on national experiences in this respect (paragraph 44.2(b) of document UNEP/CBD/BS/COP-MOP/2/11). This document has been prepared by the Executive Secretary in response to this request.

3. Financial security includes insurance, bank guarantees, internal reserves, and industry pooling schemes among other mechanisms. The following note focuses for the most part on information on insurance for liability resulting from transboundary movements of living modified organisms. Part II of

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the note includes information on relevant concepts from the insurance industry. Part III discusses different heads of damage and the availability of insurance for these different heads. Part IV discusses other options, namely compulsory insurance and compensation funds. There are two annexes to this document. Annex A contains a submission of information and experience from the European Union on financial guarantees and liability for damage resulting from LMOs and Annex B presents a compilation of some relevant materials from the Swiss Reinsurance Company that were made available in an electronic form at the previous meeting of the Working Group.

II. RELEVANT CONCEPTS FROM THE INSURANCE INDUSTRY

A. Concepts pertaining to requirements for a risk to be insurable

4. In order for a risk of liability to be insurable, it must be possible to clearly calculate the risk for which the insurance is sought. The criteria on which the risk is evaluated are: the assessability of the risk, the randomness of the risk, the mutuality of the risk, and the economic efficiency of the risk.

5. For a risk of liability to be assessable, it must be possible to quantify both the probability that liability for the damage will occur as well as the extent of the liability. Multiplying the probability by the extent gives the 'expected liability'. These calculations are necessary to determine the potential exposure of the insurer and the premium necessary to cover this exposure. It must also be possible to allocate damage to a particular insurance period.¹ The assessment of any particular type of risk for liability is based on actuarial statistics and information about legal requirements as well as the nature of the risk involved (e.g. for risk of liability for environmental damage, the nature of the risk would include the physical, chemical and/or biological characteristics of the substance that could cause the damage leading to liability.)

6. The defining elements of liability thus influence the availability of insurance to cover the risk of the liability. These elements include the definitions of:

- Damage and loss;
- The heads of damage (injury to persons or property, environmental damage, economic loss);
- Acceptable impact (including thresholds);
- Exemption from liability;
- Limitation periods;
- Burden of proof;
- Beneficiary;
- Claimant.²

7. The standard of liability – either strict or fault-based – also plays an important role in the assessment of risk and thus the availability of insurance: “Fault-based liability solutions promote insurability. If strict liability is put in force, insurability requires at least: a) that the claimant bears the burden of proof of causality (no reversal); b) that the insured is allowed specific defences beyond Act of

¹ Swiss Reinsurance Company, *The Insurability of Ecological Damage* (Zurich: Swiss Reinsurance Company, 2003) at p. 27.

² Letter from Swiss Reinsurance Company, ““Availability of financial security to cover liability resulting from the transboundary movement of living modified organisms (LMOs) and the prices as which such financial security is available”. General considerations provided by Swiss Re on demand of the Secretariat CBD”, 23 May 2005 at p. 3.

God (“force majeure”), in particular the state-of-the-art defence and the compliance-with-permit defence; c) that the limitation period is reasonably limited.”³

8. Caps can also promote insurability as they help to quantify the risk to be insured. A number of international liability conventions place caps on the maximum amount any one injurer may be held liable – see, for example, the 1960 *Paris Convention on Third Party Liability in the Field of Nuclear Energy* (as amended, Article 7), the 1989 *Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels*⁴ (Article 9), the 1992 *International Convention on Civil Liability for Oil Pollution Damage* (Article V), and the 2003 *Kiev Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters*⁵ (Article 9 and annex II). The extent to which caps on liability encourage insurability may be limited, however, as insurance companies can also impose financial limits as part of the insurance policy (see paragraph 15, below.) Caps may also lead to under-compensation of the victim and violate the polluter pays principle.⁶ (See the discussion on compensation funds in section IV.B, below, for possible solutions to these problems.)

9. Ongoing changes in knowledge, however, introduce uncertainty into the assessment process: “Normally, such uncertainties are accounted for by adding a surcharge (“loading”) to the premium; yet if a factor is new or unfamiliar – or when it represents a new category, such as ecological impairment – calculating its probability is more difficult, even if it is the result of a sudden or accidental event. In the past, such damage has just not been insured. Insurers have little or no experience – ie statistics – for this kind of loss and it is presently almost impossible to calculate an “adequate premium”.”⁷ These changes in knowledge can cause uncertainty in relation to both the probability of liability as well as the extent of liability.

10. Quantifying the scope of damage also requires an understanding of what the damage is or may be. For ecological damage, this could include tangible and/or intangible components. Swiss Re describes damage to biodiversity as “basically intangible, although the actual, underlying damage to flora and fauna are tangible.”⁸ The tangible component of ecological damage includes defined, quantifiable damage to public goods such as water, soil, air, and fauna and flora. The intangible component includes damage to intrinsic values such as a particular view, an area rich in biological diversity, or quality of life – damage that is much more difficult to quantify. There are a number of different methods for quantifying damage including contingent valuation (which was used to assess intangible damage in the Exxon Valdez case), the travel cost method, hedonic pricing, and restoration or replacement cost. Insurance for liability for damage to tangible components is available through insurance for the traditional heads of damage (damage to persons, property, or economic losses) or environmental damage; insurance for liability for the intangible component is much more difficult.

11. For a risk to be random, the time at which an insured event occurs (i.e. an event creating liability for damage) must not be predictable and its occurrence must be independent of the will of the insured. Many insurers still require a polluting event to be sudden and so will not insure against liability for damage from gradual pollution. Insuring against liability for damage from gradual pollution exposes the

³ Thomas K. Epprecht, Swiss Reinsurance Company, “Cartagena Protocol on Biosafety: Insurance Industry and Art 27 (Liability and Redress) of the Cartagena Protocol” 22 March 2002 at p. 3.

⁴ Not in force.

⁵ Protocol to the 1992 *Convention on the Protection and Use of Transboundary Watercourses and International Lakes* and to the 1992 *Convention on the Transboundary Effects of Industrial Accidents*. The Protocol is not in force.

⁶ See the submission from the European Union in Annex A of this document

⁷ Swiss Re, *supra* note 1 at p. 27.

⁸ Swiss Re, *supra* note 1 at p. 33.

insurer to a “potentially powerful loss generator.”⁹ The liability could include both historical activities that prove to cause damage and current and future activities that lead to damage (or the recognition of damage) well into the future. Furthermore, insurance is not available for systemic risks, such as a stock market meltdown, that affect everyone at the same time. Risks must be stochastically independent to exclude systemic risks and be eligible for insurability.

12. For a risk to be mutual, “[a] large number of endangered parties must join together to carry the hazard jointly.”¹⁰ The relative success of the international agreements pertaining to liability for damage relating to oil pollution is due at least in part to of the ‘mutuality’ or homogeneity of the interests of the oil industry. Creating international liability regimes for damage caused by substances other than oil or nuclear energy can be difficult because of the diversity of interests.

13. Finally for a risk to be economically efficient, it must be possible for the insurer to charge a premium that covers the risk (as required by law) and for the insurer to earn a profit through the conduct of its business. Without these conditions, an insurance company could incur claims beyond what it is able to cover and risk bankruptcy, potentially leaving many victims uncompensated for the damage they have suffered.

B. Concepts pertaining to problems associated with insuring risks

14. There are two standard problems associated with insuring risks: moral hazard and adverse selection. With moral hazard, the incentive for the potential injurer to take care is removed at the same time as the same potential injurer’s exposure to risk is removed by an insurance policy. For example, automobile insurance reduces the costs to insured people who have accidents, making people less cautious when they drive compared to how they would drive if they paid 100 percent of the damages they caused in an accident.

15. Insurance policies can be designed to minimize moral hazard by monitoring the insured through control of the insured and adaptation of the premium, and by partially exposing the insured to risk. Control of the insured and adaptation of the premium can be done either *ex ante* by charging a higher premium for certain high risk groups, or *ex post* by increasing the premium and changing the conditions of the policy based on past behaviour.¹¹ Exposing the insured to risk can be done by charging a deductible whereby the initial costs of damage are paid by the injurer rather than being covered by the insurance policy, or by capping the insurance policy at a certain level so that any costs beyond this level are again paid by the injurer rather than the insurer. Usually, control of the insured and adaptation of the premium are used in combination with exposing the insured to risk in order to control moral hazard.

16. Insurance is most appealing to those who are most likely to need it – the so-called ‘bad risks’ – creating the problem of adverse selection. Insuring bad risks raises premiums leading to a situation where good risks will often prefer to go uninsured. If adverse selection becomes a serious problem, insurance companies may be reluctant to offer insurance for the risk in the first place, either leaving everyone uninsured or leading to such high premiums that only the wealthiest can afford them. One remedy for adverse selection is risk differentiation. Risk differentiation is related to control of the insured and adaptation of the premium in that it requires differentiation among risks in order to define a risk pool as narrowly as possible so that the premium can be set at a level that reflects the risk of the average member of that pool.¹² If risks are well-differentiated, premiums should not be so high as to encourage good risks

⁹ Swiss Re, *supra* note 1 at p. 39.

¹⁰ Swiss Re, *supra* note 1 at p. 27.

¹¹ Michael G. Faure & David Grimeaud, *Financial Assurance Issues of Environmental Liability* (Maastricht University, METRO & European Centre for Tort and Insurance Law, 2000) at p. 121.

¹² *Ibid.* at p. 123.

to leave the pool. Adverse selection can also be countered by including deductibles in an insurance policy or by making insurance compulsory. (See section IV.A, below, for a more detailed discussion of compulsory insurance.)

III. INSURANCE FOR DIFFERENT HEADS OF LOSSES

A. Heads of Losses

17. To a certain extent, the availability of financial security to cover liability resulting from transboundary movements of living modified organisms depends on the type of liability in question. Insurance for liability from the traditional heads of damage – damage to persons or property and economic loss – is generally available. Insurance for liability for environmental damage or ecological damage may be more limited.

18. The traditional heads of damage are damage to persons, damage to property and economic losses. Insurance for liability for these types of damage is widely available, although sometimes claims for damage to persons or property or economic losses that arise from substances released into the environment are excluded from insurance policies. It should be noted, however, that civil law and common law systems differ in their treatment of economic losses. In civil law, economic loss includes losses resulting from both physical damage to property and where there is no physical damage. In common law, there is a distinction “between economic loss which is a consequence of physical loss or damage to property (“consequential damage”) and loss of profit or earning sustained otherwise than as a result of physical loss or damage to property (“pure economic loss”).”¹³ Insurance for pure economic loss is not as widely available although it is covered in some new environmental policies, “usually containing various requirements as to the professional activity of the injured persons.”¹⁴ Furthermore, liability for pure economic loss at common law is rare.

19. Insurance for liability for environmental damage depends, furthermore, on the definition of environmental damage. Where environmental damage means damage to persons or property or economic damages, liability for this type of damage may be covered by the insurance schemes for traditional heads of damage, as discussed above. Environmental damage, or, perhaps more accurately, environmental liability, can also include the costs of preventative measures or response actions as well as clean-up and restoration costs. Liability for clean-up and restoration costs are insured to the extent that they fall within any of the traditional heads of damage covered by a policy. Preventative measures or response actions can include measures taken after an incident to prevent or minimize further damage as well as measures taken to avert the imminent danger of damage.¹⁵ The costs of preventative measures or response actions are covered by insurance policies available in some countries.

20. According to Swiss Re, “[e]cological damage is *primary* environmental damage done directly to the water, air, soil, flora or fauna.”¹⁶ Ecological damage involves damage to ecological goods, which are public goods belonging to no one, or damage to the environment *per se*. As such, civil liability often does not apply although some States and international agreements give public authorities and/or public interest

¹³ Maja Seršić, “The Impact of Multilateral Insurance and Compensation Funds on Liability for Environmental Harm” in Michael Bothe & Peter H. Sand, eds., *La politique de l’environnement : de la réglementation aux instruments économiques* (The Hague: Martinus Nijhoff, 2003) 583 at p. 587.

¹⁴ *Ibid.* at 588.

¹⁵ John H. Wasnick, “Environmental Liability Insurance: Tour d’Horizon in Europe” in Ralph P. Kröner, *Transnational Environmental Liability and Insurance* (London: Graham & Trotman, 1993) 1 at p. 14-15.

¹⁶ Swiss Re, *supra* note 1 at p. 5.

groups standing to sue to protect public ecological goods. To date, it has been very difficult for insurers to calculate either the losses involved in ecological damage or the probability that they will occur so the availability of insurance to cover liability for ecological damage is very limited, if it is available at all. It should also be noted that the definitions of environmental and ecological damage are not necessarily universally accepted and the distinction between the two is not always maintained. Furthermore, neither ‘ecological damage’ nor ‘environmental damage’ necessarily encompass the full scope of ‘biodiversity damage’ as this is understood in the context of the definition of ‘biological diversity’ in Article 2 of the Convention.

B. Availability of Insurance

21. In France, all liability claims from environmental damage are insured by the French environmental insurance pool “ASSURPOL” as conventional liability in the country usually excludes such claims. The pool covers claims for damage to persons or property and some kinds of economic loss but it does not cover ecological damage.

22. In the Netherlands, liability policies for businesses exclude all claims arising from environmental damage except for bodily injury. Companies can purchase a separate environmental damage policy which covers clean-up costs for soil on contaminated sites or bodies of water. Ecological damage is explicitly excluded from the policy.

23. In the U.S., commercial general liability insurance policies absolutely exclude environmental damage. Complementary coverage is available but is limited to claims following a sudden, accidental event. Special coverage for liability exposure under the *Comprehensive Environmental Response, Compensation and Liability Act* is difficult to obtain as it sets strict insurability requirements, exclusions from coverage and high premiums. These special policies focus on bodily injury, damage to property and site cleanup.

IV. OTHER OPTIONS

A. Compulsory Insurance

24. Some international liability regimes – such as Article 8 of the 1977 *Convention on Civil Liability for Oil Pollution Damage resulting from the Exploration for and Exploitation of Seabed Mineral Resources*¹⁷, Article 11 of the 2003 *Kiev Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters*, and Article VII of the 1963 *Vienna Convention on Civil Liability for Nuclear Damage* – require the industry or activity being regulated to carry insurance or some other form of financial security. Indeed, the provisions on the minimum amount of financial securities in the Kiev Protocol were agreed to by the insurance sector making them “realistic and appropriate.”¹⁸ There are two common rationales behind compulsory insurance. The first is an economic argument that compulsory insurance will remove the risk from risk averse persons and increase their utility as investors.¹⁹ The second is a legal argument that compulsory insurance will increase the likelihood of compensation in case damage occurs, particularly in cases where the author of the damage is insolvent or becomes insolvent by virtue of a large award for damages.

¹⁷ Not in force.

¹⁸ “Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters” at <http://www.unece.org/env/civil-liability/welcome.html>.

¹⁹ Faure & Grimeaud, *supra* note 11 at p. 147.

25. There are also two common arguments against compulsory insurance. The first is that the provision of insurance by insurance companies is or should be based on the “willingness to insure” of the financial and insurance markets. Simply mandating that an industry carry insurance will not automatically lead to the provision of this insurance by insurance companies. There are always gaps between risks and possible legal liability, and the insurance available to cover these. A second argument against compulsory insurance is that it may put the insurance companies in the position of enforcer, which is not their role: “the exercise of a particular activity should not depend solely – or even mainly – on having insurance cover ... Hazardous activities should not be approved only because the activity is insured.”²⁰ At the same time, compulsory insurance may exacerbate the moral hazard problem if the compulsory insurance provisions do not allow exposing the insured to any degree of risk.²¹ On the other had, insurers acting to control moral hazard can also be understood as a form of enforcement. If an insurer requires the insured to meet a standard that rules out negligence in order to be covered by an insurance policy, the insurer is enforcing a standard. Furthermore, compulsory insurance may be effective to prevent adverse selection.

26. Germany has enacted compulsory insurance requirements for environmental damage. Under §19 of the German *Environmental Liability Act* of 1990, the operators of facilities listed in an appendix must ensure that they are able to provide compensation for damage to persons or property that arise from an environmental impact of the facility. The coverage to be provided may be in the form of liability insurance, or an indemnity agreement or guarantee made by the federal government or a credit institution. According to the European Commission *White Paper on Environmental Liability*, there have been difficulties in implementing this provision, which have prevented the necessary implementing decree from being established.²²

27. Sweden has also enacted a form of compulsory insurance system. In 1989, a new insurance scheme came into force that requires companies conducting environmentally hazardous activities to contribute to the scheme. The fund then provides direct coverage to natural persons who suffer pollution damage but only where the actual polluter is insolvent or cannot be identified or the right to indemnity under the *Environmental Damage Act* is statute-barred. According to Wansink, the impact of the scheme has been disappointing due at least in part to its very restrictive coverage.²³

28. Amendments to the Austrian Law on Genetic Engineering have introduced provisions on liability including requirements for financial security. The notifier of a contained use or deliberate release of an LMO must take adequate measures, such as the purchase of insurance, to settle claims for damages from the LMO. The Act sets minimum amounts of liability insurance for contained use in biosafety level 3 (large scale), and biosafety level 4 and deliberate release (large scale).²⁴

B. Compensation Funds

29. Another form of financial security against legal liability is the creation of compensation funds. These can either supplement or act in stead of awards for damages. A few international conventions have created compensation funds, such as the International Oil Pollution Compensation Fund created under the 1971 *International Convention on the Establishment of a Fund for Oil Pollution Damage*, which, in turn, supplements the 1969 *International Convention on Civil Liability for Oil Pollution Damage*, and the

²⁰ Swiss Re, *supra* note 1 at p. 31.

²¹ Faure & Grimeaud, *supra* note 11 at p. 150-151.

²² European Commission, *White Paper on Environmental Liability*, COM(2000) 66 final, 9 February 2000 at p. 24.

²³ Wasnick, *supra* note 15 at p. 20.

²⁴ UNEP/CBD/ICCP/3/INF/1, *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* at p. 4.

International Hazardous and Noxious Substances Fund that will be established under the 1996 *International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea* once the latter enters into force.

30. Compensation funds function by bringing together a group of potential polluters (or, more broadly, potential authors of damage) who pay into the fund based on the risk they create. For example, payments into the International Oil Pollution Compensation Fund are made by oil importers in the contracting states on the basis of the annual number of tons of oil received by sea. When damage occurs, compensation is paid by the compensation fund thus spreading the individual risk and liability of any one potential author of damage over the larger group. The main objective of compensation funds, therefore, is to improve the position of the injured parties. As with insurance, compensation funds work best if a relatively homogenous group of interests can be brought together to share the risk. This lack of homogeneity has been one of the main challenges to participation in the 1996 *International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea*.²⁵

31. The advantages of compensation funds include that they “ensure payment in cases where the individual polluter cannot be identified, or where the polluter is known but his fault cannot be established, or he is insolvent, or exempted from liability, or in cases where the damage exceeds the ceiling of the liability of the liable person or the amount covered by insurance.”²⁶ The main drawbacks of compensation funds include an unwillingness on the part of companies to participate in a scheme where they may be required to pay large sums to cover damages arising from other firms’ pollution, particularly where these firms are their competitors. This argument could also, however, be applied to insurance. Companies may not be willing to pool risk through the purchase of insurance if this will support their competitors. This can also contribute to adverse selection where companies that are good risks do not want to support their bad risk competitors by pooling their risks together through the purchase of insurance. A further drawback to compensation funds may be that they could fail to implement the polluter pays principle – and thus fail to create a disincentive to causing pollution or damage – if contributions to the fund are not proportional to the actual damage caused by any one contributor. If the proportional contributions can be determined, however, then there is less need for the fund in the first place.²⁷

²⁵ Seršić, *supra* note 13 at p. 598.

²⁶ Seršić, *supra* note 13 at p. 589.

²⁷ White Paper on Environmental Liability, *supra* note 22 at p. 43.

**Submission of information and experience from the EU
on
Financial Guarantees 28 and Liability for Damage resulting from LMOs**

I. Introduction

The first meeting of the open-ended ad hoc Working Group of legal and technical experts on Liability and Redress in its conclusions (see UNEP/CBD/BS/COP-MOP/2/11, paragraph 44.2(b)) requested the Secretariat *inter alia* to gather information from Parties and other Governments on financial security to cover liability resulting from transboundary movements of living modified organisms (LMOs).

Given the EU's experience, both within national legal systems and in developing the Environmental Liability Directive (ELD), in particular bearing in mind Article 14 of the Directive, we would like to take this opportunity to share our experiences with the participants at 2nd OEWG.

II. Environmental Liability Directive

In the context of the preparation of the ELD, the European Commission financed, *inter alia*, two studies dealing with financial securities with respect to environmental liability, namely:

a) "*A General Analysis of the Financial Assurance Issues of Environmental Liability*"

http://europa.eu.int/comm/environment/liability/insurance_gen.htm

b) "*A Market-Based Analysis of Financial Assurance Issues Associated with U.S. Natural Resource Damage Liability*"

http://europa.eu.int/comm/environment/liability/insurance_us.htm

These studies do not focus on GMOs as such but may help focusing on relevant issues for financial securities in the field of environmental damage (or damage to natural resources)²⁹.

These studies should be understood as potentially useful information and not as a reflection of EU positions.

In order to facilitate the discussion at the 2nd OEWG, we have reformulated here below some issues raised by these studies which we believe are worth considering when discussing financial guarantees regarding liability for damage caused by LMO-related activities. In addition, it might be interesting to focus on various instruments that aim to provide protection against the insolvency of the polluter. It is worth considering not only traditional insurance but also other instruments whereby the potential polluter can choose another market solution, or can be forced to provide some kind of compensation, bank guarantee, or other form of "ex ante" payment as guarantee for compensation in the event damage occurs.

²⁸ "Financial securities" do not need to be "traditional insurance"; as it is mentioned later in the document other instruments that the potential polluter may choose as guarantee for compensation to the victim in the event that damage occurs should be considered.

A. Insurability in the context of rules and procedures on liability and redress for damage caused by GMO-related activities.

The insurability of a particular category of damage depends on a lot of variables and it is difficult to assess it in a merely theoretical manner. It is the insurance and financial markets that will decide in practice whether they are willing to provide coverage for a certain risk. Such willingness will first depend on their ability to anticipate with an acceptable margin of uncertainty the probability distribution of risks, and thus both their possible payments, margins and benefits. If they do not have enough information, they will tend to impose security margins and only accept insuring possible damages if huge risk premiums are included in insurance prices. Insurability is ultimately the "willingness to insure" of the financial and insurance market. Taking into account this limitation, nevertheless some observations can be made on issues which influence insurability.

It seems necessary to develop criteria and guidelines for the assessment of "natural resource damage". A lack of guidance on the assessment of damage, could - because of the complexity of the issue - influence the motivation of the parties to claim compensation, hold the polluter liable and address the damage.

The "reinstatement of the natural resource" is often the preferred option. Insurance practice in relation to damage to natural resources shows that liability is in this case usually insured as "remediation costs". The scope of remediation costs may to some extent be better predictable than a vague notion of damage, as "damage to biodiversity". Thus, when the remedy to be provided is a duty to pay for reasonable and proportional remediation costs, practice shows that policies covering remediation costs are possible.

There are a number of issues that policy makers could consider when developing rules and procedures on liability in order to facilitate insurability. These include:

- To be cautious with a shift of the burden of proof as far as causation is concerned;
- Joint and several liability systems may decrease insurability as one party may be held liable independently of its role in the activity that caused the damage;
- Retrospective liability may be uninsurable;
- Allowing "claim made" coverage of the environmental risk, may facilitate insurability;
- the introduction of financial caps to liability may not be necessary to increase insurability, since insurers could put themselves a financial limit on liability; caps may lead to under-compensation and violate the polluter pays principle.
- Involvement and participation of all relevant stakeholders and actors in the insurance market is essential from the early stages of the development of rules and procedures on liability in order to ensure that the development of the rules and of the market can proceed in parallel.

Even when all the theoretical conditions for an optimal insurability of environmental damage liability can be met, insurance doctrine has indicated that in many countries the environmental liability market is still relatively under-developed.

Finally, to increase the insurability and capacity of financial compensation a co-operation between insurance undertakings or industrial operators may be helpful. This could for instance be the case for the co-operation between insurers to acquire adequate and reliable statistics on risks; and the co-operation between insurers to create a larger capacity via e.g. pooling.

B. Alternatives to insurance

Financial security should not necessarily be liability insurance; policy makers could indicate that a wide variety of mechanisms may be used to provide this financial security provided that they are considered adequate. When administrative authorities impose a duty to provide financial security, they should make

sure that sufficient varieties of financial securities exist on financial and insurance markets in order to avoid that governments or administrative authorities would become dependant upon the financial or insurance industry, which would then effectively become the licenser of industrial activities.

Alternatives to liability insurance include self-insurance; risk sharing agreements; *ex ante* guarantees and deposits into an environmental savings account. It has to be borne in mind that these instruments may not answer the risk of insufficient security in the case of major risks/disasters.

At the policy level, it may not be necessary to make a decision in favour of any of those instruments provided that the financial security offered *is effective to guarantee that money will ultimately be available* when it will have to be used, i.e. when environmental damage appears.

III. National Laws

We would also like to share with participants' information with respect to two States experience of financial security to cover liability resulting from activities with LMOs at the national level.

Netherlands

With respect to existing liability insurances, information from the Dutch Association of Insurers demonstrates that:

- Agricultural businesses are insured by the Liability Insurance for Businesses;
- This insurance covers activities with LMOs;
- The insurance is limited to damage that includes damage to human health or material damage to third parties.
- National insurance companies are currently developing more awareness on the issue of biotechnology in general and LMOs in particular through the organization of expert meetings;
- The insurability of LMOs may be revisited when more insight is gained into possible adverse affects of LMOs and/or when the economic activities with LMOs would show significant changes.

As regards coexistence of farmers of LMO and non-LMO crops national stakeholders have signed an arrangement in which necessary measures are laid down to minimize co-mingling of LMO-material with non-LMO cultures. The primary objective of this arrangement is to further improve the coexistence of the different types of agriculture. This is achieved, among others, by encouraging and further facilitating mutual settling of liability claims regarding damage due to economic loss or loss of income as the result of negligence by stakeholders of the provisions in the contract. If a voluntary settlement would fail or not be possible, national legislation allows for a liability law suit due to a wrongful act. For any remaining damage due to economic losses or loss of income, the stakeholders have proposed to raise a fund covering these costs. This fund should be raised for each type of crop and be pledged by all stakeholders involved. In addition, the government would have an obligation to provide financial means to cover startup and overhead costs. The stakeholders are currently in a process to elaborate the design and functioning of the fund, including the conditions for a farmer to appeal to this fund.

Finland

The Environmental Damage Insurance Act (EDIA 81/1998) guarantees full compensation for environmental damage in cases where those liable for compensation are insolvent, or the liable party cannot be identified. Thus, the act creates a complementary compensation scheme for environmental damage occurring in Finland.

The act guarantees full compensation not only to those suffering from environmental damage, but it also covers the costs of measures taken to prevent or limit the damage and to restore the environment to its

previous state. In that context, the scope is similar to the Environmental Liability Act (ELA 737/1994), which prescribes primary liability concerning environmental damage.

However, it does not cover compensation for oil spills, because there is a specific Oil Pollution Compensation Fund from which compensation for oil spills is paid.

The scheme is financed by special insurance which is compulsory for the companies whose activities cause risk to the environment. All parties holding an environmental permit are obliged to take out insurance.

The system is run by the insurance companies. They have established the Environmental Insurance Centre, which handles all the claims for compensation under the scheme.

Finnish Gene Technology Act (377/1995) and Decree (928/2004) were adopted in 1995 and amended in 2000 and 2004. Article 36 in the Act has a general reference to Environmental Liability Act. Therefore the point of departure is that if a certain GMO damage enters into the scope of ELA it would also be covered by the EDIA. The definition or scope of damage in the Gene Technology Act however is broader than in the ELA and therefore all GMO damages would not be covered by the ELA and EDIA. There have not been practical cases to test the scope, but hesitations remain whether all GMO damages would be covered from the mandatory insurance.

More information regarding Finnish national legislation, including English translation of EDIA, is available at <http://www.ymparisto.fi/default.asp?node=6466&lan=en>

Annex B

This Annex is a compilation of documents relevant to the issue of financial security obtained from the Swiss Re-insurance Company. The documents were made available to the first meeting of the Working Group on Liability and Redress in an electronic form.



International Biotechnology Forum
November 2003

Conference report
Swiss Re Centre for Global Dialogue

 Swiss Re
Centre for Global Dialogue

**International Biotechnology Forum
November 2003**

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Centre for Global Dialogue**

The increasing use of genetically modified organisms (GMOs) in the production of pharmaceuticals, and in agriculture and foodstuffs, will definitely have implications for liability insurance. This was the conclusion reached at the International Biotechnology Forum held at Swiss Re's Centre for Global Dialogue in November 2003.

Swiss Re has been quick to recognise that growing public sensitivity towards gene technology¹ issues is changing the risk landscape and has triggered a worldwide debate which will not leave the insurance industry untouched. "The decisive element is not whether genetic engineering is dangerous, but how dangerous it is perceived to be." This statement, taken from the initial Swiss Re publication on genetic engineering and liability insurance issued in 1998, introduced the power of public perception as the decisive risk surrounding gene technology and spawned numerous stakeholder discussions and articles in the media, paving the way for the International Biotechnology Forum.

The event was divided into two parts: the Open Forum and the Specialist Forum. The Open Forum was accessible to a wide group of interested parties. It gave participants the opportunity to hear experts' opinions, engage in lively discussions on issues such as risk perception and trust, and discuss the threats and benefits of such innovations with the various stakeholders involved².

The second day of the conference, the Specialist Forum, was aimed at professionals from both the biotechnology and insurance industries as well as experts from academia and public institutions. The forum examined the nature of risk perception as a crucial political and legal driver and assessed framework conditions for the economic future of the biotechnology sector. The focus during this debate was on the interrelated areas of regulation, liability, claims and insurability. Participants looked at possible remedies for gene technology issues in various keynote speeches, an expert panel discussion and two sets of parallel workshops.

¹ Gene technology is also referred to as modern biotechnology, genetic engineering or recombinant DNA technology.

² A brief report on the first day of the conference distributed to all participants is available separately.

Speakers, panellists and moderators

Klaus Ammann, Professor	Director, Botanical Garden, University of Berne	7
Thomas Bernauer, Professor	Associate Professor, Center for Comparative and International Studies, Swiss Federal Institute of Technology, Zurich	14/ 17
Mark Cantley	Directorate General for Science, Research and Development, European Commission, Brussels	15
Willy de Greef, Dr	International Biotechnology Regulatory Services	15
Thomas Epprecht, Dr	Member of Management, Chief Underwriting Office, currently in charge of the Top Topic gene technology, Swiss Re	17/ 22
George Gaskell, Professor	Professor, Centre for Analysis of Risk and Regulation, London School of Economics and Political Science	6
Malcolm Grant, Professor	Provost and President of University College London, Chairman of the UK Agricultural and Environment Biotechnology Commission	12
Matthias Haller, Professor	President, Risk-Dialogue Foundation, St Gallen	5/ 21
Benedikt Haerlin	Head of Berlin Office, Foundation on Future Farming	7
Ariane Koenig, Dr	Senior Research Associate, Harvard Center for Risk Analysis, Harvard School for Public Health	18
Klaus Leisinger, Professor	President and Executive Director, Novartis Foundation for Sustainable Development	7
Ruth Mackenzie	Assistant Director, Centre for International Courts and Tribunals, Law Faculty, University College London	14
Erik Millstone, Dr	Director of Studies in Social Policy Research, University of Sussex	13
Richard Murray	Chief Claims Strategist, Swiss Re	15
Gabriele Neuhaus-Url, Dr	Process Manager, responsible for scientific communication, Syngenta, Basle	7
Vincent Pétiard, Dr	Head of Plant Science, Nestlé Research Centre, Tours	8
Bruno Porro, Dr	Chief Risk Officer and Member of the Executive Board Committee, Swiss Re	5/ 11
Ortwin Renn, Professor	Chairman of the Board of Directors of the Center for Technology Assessment, Stuttgart	21
Michael Siegrist, Dr	Senior Researcher and Lecturer, Social Psychology, Zurich University	7
Rolf Tanner, Dr	Head of Socio-Political Risk Research, Swiss Re	14
Peter Wiedemann, Dr	Head of the Programme Group “Humans, Environment, Technology”, Research Centre Jülich, Conference Manager	9/ 21
Antje Hellmann-Grobe, Dr	Moderator, Risk-Dialogue Foundation, St Gallen	7
Christoph Meili, Dr	Moderator, Risk-Dialogue Foundation, St Gallen	8

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**“The decisive element
is not whether genetic
engineering is dangerous,
but how dangerous it
is perceived to be.”**

Part 1: Open Forum: 3 November 2003

Perceptions of risk perception

When dealing with controversial topics, such as modern biotechnology, it is essential to distinguish between scientific and technical risk on the one hand and cultural and societal influences on the other. Whilst both of these aspects are equally important and intimately connected, they must be looked at separately for the purposes of a lucid debate.

The biotechnology industry quite rightly maintains that no health impairments have been attributed to commercially available GM products to date. And yet, despite this incontrovertible fact, modern biotechnology, like other novel technologies, creates new realities that the public tend to mistrust – realities that take them out of their collective comfort zone. But it is not only ordinary citizens and politicians that have been disconcerted. Actuaries and (re)insurance underwriters are also becoming more cautious and asking themselves whether the technical information available to them on modern biotechnology safety is, in fact, sufficient to be used as the only basis for estimating future loss scenarios. Tighter legislation or the emergence of matters of fact which become defined as indemnifiable losses both have a direct influence on the amount of liability risk insurers may have to bear.

Conference goal

Bruno Porro, Chief Risk Officer and Member of Swiss Re's Executive Board Committee, sketched the backdrop to the conference. In his opening address he explained that the event was one of the ways in which Swiss Re was contributing to the worldwide discussion on biotechnology, with a special focus on the associated liability risks. He explained how insurance solutions are currently being examined with a view to providing protection against measurable risks and stressed that, as it is patently impossible to exclude risk entirely, lawmakers should acknowledge that legal liability necessarily implies some exposure to risk and accept that this risk must be quantifiable if it is to be insurable. Porro stated that the insurance industry fundamentally supported the development of modern biotechnology but warned that only those risks which society is willing to accept can be deemed insurable.

The socio-political approach

Matthias Haller of the University of St Gallen introduced the issue of risk perception and underlined its general significance as a factor that influences the way society deals with core technologies.

According to Haller, risks exist where there is a possibility of a given action or process causing a result that deviates from what is predicted. He drew a distinction between "risk of action" and "risk of conditions". The term "risk of action" is used to describe deviation that affects strategies and plans over which one has a certain amount of control whereas "risk of conditions" is applied to parameters over which the individual has no influence. Thus the dominant factor for the "risk of action" is opportunity, whilst for the "risk of conditions" hazard aspects are at the fore.

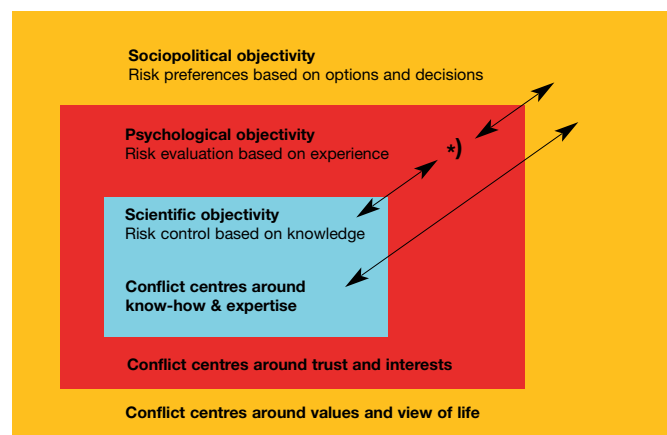
In traditional risk analysis, the "risk of conditions" only becomes perceptible when it obstructs or impedes plans and objectives. This is especially the case if the need for safety also arises in an environment which is involuntarily affected. Haller therefore hypothesised that the risk analysis of a specific technology should not only take into account scientifically objective criteria, but should include two further dimensions: psychological factors; and the pluralistic view of society.

As the figure below shows, Haller conceptualised the issue of risk perception by means of three levels of objectivity:

1. Scientific objectivity based on "knowledge and expertise" (blue),
2. Psychological objectivity based on "experience and competence" (red), and
3. Societal objectivity based on "options, decisions and values" (yellow).

Haller explained how the socio-political dimension is becoming increasingly important because, in today's world, where safety is uppermost in people's minds, the debate is no longer simply about threats, but increasingly about choices and values.

The three levels of notion related to risk



*) Conflict fields are simultaneously level-specific and level-transcendent

Adapted according to M. Haller and O. Renn

Relating this to practice, the basic idea of three levels of objectivity holds a key message for risk management, according to Haller: it all comes down to trust. Trust in politicians, the economy and science is diminishing. It is therefore no wonder that there is such widespread scepticism about modern biotechnology. Haller predicted that risk perception would become more volatile in the future, making it all the more important for companies to invest in building and maintaining "trust". He reminded the audience of the adage: trust is earned, not bought.

Open Forum

Haller concluded that unless the focus is considerably broadened, all risk assessment efforts would remain inadequate. One example he gave was the application of the “precautionary principle” in environmental legislation. This concept is gaining increasing significance in the debate on core technologies.

As emerged in the ensuing discussions, the precautionary principle is often misunderstood to mean the total exclusion of risk. For some lawmakers, no safeguards are safe enough. Representatives from the insurance industry therefore reminded participants of the frequently overlooked fact that legal liability is a conceptualised societal agreement on acceptable exposure to risk. For it is only accepted risks that can be dealt with psychologically by those affected by a related loss, borne by society and compensated in the form of insurance benefits.

The socio-economic approach

George Gaskell, of the London School of Economics and Political Science, added a further dimension to Haller’s levels of objectivity, namely the methodological contrasting of notions of risk. Referring to the Eurobarometer Surveys that were conducted in EU countries between 1991 and 2002, he came to the conclusion that public risk perception remains ambivalent. While Europeans are generally still waiting to be convinced, the Eurobarometer Surveys detected a slight shift towards a more positive appraisal of biotechnology in Europe overall: the number of people surveyed who were basically positive about modern biotechnology in 2002 was almost on a par with the 1993 figure. Furthermore, a comparison of data from 1999 and 2001 showed a clear rise in the number of people who were conscious of the benefits, as well as the risks, of genetically modified food. This is significant as the public’s awareness of the benefits of such a technology impacts their perception of the risk (ie if a given innovation is seen to have no benefits, it is likely to be perceived as more risky). However, Gaskell reminded his audience that public perception of risk and benefits still varied significantly depending on the specific application of biotechnology and depending on the country.

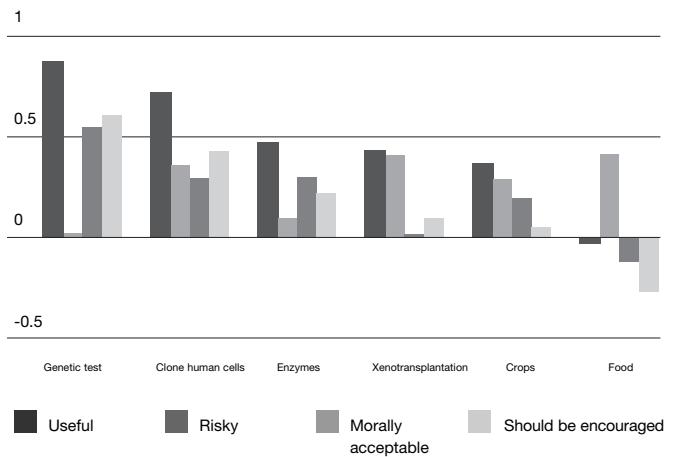
Gaskell went on to address the way risk perception is managed by politicians. He described the well-known fact that non-experts generally weight losses higher than gains, preferring safety to uncertainty, and explained his belief that it is not only scientific uncertainty and doubts about adequate risk management that play an important role in the public’s eye. There is also the question of ethical/moral uncertainty (Will scientific hubris meet its nemesis?), social insecurity (Can we trust the experts?) and the relationship between democracy and technological progress (Who decides what?). Last, but not least, the debate revolves around the issue of whether there are any viable alternatives to modern biotechnology that are worth exploring.

Finally, Gaskell turned his attention to cognitive methods of risk assessment: when assessing risks, the general public thinks more in terms of stories and pictures than abstract figures.

As a result, scientific risk assessments, including statements on the (low) probability of risks, will do little to resolve thorny biotechnology issues. In this respect, Gaskell agreed with Haller. According to Gaskell’s theory, the future of modern biotechnology depended on how well the perspectives outlined by Haller and himself were integrated and established within society.

The presentations by Matthias Haller and George Gaskell were followed by two panel sessions, where the biotechnology controversy was discussed from the three distinct angles of risk, trust and benefit.

Acceptance of six biotechnology applications in Europe



The figure shows the mean scores on a scale ranging from +1.5 to -1.5 for each assessed application of biotechnology, ie. zero represents the midpoint (2.5) of the raw data ranging from 1 to 4.

Source: Eurobarometer survey 58.0 2002

Perception and trust – a question of science or mindset?

What is the link between trust and risk perception? The first panel comprising experts from academia and industry dealt with trust as a basic prerequisite for accepting risks. There is evidence that trust can be built more easily if values are shared, and this is particularly the case where the public does not understand the underlying technologies.

Whilst there was consensus among the three panellists about the ways in which trust is lost – preaching and promoting, neglecting concerns and downplaying risks – some of the corporate approaches to regaining trust that were discussed proved to be much more controversial.

Klaus Leisinger, President and Executive Director of the Novartis Foundation for Sustainable Development, signalled the need for companies to inform themselves better on public opinion and to work together in dialogue with major stakeholders. He suggested that those who criticised the practices of a given company should be invited to discuss them with the organisation directly and thereby stimulate a continuous learning process.

Gabriele Neubaus-Url, Process Manager and responsible for scientific communication at Syngenta, in contrast, expressed her belief that more knowledge about science and GM products are the best basis for building and gaining trust. In her view, consumers know too little about gene technology and its potential uses and benefits. Her overriding message was that “we have to inform the public and seek for a constructive dialogue with the stakeholders”.

Representing the social sciences, *Michael Siegrist*, from the University of Zurich, stressed that knowledge alone does not create trust. He noted that many critics of modern biotechnology who were often extremely knowledgeable still fundamentally distrust biotechnology. This, Siegrist claimed, was to do with the relationship between visible benefits and hypothetical risks. As Gaskell had stressed previously, the tendency for people to weight the risks more heavily than the benefits is not a new phenomenon. As long as consumers are unable to perceive the benefits of modern biotechnology in a tangible form, eg in better-tasting fruit or vegetables, it will be virtually impossible to create genuine trust. The hypothetical risk will always remain dominant. In the course of the discussions it also became clear that letting consumers know precisely what it is they are buying is a vital part of the process of building trust. Customers can only make truly free and informed choices if GM products are suitably labelled.

Individual perception

Following on from this discussion, moderator *Antje Hellmann-Grobe* from the Risk-Dialogue Foundation, asked the audience to plot their position on an axis between the two ends of the room representing the poles “trust is increasing” and “trust is decreasing”. Interestingly, the result was an expected symmetrical Gauss distribution between the extremes.

However, the motives of participants for their choices were very different as the brief interviews carried out afterwards showed. Some participants had chosen a position based on their own attitudes, whilst others had tried to assess the most probable direction that public opinion would take. Other groupings tended to focus either on agricultural or pharmaceutical biotechnology, or to reflect the geographical location most relevant to them.

Various votes on the pessimistic end of the axis highlighted the cautious approach of insurers in contrast to excessive technical euphoria. Optimistic respondents underlined the importance of being able to show a direct benefit for consumers if trust in GM agricultural products in particular is to be boosted. Some of the voters reiterated that up until now the debate on benefits had failed to take sufficient notice of pressing food shortage issues in the Third World. Indeed, this point was barely touched upon in the Biotechnology Forum programme, mainly because the insurance industry is currently focusing most of its energy on liability issues associated with biotechnology, which chiefly affect the developed world.

Individual benefit

In a second panel discussion involving a representative of the food industry, academia and NGOs, the interrelation between risk perception and benefit was examined further. There was general agreement that demonstrating the benefits of modern biotechnology for users and consumers is crucial, but less agreement on precisely what these benefits would be, or what arguments should be used to get these messages across. A lively exchange took place between *Klaus Ammann*, Director of the Botanical Garden at the University of Berne, and *Benedikt Haerlin*, from the Foundation on Future Farming in Berlin, who both had widely differing views on the potential benefits of biotechnology.

Ammann’s arguments centred on the opportunities for the Third World. He cited ongoing research projects involving sweet potatoes and papaya, important sources of calories, vitamins and minerals for subsistence farmers in Africa and Asia, respectively. He described in some detail how the yields and quality of these crops are hampered considerably by viral diseases. Newly developed virus-resistant transgenic varieties will provide hope of better yields in the future. He also mentioned Golden Rice, a transgenic rice plant rich in vitamin A, which has been created to help fight vitamin A deficiency and the resulting health impairments in developing Asian countries.

Haerlin intervened with a request for examples of major innovations which had so far proven to be effective. A heated discussion ensued on how the benefits of GM products – such as the vitamin A rice already mentioned – rate against alternative possibilities. According to Haerlin, “trust in blue” (ie true science) is very “red” (ie subjective), to use the colours in Haller’s model of the three levels of the notion of risk (blue,

Open Forum

red and yellow). Ammann argued in favour of a “symmetry of ignorance” on the “yellow” level due to the lack of conciliation, and expressed the hope that better products would lead to better dialogue.

The question of which genetically modified foods would actually be brought to market was directed to *Vincent Pétiard* from the Nestlé Research Centre in Tours. He stated that global food manufacturers are highly consumer-driven and respond to regional markets and customer preferences with a range of products. This means that GM soy for example, or coffee that is already caffeine-free when grown – an option currently being researched – may turn out to be successful in one market, but fail spectacularly in another. Pétiard staunchly defended the view that the regulations governing GM products were disproportionately tough compared to those applied to conventional ones, adding that such an approach was increasingly restricting important innovation, especially for orphan crops essential for developing countries which do not afford the costs for registration imposed by tighter international regulation.

What about the developing world?

The subsequent discussion, moderated by *Christoph Meili* of the Risk-Dialogue Foundation, then turned to the question of how to develop innovative and useful products needed to solve medical and nutritional problems. Around one billion people do not have enough food to eat and half of the world’s population does not have access to appropriate medical care. Whilst some participants were of the opinion that under these circumstances questions of safety and security paled into insignificance, others maintained that it was vital to resolve possible long-term risks associated with biotechnology in spite of urgent food shortages in many regions of the world. As one participant noted, at the end of the day, the issue is whether a product coming under scrutiny makes sense and adds value.



Conclusions and fallacies

Conference Manager, *Peter Wiedemann*, from the Research Centre Jülich, took on the challenging task of summarising and evaluating the key statements from the Open Forum for participants of the second day of the conference. Under the heading “Risk, trust, benefits and framing fallacies”, Wiedemann addressed a sticking point in modern biotechnology – to which, in his opinion, too little attention had been paid – namely the issue of preferences and options, which is often not a matter of risk. In other words, the debate framing the “risk” issue does not necessarily deal with public concerns in their entirety.

The risk-framing fallacy


According to Wiedemann, fundamental ethical issues and attitudes to global economic development play a key role in the discussion on modern biotechnology, but neither supporters nor opponents really bother to address these issues. In other words, anyone involved with Haller’s (yellow) objectivity level is faced with the additional challenge of having to factor in diverging patterns of thinking and a whole range of values.

These values apply, in Wiedemann’s view, to both “left” and “right” political stances, exponents of which do not always manage to fully comprehend public ethical considerations because they are, necessarily, too focused on scientific risk assessment issues. Furthermore, risks are easier to debate than values. If politicians and scientists choose to avoid a debate on fundamental values and ethic considerations, they risk providing answers to questions which the general public does not always understand and which, more importantly, are not even perceived to be of relevance to the issues at hand.

The trust-framing fallacy

Wiedemann also summarised the discrepancies between what the biotechnology industry says and what it actually does, as well as between what it does and what the public expects, all of which results in a loss of trust. With this observation, he introduced a counterpoint to the conclusion of the Open Forum that open communication was the ideal way to build trust. However, who in the biotechnology community would have thought a number of years ago, for example, that environmental organisations would oppose transgenic plants – plants that require fields to be sprayed with fewer chemicals? At that time, many researchers believed that the general public saw no major contrast between “genetically modified” and “ecological”. Researchers long thought that the problem was not paucity of information but a lack of knowledge. This made it difficult for scientists to identify the public’s expectations.

One of the key reasons for this error: parallel to economic perspectives, too little attention had been paid to both the perception of individual benefits and to societal discourse. Thus, Haller’s observations on the risk are also applicable to the evaluation of benefits. Admittedly, so far no empirical studies have been carried out in this area, although they have been available for the risk aspect for many years.



**“Different value systems
make it difficult for
international bodies
to create a meaningful
framework and multilateral
regulations that are
respected by all.”**

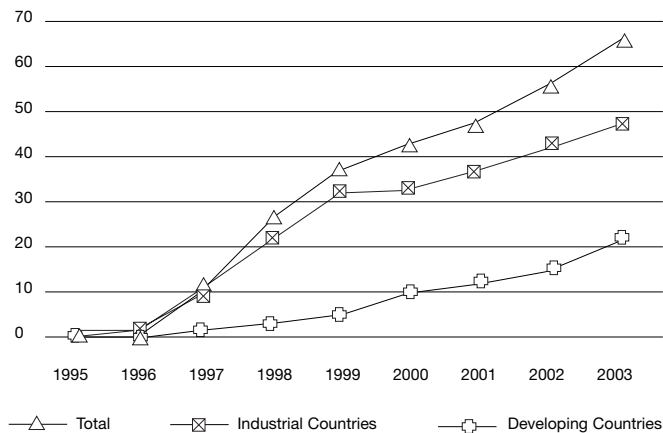
On the cutting edge between regulation and renunciation

In the Specialist Forum on liability and insurability in biotechnology, the focus shifted from public perception of risk, benefits and trust, to the consequences for the political agenda, legislation, court decisions and liability insurance.

The participants further looked at the area of modern biotechnology whose future application is most in jeopardy: agricultural (or “green”) biotechnology. This prioritisation inevitably meant that less attention was paid to pharmaceutical (or “red”) biotechnology risks, although these are just as relevant from a regulatory and economic point of view.

Is agri-biotechnology doomed to the same fate as nuclear technology or is it set to revolutionise food manufacturing? Are the current strategies capable of resolving conflicts within individual societies or in bilateral trade? What is – and what isn’t – the insurance industry’s role? The aim of the second day of the conference was to come up with some answers and approaches to solving the issues discussed.

Increasing global area of GM crops



GM Crop Countries (2003):

USA	42.8 m ha	Honduras	0.5 m ha
Argentina	13.9 m ha	Indonesia	0.5 m ha
Canada	4.4 m ha	Mexico	0.5 m ha
Brazil	3.0 m ha	Philippines	0.5 m ha
China	2.8 m ha	Spain	0.5 m ha
Germany	0.6 m ha	South Africa	0.5 m ha
Rumania	0.6 m ha	Uruguay	0.5 m ha
Bulgaria	0.6 m ha	Australia	0.1 m ha
Columbia	0.5 m ha	India	0.1 m ha

Total: 67.7m ha = 123% surface France
Source: Clive James, 2003

A framework for insurability

Bruno Porro, Chief Risk Officer with Swiss Re, opened the Specialist Forum by explaining why the insurance industry is participating in the debate on modern biotechnology: “Put up or shut up?” was the underlying question of his keynote address.

Insurance companies have for many years kept a low profile in public. Insurance was considered to be a “gentlemen’s business” that went on quietly in the background. Even more than other commercial activities, insurance business is based on trust between insurers and the insured. But what is the key element of this relationship of trust? First and foremost, policyholders and insureds have to know that the insurer will be in a position to fulfil its contractual obligations in the case of a loss. Consequently, insurers are constantly having to maintain others’ confidence in their solvency through competent risk management. Only if they openly communicate to the public about the risks that they insure will they be in a position to demonstrate the benefits that they can provide and identify the limits imposed upon them.

As liability issues relating to modern biotechnology increasingly began to take centre stage, Swiss Re overcame the industry’s traditionally reserved attitude and regularly engaged in debate with other political, economic and social interest groups. According to Porro, the intention was to make clear to all stakeholders at an early stage just where the limits of insurability for modern biotechnology lay: if the function of insurance in an industrialised society is to allow riskier behaviour and temper the possible consequences, then what was needed was a consensus within society on which tangible and intangible values can be replaced by money in the case of a loss.

Porro outlined how “zero risk” and the formulation of strict liability laws to cover the eventuality that conventional agricultural products become contaminated with GMOs in the global chain of commerce were two factors that called into question an essential cornerstone of traditional risk transfer, namely the fundamental acceptability of insured risks. Without this condition, claims for damage will be asserted for the slightest thing or may even be inevitable. This would mean that a number of criteria for insurability – such as fortuitousness, measurability and an involved party’s inability to influence a specific loss – would no longer be fulfilled.

Porro went on to describe how, on the back of these developments, Swiss Re had introduced measures in risk management, claims management and risk underwriting to limit this exposure. Specially adapted wordings provide a clear description of the conditions applying to the cover of bodily injury and property damage arising from gene technology³. Thus, Porro passed the ball to the politicians. The political mechanisms were described by the speakers that followed using the example of the UK.

³ Further information on insurability can be found in the section on Thomas Epprecht’s workshop, pages 17.

Specialist Forum

Risk policy and political risk as a reflection of public opinion

Political decisions result from societal, scientific and economic discussion. This was the subject of two further presentations. In the first of these, *Malcolm Grant*, in his capacity as Chairman of the UK Agricultural and Environment Biotechnology Commission (AECB), outlined how the British government is steering the information-gathering process in practice and what conclusions it has reached⁴. The second speaker, *Erik Millstone*, provided a theoretical view of how politics and science can interact with one another, how the relationship has changed over time and what conclusions the insurance industry can glean from this.

The role of the public in setting the political framework

The process set up by the British Government on advice from *Malcolm Grant's* commission (AECB) was based on a wide-ranging dialogue with the public, scientists and business people and formed part of a far-reaching public evaluation on three levels: the science review, the economics review and public debate (GM Nation).

A) The science review

The first dialogue level, the science review, dealt with the state of scientific knowledge and the remaining scientific uncertainties. Grant summarised the four key points derived from the science review:

1. There is no reason to ban GM crops, but also no reason to grant blanket approval.
2. Whilst the risks posed by GM crops are estimated to be very low, uncertainty remains particularly with regard to allergenicity, fitness and the impact of such crops on wildlife.
3. Gaps in knowledge, uncertainty and complexity will increase as the number of transgenic plants on the market rises.
4. The industry has a particular duty of care with regard to transgenic design and the selection of plant hosts.

B) The economic review

The second level, the economic review, undertaken by the Prime Minister's Strategy Unit, concentrated on a comprehensive report on the costs and benefits of GM crops in the UK. Various scenarios were selected for the forecast which showed that the economic future of transgenic food is dependent in particular on consumer behaviour; they also highlighted the significant potential benefits that future developments in GM crops could hold. Against the backdrop of possible – or, in the case of WTO conflict, existing – international implications, it was finally concluded that national decisions on GM crops could have a major impact not only on the UK.

C) The public debate

Malcolm Grant was asked by the Government to lead the third dialogue level, the public debate (GM Nation) which formed the core of his comments. Grant was given complete independence, within tight budgetary and timescale constraints,

on its organisation and management. For the first time in the history of technology, a far-reaching risk dialogue had been held with some 36,000 participants. Taking the possibility of commercial production of GM crops in the UK, the aim of the dialogue was to obtain meaningful information about the nature and range of the public's views, particularly at grass-roots level. The government's GM Nation project was aimed at creating as broad a base for making decisions as possible.

Grant summarised the results of the public debate in seven points⁵:

1. People are generally uneasy about GMOs.
2. The more people engage in issues of modern biotechnology, the harder their attitudes and the more intense their concerns.
3. There is little support for early commercialisation of GMOs in agriculture.
4. There is widespread mistrust of government and multinational companies.
5. There is a broad desire to know more and for further research to be done.
6. Developing countries have special interests.
7. The debate was welcomed and valued.

D) More knowledge – better politics?

Grant used the example of three-year farm scale evaluations (FSEs) in the UK to show that increased knowledge does not necessarily increase acceptance. The FSEs looked at whether weedkiller-tolerant GM crops affect the abundance and diversity of farmland wildlife compared with the growing of conventional varieties of the same crops (rapeseed, beet and maize). In short, the FSEs did not demonstrate evidence of an adverse environmental impact from GM maize, while GM sugar beet and rapeseed testing indicated the environment could be at risk: they diminished the number of insects and seeds on which farmland birds depend, for example. Whether this marks a victory for traditional agriculture remains to be seen, as this too, as an anthropogenic activity, impairs biodiversity through the use of pesticides or, as in the Third World, clearing and inefficient land use. Grant concluded that, whilst discussion is an integral part of understanding complex relationships, any decisions would ultimately always remain a political matter.

The role of science in regulatory policy-making

As the example of farm scale evaluations shows, scientific results cannot replace political decisions. The situation for lawmakers becomes difficult if a specific effect cannot be established or definitively ruled out. The situation is aggravated because the modern scientific concept of causality is based on probability considerations. Politics and the legal system require certainty – something which modern science is seldom able to provide.

⁴ See also www.aebc.gov.uk

⁵ For more details refer to http://www.gmnation.org.uk/ut_09/ut_9_6.htm#summary

Risks whose very existence is unproven and perhaps unprovable, yet which raise real scientific and legal dilemmas, are called “phantom risks”. The question of how politics can react to these risks and other, real, dangers was the topic of the speech by *Erik Millstone*, Director of Studies in Social Policy Research from the University of Sussex. He discussed three different models for public regulatory policy-making and compared their suitability for identifying emerging risks and affording protection.

A) “Sound” science: the technocratic model

Millstone placed “industrial self-regulation” on the lowest level of public control. He considered it “inherently unprecautionary and inappropriate in most risk policy contexts”. According to him, this approach begets the “technocratic model”, where policy is based on “sound science”. In a regulatory context, this model remains the dominant one used in the US. Millstone criticised: “Under those conditions regulatory capture is almost inevitable, and the underlying nature of decision-making is typically disguised as if it were based on what is often referred to as “sound science”. However, when public controls on risks are represented as being based on “sound science” that typically means that uncertainties have not been acknowledged and that the criteria for assessing claims are similar to those used in academic science, where claims are only accepted if they are very highly certain.”

B) “Neutral” science: the decisionist model

A step forward according to Millstone was the introduction of the “decisionist model”, which acknowledged that scientific considerations alone cannot determine policy decisions, and that non-scientific and political issues have an indispensable role to play. In this model, scientific risk assessment comes first, followed by policy-making. As a result, however, science would be represented as if it operated in a social, political and economic vacuum, assuming that scientific advisors assess risks in a socially and ethically neutral way. Millstone illustrated the limitations of the decisionist model using disputes between the US and the EU over GM crops, and between EU member states. He explained that these arose not because the expert advisors had conflicting views on common issues, but because the issues they were addressing were themselves different. Below are some examples of non-scientific assumptions that impact risk assessment:

1. What is to be counted as “harm”?
2. Which environmental changes should be assessed and which of them are unproblematic adaptations?
3. What kinds of evidence is relevant and which uncertainties really matter?
4. How is the benefit of the doubt to be awarded? and
5. What are the benchmarks by which evidence should be evaluated?

C) “Integrated” science: the co-evolutionary model Millstone described his preferred model co-evolutionary. Such a model recognises that scientific risk assessments are conditioned by a set of “upstream” framing assumptions. These framing assumptions clearly influence the way in which scientific risk assessments are conducted and set the agenda for those deliberations. Thus, the choice is not between making, or not making, upstream framing decisions but between doing so implicitly and covertly or explicitly and legitimately. He pointed out that transparency and stakeholder participation are thus not a matter of political correctness but of analytical rigour.

D) Conclusions for insurers

Millstone recommended that the insurance industry should not rely exclusively on science-based risk assessments provided by the biotechnology industry or governments, but rather on their own considerations to ensure that they are scoped by reference to the risks they envisage underwriting. He encouraged insurance companies to gather multiple scientific opinions and as broad a range of stakeholder perspectives on the risks as possible. In this, Millstone was preaching to the converted: in-house risk assessments are continuing to gain in importance amongst re/insurers writing industrial business.

From the conference organiser’s point of view, one final point should be made: it is often the case in connection with strict liability regimes that compulsory insurance cover is pushed with the line that insurance companies use strict risk selection criteria and should be able to filter out dangerous activities. In other words, the regulator can shift its own role to the insurer. This should be prevented, for two reasons. Firstly, because the role of insurance companies in society is to facilitate inherently risky activities. Secondly, an insurer’s risk selection criteria are geared primarily to the liability risk for which cover is offered, and the risk decisive for society in its broadest sense is subsidiary in this respect.

Specialist Forum

Globalisation with borders – risk management as a form of trade policy

The third panel discussion examined the regulatory polarisation and trade conflict over GM crops between the US and other GM-producing nations and the EU and other countries that generally favour a more “precautionary” approach. The discussion did not focus on the pending transatlantic WTO dispute over GM crops, however; rather, it centred on the cultural and intellectual background, the dominant models of regulatory policy-making in both regions and the possibility of resolving the trade conflict.

Conflict levels and intellectual tradition

The world has global and local traits: global with regard to the use and commercialisation of biotechnology products; local because rapid market liberalisation on a global scale is always accompanied by a multitude of efforts to protect local traders and traditions. The trade disputes that this begets primarily take place on two levels, as *Rolf Tanner*, Head of Socio-Political Risk Research at Swiss Re, explained: on the one hand there are tangible commercial interests and policy issues, which do not differ significantly from the disputes on bananas, hormone-treated beef or steel tariffs; on the other we have friction between consumer values in Europe and the US, which forms the socio-cultural basis for the current WTO trade dispute between these two powers.

This difference in values is due, in part, to different intellectual traditions. By nature, the US tends to adopt a proactive stance in line with the motto “make the world your own”. This culture relies on rehabilitation and reinstatement in the case of harm. Europeans take a different view. They tend to be more reactive and suspicious of technological advances. The precautionary principle – ensuring harmony between man and nature – is often factored into decisions. So, whilst public discussion in the US revolves around the economic opportunities that biotechnology represents, in Europe the focus is on the risks.

As a result, people in the US have far greater confidence in their regulatory authorities (EPA and FDA) than Europeans have in their counterparts.

A common framework for different value systems?

As *Ruth Mackenzie* from the Centre for International Courts and Tribunals of the University College London described, these differing value systems and domestic approaches make it difficult for international bodies like the Convention on Biological Diversity and the WTO to create a meaningful framework and multilateral regulations that are generally respected by all. While any resolution of the current dispute

between the US and the EU in the WTO might provide some further guidance, it was unlikely to address all outstanding areas of disagreement, that are frequently characterised as a debate between a “sound science” approach and the “precautionary principle”. In particular, she suggested that progress resolving ongoing disagreements between the US administration and the EU authorities over the need for and approaches to traceability and labelling, which had been debated in WTO Committees, would be slow until Cartagena Protocol negotiations on these issues had been concluded⁶.

Prognosis: on the pessimistic side

The panellists agreed that future harmonisation would be improbable because the trends are moving in different directions. *Thomas Bernauer*, from the Center of Comparative and International Studies at the Swiss Federal Institute of Technology, argued that the global regulatory polarisation and the WTO conflict not only exacerbated existing domestic controversies, especially in EU countries, but also threatened to fragment international agricultural markets, reducing returns on investment from agri-biotechnology and discouraging further private-sector investment in this area.

Faced with this transatlantic controversy, other countries are being forced to either align with one or the other of the world’s two largest economies or struggle to find some middle ground. Participants were of the opinion that the trade conflict might exert a chilling effect on public-sector research in developing countries, where, debatably, modern agri-biotechnology is needed most to raise local crop yield. They also noted that there was a risk that farmers around the world would slow down the adoption of this technology due to uncertainties about market access for GM products.

Bernauer was pessimistic about the chances of reaching consensus in the WTO dispute. He forecast further escalation if the US trusts only in its own market force and the EU refuses to ease its de facto moratorium and regulations on labelling and traceability⁷.

⁶ Note: The Conference of the Parties (COP/MOP1 – Biosafety Protocol), which took place in Kuala Lumpur in February 2004, did not feature in the discussions at the International Biotechnology Forum (for more information see <http://www.biodiv.org/biosafety/>)

⁷ Given the new, tougher EU rules on traceability and labelling of GM foodstuffs that came into effect on 18 April 2004, there is no longer a basis for the “de facto” moratorium that has been in place for more than five years preventing new GM plants or foods being authorised. A meeting of EU agricultural ministers on 26 April 2004 failed to reach a qualified majority to prevent authorisation of a new transgenic type of maize. This could herald the end of the moratorium.

Workshops: Reflecting on mindsets

The different approaches to regulation

Workshop series one

The different approaches to regulation were broached in-depth in three parallel workshops on prevention, precaution and liability law. Taking current GMO legislation in Europe, the US and at international level as a basis, speakers and participants discussed the implications for environmental protection, technological development and informed choice.

The US approach: Product-oriented quality standards as the legal driver

Richard Murray, Chief Claims Strategist at Swiss Re, described the possible consequences of the US “litigation culture” for gene technology. Whilst the European system of process-oriented regulation of technology means that legislation already exercises a strong gatekeeper function, this is largely lacking in the American system. In the system of product-oriented approval, decisions are taken on a case-by-case basis, following the principle of substantial equivalence; in this system the approval body is the sole “gatekeeper”, meaning that a product and its manufacturer are much more exposed to liability suits in the US once approval has been granted, firstly because people’s propensity to file a suit is significantly higher and, secondly, because class action suits are a very effective means for lawyers to put pressure on industry.

Murray used a number of examples to underline the growing importance of the duty of care for a company to accompany its product safety measures. The result of this development could be the carving up of large companies into smaller independent units, which will prevent entire companies being at risk if liability claims are lodged against “risky” parts of the business. Naturally, this will have repercussions for the insurance industry. With time there will be less diversification of risk under one large individual policy.

With regard to the key role played by the approval authorities, Murray believed the key question was how power would be distributed between the authorities and the justice system, and what status the authorities’ assessment criteria would have with regard to law suits filed. Possible ramifications could include stricter rules for granting approval and tougher regulatory hurdles, or further empowerment of the bar association.

The EU approach: Process-oriented prevention goals as the legal driver

Mark Cantley started his presentation by looking back at the historical development of gene technology regulations in the EU compared with the US and elucidating how the conflict

between the two regions arose. When recombinant DNA technology first emerged in the mid-seventies to the mid-eighties, researchers imposed their own restrictions and guidelines for safe procedures in order to obviate possible risks. As experience with the new technology grew, so did scientific trust in it. Finally, in 1986, US regulatory policy was set out in the “Coordinated Framework”, which stated that the new techniques did not raise new or special risks. In parallel, the OECD published the “blue book”, which noted “that there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms.” At first, even the EU followed a similar course until existing national regulations forced it to take action and introduce EU Directives 90/219 and 90/220 covering the use and release of GMO for research purposes.

Shocked by images of mad-cow disease in Britain, contaminated blood in France, adulteration of cooking oil in Spain and dioxin-contaminated animal feed, the public rapidly lost faith in self-regulation. The political agenda adopted the precautionary principle, which found widespread support at grass-roots level; the list of EU regulations and directives and restrictive national policies grew longer and longer⁸.

The most recent spin-off of these diametrically opposed positions is the WTO dispute between the US and the EU. The US administration is demanding that the EU not be allowed to impede the import of GM products by claiming the need for increased safety or labelling regulations.

The UN approach: Procedure-oriented consensus-building as the regulatory driver

In parallel to the two workshops on the US and EU approaches, *Willy de Greef* investigated what is happening to regulation on the international stage. He focused on the UN Cartagena Protocol on Biosafety (CPB), which came into effect on 11 September 2003.

In essence the Protocol:

1. Sets out principles and methodologies on how to conduct a risk assessment,
2. Requires advanced informed agreements (AIA), ie sets out procedures that have to be followed, and the permits obtained, before a living modified organism (LMO) may be moved across national borders,
3. Denominates responsibilities for the exporting parties, and
4. Creates a biosafety clearing house (BCH) which makes the relevant information available to all parties and operators involved.

⁸ – Regulation 258/98 on novel foods and novel food ingredients
 – Directive 1998/44 on legal protection of biotechnological inventions
 – Directive 2001/18 on deliberate release into the environment (90/220/EC)
 – Regulation 1829/2003 on GM food and feed
 – Regulation 1830/2003 on traceability and labelling of GMO (001/18/EC)
 – Regulation 1946/2003 on transboundary movements of GMOs
 – Directive 2004/35 on environmental liability with regard to the prevention and remedying of environmental damage

Workshops: Reflecting on mindsets

Although de Greef basically welcomed the Protocol as a positive step, he did point out a number of its shortcomings. He emphasised that the Protocol was alarmingly out of touch with reality and current developments in the biotechnology field. He felt that the Protocol had been drawn up under the assumption that multinational corporations (MNCs) are more or less the only companies who deal with GMOs internationally. He also noted that the CPB had essentially been exclusively negotiated by national environment ministries from industrialised countries. The UN had received very limited input from other stakeholders – agricultural researchers, farmers, scientists and food producers – when compiling the CPB.

De Greef observed that developing countries did not have sufficient capacity to fulfil the comprehensive documentation obligations and that operators lacked practicable guidelines. According to de Greef, the Protocol failed to provide for transition guidelines. In short, he believed the Protocol still has a long way to go.

De Greef reminded his audience that many liability-related issues still remained unclear – Who is liable? Strict or fault liability? Does “damage” mean damage to biodiversity or damage in general? – and rounded off his presentation with the comment: “There is a great need for more direct involvement of operators – public and private – in the process.”

Discussions

The ensuing discussion made it clear that one issue is paramount for industry representatives: international harmonisation. It is key because the various regulatory systems – with their different tolerance values of GM crops commingled with conventional crops and, in some cases, laborious labelling and traceability procedures – generate costs and liability risks which are restricting free trade. At the moment, the only alternative is to define a separate strategy for each individual market. However, commingling remains a problem along the entire production chain.

At this point representatives of the insurance industry intervened in the discussion with the watchword *StarLink*⁹ and debated the question of whether further cases of this kind were inevitable if legislation were not harmonised. They discussed what claims

pattern could emerge from attempts to conciliate support for free trade with the need for precautionary protection against risks.

This prompted heated exchanges on the threat of numerous related claims from various players in the trade and value chain, including the controversial Anglo-Saxon legal practice of class action.

Discussions revealed that, despite the US government’s and public’s liberal attitude to gene technology, the US’s litigation culture risked being no better protected against costly gene technology claims than any other.

⁹ The StarLink case: In September 2000, Genetically Engineered Food Alert (GEFA), a coalition of food safety and environmental organisations active in the US, claimed that traces of genetic material from StarLink corn had been found in corn tortillas produced by Kraft Foods. Kraft immediately recalled some 2.5 million packages of their US supermarket “Taco Bell” brand. Later, many other food producers joined the voluntary recall campaign, removing from the shelves about 300 products made with the suspect yellow corn flour. In total, the economic costs arising from the unauthorised commingling were estimated at more than one billion US dollars. What had gone wrong? StarLink corn entered the food supply chain after the relevant US authorities (EPA, FDA, and USDA) had issued a split approval, permitting its use for animal feed and industrial use, but withholding clearance for human consumption, since it was suspected of possibly triggering allergic reactions (which, incidentally, has never been proved).

Workshops: Reflecting on mindsets

Implications of the various regulatory approaches

Workshop series two

A further set of three parallel workshops looked at the implications of the various regulatory approaches discussed in the previous round for the system of world trade, the insurance industry and the biotechnology industry.

Implications for world trade

Because risk policy is always also a question of trade policy, *Thomas Bernauer* started by re-examining the whys and wherefores of the emerging trade conflict on agri-biotechnology between the US and the EU. It again became clear that regulatory differences and approval procedures involving distinct criteria – substantial equivalence in the US, precautionary principle in the EU – arose from different value systems and upstream framing decisions (Millstone).

Are cooperative or unilateral policy tools suitable for coping with trade disputes? According to Bernauer, voluntary non-coercive measures such as mutual recognition, compensation or unilateral regulatory adjustments for harmonisation have only limited effect when dealing with regulatory diversity. Nevertheless, measures imposed by the WTO would have too little impact, either because WTO rules do not provide enough guidance as to whether the defendant's regulations are legitimate, or because the defendant is economically powerful and is unlikely to comply with an unfavourable verdict.

Looking to the further development of the conflict, the speaker outlined three possible scenarios:

1. The EU lifts its moratorium on approvals and the US withdraws its case from the WTO.
2. The EU lifts its moratorium, but the US maintains its collision course on labelling and traceability. The conflict escalates and the WTO issues a formal ruling, which, should the US be successful, will mean punitive measures for the EU.
3. The EU maintains its moratorium and the conflict escalates.

The participants agreed that an escalation under scenario 2 was the most likely. This is because the effects of EU restrictions are felt by a small but powerful group of economic actors in the plaintiff country. This small group would benefit from concessions by the EU, should escalation in the WTO be successful. It thus has a powerful incentive to organise and push the US government toward escalation. The costs of

escalation for the plaintiff country – in terms of economic countermeasures or disruption of further trade talks, for example – would obviously be more widely dispersed. Thus, the incentive of those bearing the costs of escalation to lobby the government not to escalate is much smaller. However, the still unforeseeable ramifications, for other trade issues as well, means that there will be no real winners and developing countries will once again be the main losers.

Implications for the insurance industry

Thomas Epprecht, responsible for the Top Topic gene technology at Swiss Re¹⁰, took up the comments made by Bruno Porro that morning in his workshop.

What happens if you add a drop of blue food colouring to a glass of water? The colouring spreads quickly and after a short time the water is a uniform light blue. The speaker used this short experiment to illustrate the problem of commingling of genetically modified crops with conventional crops. As in the case of the coloured water, it is not the health risks that are at the core of the issue – although these do often dominate the debate. The commingled amounts are usually small, but – and this is the essential point – they can no longer be removed, and the quality of the entire product is impaired.

A) The commingling problem

Epprecht continued with the coloured water metaphor pointing out that people may refuse to drink it if they were not convinced by the argument that it does not affect their health. The same applies, he said, to gene technology. To date, most insurance claims concerned unintentional or unlawful commingling in the production chain of mass agricultural goods, where it is virtually impossible to segregate GM food ingredients entirely from conventional products. And yet this is precisely what many consumers or national regulations are demanding.

The speaker used the StarLink case to illustrate the potential size of losses caused by commingling. This case, which resulted from a so-called split approval, is the most expensive in the history of agri-biotechnology. Epprecht warned that simply abolishing split approvals for animal and human foodstuffs would not solve the issue of commingling, and mentioned another case in point, the “ProdiGene Case”, named after the company that had sown a GM corn variety containing a pig vaccine which was subsequently found to have contaminated edible soybeans¹¹.

¹⁰ Swiss Re continuously monitors industry developments which could potentially impact its corporate value, bottom line or strategy. “Top Topics” is the process through which Swiss Re works to anticipate, identify, analyse and communicate to stakeholders the key issues affecting the global management of capital and risk.

¹¹ The ProdiGene case: the questionable planting of a GM corn variety which contained a pig vaccine was conducted on a trial basis with approval by the US Department of Agriculture (USDA). It used the same fields in which edible transgenic soy was sown the following year. After harvesting the soy, it was found to be mixed with the previous year's corn containing the pig vaccine. The commingling, probably due to remaining scattered corn seeds on the fields, was only detected in the warehouse. Subsequently, the entire crop of potentially contaminated soybeans had to be burned.

Workshops: Reflecting on mindsets

Commingling claims similar to those filed against StarLink or ProdiGene will continue to arise, he claimed, for as long as there is zero tolerance towards commingling or for as long as differing legal regulations – on approvals granted, threshold values or rules on declaration – provoke a situation in which permissible commingling in one country is not permitted in another, and thus force a liability issue as soon as the product crosses the border.

Although this means that losses are inevitable, global agriculture is avoiding a plea for complete segregation for reasons of cost and practicality. Epprecht explained that whilst this is understandable from an economic viewpoint, the insurance industry cannot be expected to provide cover for such unquantifiable financial losses stemming from attempts to cut costs along the agri-food value chain.

Given the legal environment, which is becoming increasingly stringent regarding safety, control and reversibility particularly in Europe, Epprecht pointed out that the cover options for the risk of harmless but unwanted commingling are diminishing. This presents the insurance industry with a problem, since insurance cover can be provided only if there is a clear definition of loss and agreement in society at large as to which risks are acceptable and could be compensated in monetary form in the event of a loss.

B) Consequences for insurability

Epprecht continued by summarising the insurance industry's position regarding liability cover as follows:

Swiss Re and a large majority of other insurers are prepared to continue to offer liability cover for bodily injury and property damage relating to gene technology. The potential negative health implications stemming from genetic engineering products are, according to latest scientific knowledge, fundamentally no different from those of other products. However, liability risk may change as more pharmaceutical and agricultural products are launched on the market, and the potential side effects of both products and tightening regulation may not manifest themselves until much later. Nevertheless, the insurance industry is alert and is constantly monitoring modern biotechnology and associated developments in its legal and societal context. Further, insurers watch carefully for any indications of deviations from the expected, their intention being to react as early as possible, adapt the assessment of risks and apply the corresponding supporting measures to limit them.

Payment for bodily injury and property damage also makes sense from an economic and a societal point of view. However, in the case of purely ecological damage and/or claims resulting from commingling of GMOs and conventional products, there is a clear trend towards full exclusion in the insurance industry, as is the case for purely financial losses in many traditional covers. The speaker again pointed out that in these instances society

must find agreement on the definition and monetary dimensions of a loss before insurers are able to put a figure on it. This is clearly not the case with definitions of bodily injury which permit "fear of damage" claims. These should be avoided at all cost.

Epprecht underlined the importance of supporting measures to limit risks. Unforeseeable, ruinous loss accumulations in the form of class action or a flood of suits prompted by (alleged) late claims must be avoided. Therefore, claims series or batch clauses and limited cover combined with clear and precise loss and event definitions are just as important as the clear time allocation of a claims series under a given treaty. This is the only way to obviate the "stacking of limits" issue.

The speaker moved on to explain that it is advisable to apply the claims-made trigger, which allocates a claim or a series of claims to the insurance year in which they are first made. In view of the extremely long limitation periods of up to 30 years being applied to gene technology in some countries, it will become ever-more important to keep the period between collecting the premium and possible insurance payouts as short as possible. The insured should be obliged to monitor their products as best they can throughout the entire value chain, as well as provide adequate instruction to consumers. Epprecht pointed out that these conditions prompted Swiss Re to develop specimen gene technology clauses for both treaty and facultative business which take into account the complexity of the issue and have established themselves as one possible standard in the market.

Participants in the workshop were especially interested to hear about the position of leading (re)insurers on the co-existence of GM crops and conventional crops. At present, there is a dearth of tailor-made insurance products or additional cover for the risks of co-existence. Some market participants are also waiting for the development of non-traditional reinsurance products which distribute the risk between the insurer and insured. The speaker also indicated that, in the long term, it will be essential to offer special covers for those gene technology risks which are subject to special liability. For this purpose, he suggested using similar aspects in environmental liability and underwriting as a guide.

Implications for the biotechnology industry

Referring to her four years as Regulatory Affairs Manager at the European headquarters of a leading US-based biotechnology company, *Ariane Koenig* outlined the implications of regulatory diversity for corporate innovation strategies.

Her experience was that the regulatory strategy of corporates developed in parallel to technical developments: in the 1980s her former employer pushed the Reagan administration to regulate this novel technology in order to convince the public of its benefits and also to protect its leading position in the market. Environmental and consumer groups were engaged as consultants. In the 1990s, the leading company in GM crop innovation spoke out in favour of a simplified and accelerated US regulatory process and even voluntarily consulted the FDA.

Workshops: Reflecting on mindsets

It lobbied for the US approach to regulation elsewhere, and against labelling. In the early 2000s, the company combined its support for the US government's filing of a WTO suit with dialogue on customers' needs in a decentralised process.

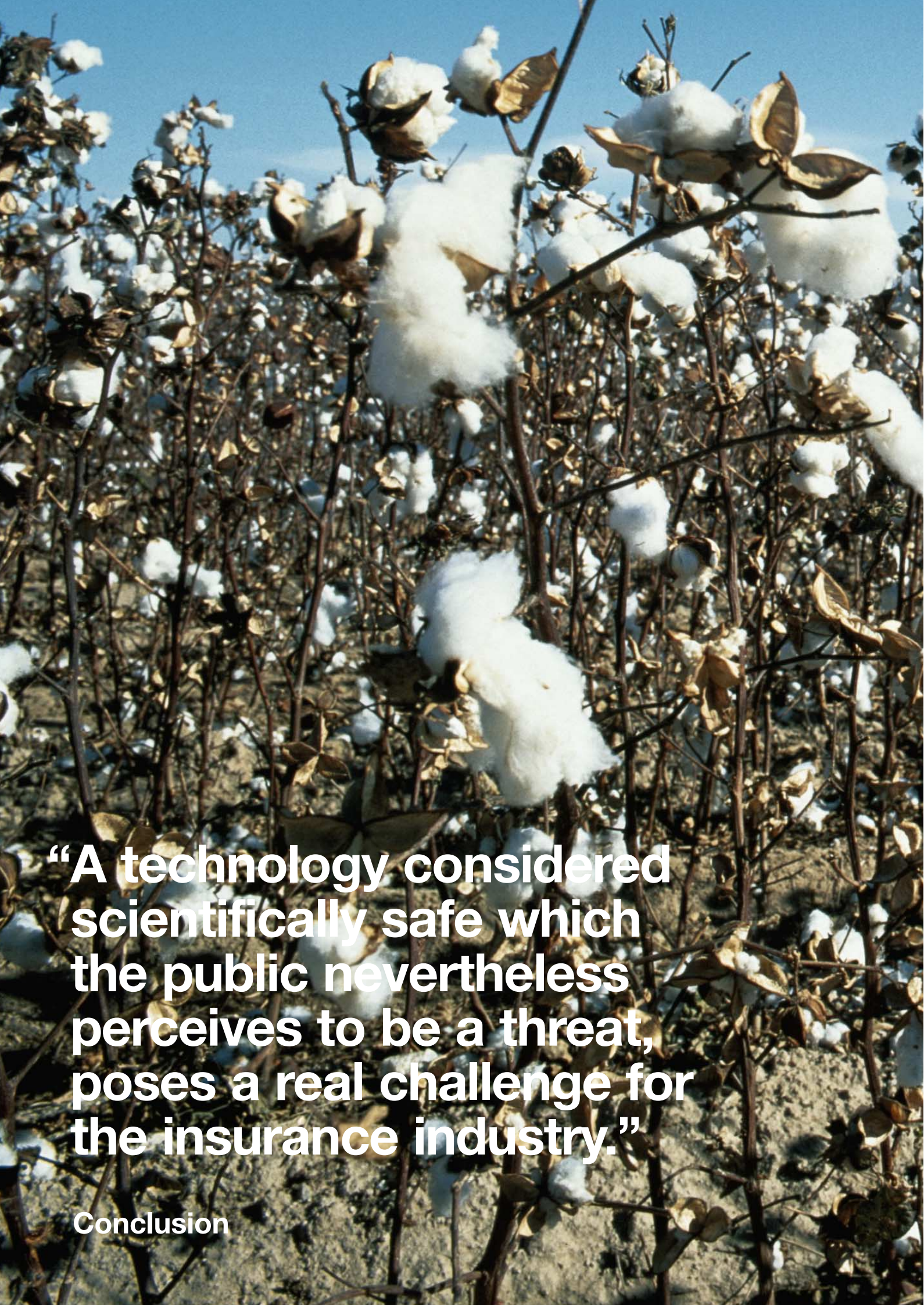
The basis for this process of change that swept through almost the entire industry, according to Koenig, was some unanticipated changes of the business model, once modern biotechnology had been adopted in the seed business. Firstly, it turned out that the complexity of the global commodity markets had been underestimated. Secondly, farmers were not the only customers; consumers had to be included. However, agri-biotechnology companies lacked both the capacity and the competence to effectively communicate with end-consumers. Thirdly, market dynamics and a clash of regulations which culminated in the WTO suit were not anticipated.

In addition, the introduction of modern biotechnology created new risks across the value chain, as was demonstrated by the StarLink case. At the same time, the uneven distribution of benefits from sales alongside this value chain diminished the product-pull through because of a reduced willingness of taking up GM crops by a number of players downstream the agri-food chain. Furthermore, the difficulty to manage their products downstream in a manner favorable for both farmers and consumers at the same time was unfavourable for the technology provider itself.

Diverse regulatory approaches across jurisdictions represent additional hurdles for marketing technological innovation, in particular when regulations are difficult to enforce or to comply with. Koenig pointed out that governments and multinational firms need to improve their interaction early in order to globally govern new technologies. Biotechnology companies, for their part, must improve their understanding of which values drive their innovation, and which ones determine behaviour of other stakeholder institutions, ie mainly governments, civil society organisations and as a third type all firms across the agri-food chain. In order to reduce the risk of litigation, the speaker recommended the conduct of international deliberations in which the three types of institutions are represented. Platforms for such deliberations may help all institutions involved in the global governance of new technologies to better understand and take into account the diverse viewpoints on the technology's objectives, risks, costs, benefits, their distribution, and regulation.

In the lively discussion between representatives of agri-biotechnology companies and several insurers, the issues of regulatory diversity and labelling were broached. The crucial question was whether product stewardship programmes must also include risk management across the value chain, or whether labels on GMO content were the only and sufficient requirement a provider has to observe. Bearing in mind that nobody has been harmed by GMOs so far, one representative of the biotechnology industry insisted on the liberal FDA practice as the only reasonable one. Some insurers, however,

pointed out that labelling and product stewardship, including the segregation of GM products from traditional ones, may help to avoid commingling losses and build confidence.



“A technology considered scientifically safe which the public nevertheless perceives to be a threat, poses a real challenge for the insurance industry.”

Conclusion

Roadmap to biotechnology in 2013

Ortwin Renn, Chairman of the Board of Directors of the Center for Technology Assessment, Stuttgart, drew the forum to a close with a look at the roadmap to biotechnology in 2013. He began by mentioning the philosophy of foresight. His message was that foresight is not a forecast, but rather a process which probes the realms of possibility and identifies possible modes of action. This especially involves the recognition of driving forces, trends and interaction and requires input from all the various stakeholders.

Renn focused on the methodological approaches known as the “scenario technique”. He defined this as the “reasonable combination of recognisable trends with simulations of the effects of possible decisions, which are integrated into one or several systematic descriptions of possible future developments.” As such, these scenarios are a mixture of hard facts and subjective judgments, which are systematically linked and multiplied to form various futures. Renn went on to discuss the pros and cons of a number of scenario types, looking in more detail at the narrative, probabilistic and the worst case/best case/desirable case approaches.

Following on from the methodological theory, the speaker presented a total of six scenarios for biotechnology. He referred to the work of the WBCSD (World Business Council for Sustainable Development), a scenario exercise applied by the Research Centre Jülich, and to the IFOK’s scenarios (Institut für Organisationskommunikation, Bensheim, Berlin, Brussels) on GM foods. In summary, Renn noted that:

- All scenario exercises assume that biotechnology foods will penetrate the international markets. The decision to apply GMOs is seen as solid. Only catastrophic events can reverse the decision. The question is thus not if, but how, and under what conditions, GMOs will be applied.
- The relevant actors seem willing to negotiate the conditions and potential regulatory rules for enabling the partial transition to GMOs in the food sector, although the positions occasionally seem to be incompatible.

According to Renn, the potential roadmaps to biotechnology development depend on:

1. The global balance between the forces of economics, politics and civil society in the different political arenas,
2. The development and workability of liability regulation,
3. The successful development of GMOs with clear advantages for the end-user and the promise to meet social needs,
4. The readiness of multinational companies to rely on dialogue and consumer-oriented policies rather than on exploiting their market power, and
5. The willingness of NGOs to withdraw from fundamental positions and use their leverage to improve the conditions for a “peaceful co-existence” of conventional, organic and GMO-oriented food supply.

Concluding panel

The closing discussion of the specialist forum involving three major voices on risk dialogue from the German-speaking area – *Matthias Haller*, *Ortwin Renn* and *Peter Wiedemann* – focused on the roadmap to 2013 and on the future shape of modern biotechnology.

Haller stressed above all the macroscopic factors that will shape the future of the economy in general and the cultural, political and legal frameworks that will influence societal attitudes towards risk and uncertainty. In his view, the future of biotechnology depends heavily on the global trends he grouped together under the term “safety society”.

Elaborating on his presentation, Renn underlined the importance of dialogue, stakeholder participation, and focused thinking on societal and personal values. The crucial question, he claimed, was whether we can reach mutual agreement on the type of society we would all like to create. The ways in which biotechnology could contribute to this aim represent an opportunity that should be explored.

Wiedemann concluded by summing up the enormous diversity of issues that might influence the future of biotechnology. He pointed in particular to the following key drivers: scientific breakthroughs in biotechnological research, the further development of safety standards and the precautionary principle. These key drivers will manifest themselves in statutory frameworks, WTO rules and trade agreements. From a global perspective, the way in which people in various countries perceive the risks and benefits, how they participate in political decision-making and their preferences as consumers will be crucial in determining whether convergence and uniformity, or divergence and diversity, dominate the future spread, growth, handling and regulation of biotechnology.

Two key questions referring to risk management and equivalence of opportunities remained unanswered. Firstly, no consensus was reached among the participants about the proper balance between scientific, commercial and public interests when managing risk. And, secondly, the drawbacks and lost opportunities for countries that miss out on the choice provided by a national biotechnology programme were beyond the scope of this conference and were only partially addressed in several of the discussions.

Conclusion

Epilogue

A technology considered scientifically safe which the public nevertheless perceives as a threat, although there is no proof of a harmful causal relationship, poses a real challenge for the insurance industry as regards the definition of the covered loss and estimation of the expected claims.

In the case of modern biotechnology, there is a solution, according to the initiator of the forum, *Thomas Epprecht*. The Swiss Re gene technology clauses are proven to be commensurate with the risk, practicable and adopted by major primary insurers, and acceptable for the contracting parties.

“Zero tolerance – of GMOs or anything else – isn’t a way to manage risk: it’s a recipe for denial. But what we deny, we can’t manage... What we can’t manage, we can’t insure... And if there’s no insurance to enable us to take a risk, we stagnate.” *Thomas Epprecht*, concluding remarks on “phantom risks”

Swiss Re appears to be well on the way to achieving its aim of “creating a place for inquiring minds and to look ahead to the future” at the Centre for Global Dialogue, as the following statements from participants – representative of the plentiful feedback received – confirm:

“It was very good to get out and meet others in the industry and to have a chance to ‘think’ away from the hustle of day-to-day business.”

“I enjoyed the sessions and came away knowing more about the role of insurance in technological risks, and with the feeling that there is further work to be done on this topic.”

“It was extremely useful for me to meet the wide range of senior-level delegates. I am now in close touch with some of them, looking forward to continuing communications.”

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The insurability of ecological damage



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ecological damage

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Foreword

Damage to the environment often infringes upon the rights of individuals, causing property damage or bodily injury. In dealing with this issue, European legislators have used civil liability as their instrument of choice. The thrust of the resulting laws – based for the most part on strict liability – is to make polluters pay for the damage they cause. Such laws generate substantial risk, and insurers have responded by offering fairly comprehensive environmental liability covers. However, these can only apply where damage is quantifiable: that is, where it can be indemnified by a certain sum of money.

With pure ecological damage, the situation is different. An ecological good is a public good: it belongs to no one, and damage to it does not affect anyone's property rights. Thus, civil liability does not apply. Insurance underwriters, for their part, have no way of calculating the probability or size of potential losses: to date, therefore, insurers have not been able to offer cover for these risks.

In this publication, we will survey current laws on ecological damage in selected European countries and in the US. We will outline existing international agreements on environmental damage liability. In addition, we will sketch out the role of the European Union, which in January 2002 touched off a political debate by issuing its "Proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage".

More specifically with regard to insurance, we will present the standard environmental liability covers currently on the market. Finally, as we anticipate a growing demand in Europe for environmental liability risk protection, we present here a basis for discussion and point out – based on our experience – the building blocks for a possible insurance concept.

Thomas Hiltmann
Head Group Product Management Casualty, Swiss Re

1 What is ecological damage?

Environmental disasters often capture the headlines. Whether natural catastrophes such as forest fires, storm or flood, or man-made catastrophes such as industrial mishaps or shipwreck, we are invariably concerned when we hear of these events and their effect on the environment.

Such was the case on 16 January 2001, when the tanker *Jessica* ran aground off the Galapagos Islands, near the coast of Ecuador. The ship was carrying 160 000 gallons of diesel oil and 80 000 gallons of bunker fuel. As the oil began leaking from the vessel's hull, the world held its breath. Several environmental authorities, the Ecuadorian army, the Charles Darwin Research Station (CDRS), the Galapagos National Park and other experts went into action to prevent the impending tragedy. They attempted to prevent the oil spill from spreading by setting out floating barriers around the ship and by offloading the oil still aboard the tanker. At the same time, best efforts were made by hundreds of people to prevent the oil from reaching the coast. The Galapagos Islands are the habitat of giant tortoises, marine iguanas, lava gulls and many other species not found anywhere else on earth, making the wreck of the *Jessica* a particularly serious event. While several beaches and animals were affected, the Islands and its unique wildlife were spared the worst: the wind turned in time, and the oil slick was blown away from the west coast and out to sea.

A year later, measurements at over 400 locations showed that though pollutants had spread over a wide area, the level of pollution was relatively low. Seventy-nine sea lions were affected. Long-term studies and monitoring will be necessary to assess the future consequences of the catastrophe. On Santa Fe Island, it was found that some marine iguanas were suffering stress symptoms: further observation will show whether this leads to higher mortality. Affected marine plants and animals are also being monitored. To date, however, no serious consequences have surfaced. Deposits on the beaches show minor contamination in the southern Galapagos, near the islands of Santa Cruz and Santa Fe.

This environmental catastrophe – and the Galapagos Islands got off lightly – is an illustration of what we think of as “ecological damage”. In the case of the *Jessica*, it included the polluted ocean, polluted coastlines and beaches, and oil-covered sea lions, some of which were saved and some of which died.

Usually, in our daily language and lives, we are not very careful with our terminology in this area. You will hear this kind of ecological damage referred to as “environmental damage” or “damage to the resources of nature”; and insurers frequently speak of “environmental impairment” or (particularly in the US) simply of “pollution”. All of these terms refer to a disturbance in the ecological balance: to “damage to the natural environment that is either irreversible or can only be corrected over an extended period”.¹ Ecological damage is *primary* environmental damage done directly to the water, air, soil, flora or fauna. It may involve a species of animal living in the wild, for example, or water resources belonging to everyone. Ecological damage always involves a free resource of nature.

¹ cf Giovanni Pelloni, “Privatrechtliche Haftung für Umweltschäden und Versicherung”, Zurich 1993, p 52

Against this background it is difficult to fit ecological damage into the current legal liability context. Legal liability is an arrangement between parties, either natural or juridical persons. It is designed to enforce certain rights: the right to be free from bodily harm, or the right to property. When we attempt to apply legal liability to ecological damage, certain questions arise:

- When a free resource of nature is damaged, who is entitled to compensation?
Who has the right to sue?
Free resources of nature such as soil, air and water do not belong to any person, whether natural or juridical; they belong to everyone.
- Who is responsible for ecological damage?
Often it is impossible (or no longer possible) to determine responsibility for ecological damage and hold the responsible party liable. Diffuse pollution² is a particular problem, as is long-distance pollution³, both of which may be caused by many different polluters who are not individually responsible. Historical contamination⁴ and chronic pollution⁵ also pose problems.
- How can we put a value on ecological damage?
It is very difficult and sometimes impossible to put a monetary value on ecological damage. Can the extinction of a species of plant or animal due to harmful emissions be indemnified by a cash amount, particularly if the species is gone forever?

However, when a negative influence on the environment at large affects humans in a concrete, direct way, and impacts our health, our property or our finances, it becomes legally relevant. This *secondary* environmental damage – damage in a legal, or liability sense of the word – traditionally includes bodily injury, property damage, and financial loss. It occurs as the *result* of primary environmental damage. It includes cases where the damaged resource of nature is someone's property (a private spring or well, for example, or private land), where legal liability may apply.

It should also be mentioned that there is a grey area between primary and secondary environmental damage, where the area of legal relevancy goes beyond the traditional areas of bodily harm, property damage and financial loss. For example, should a company be allowed to contaminate its own plant site? Why not? It's the company's own land, after all. The groundwater under a neighbour's property is (still!) pure; the neighbour does not (yet!) have any health complaints.

² Ecological damage to which many polluters have contributed: eg ozone hole, acid rain.

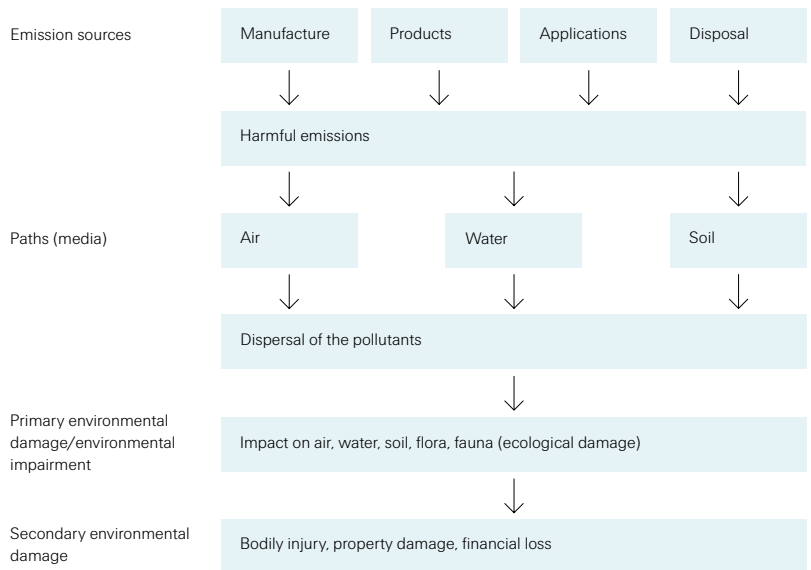
³ Ecological damage which produces its effects "far" from its point of origin: eg Chernobyl.

⁴ Ecological damage which is caused a "long time" before it is discovered.

⁵ Ecological damage that is produced over a long period of time, typically as a result of "normal" or "approved" processes and procedures that may continue for many years.

Various trends currently aim at firming up the liability situation. At the European level, for example, a directive⁶ has been proposed based on broad implementation of the “polluter pays” principle: the idea that those who cause the damage should be held financially liable. This principle is widely accepted in environmental law, and the insurance industry basically supports it.

Figure 1:
What is environmental damage?



Thus, this directive stipulates liability for *some forms* of ecological damage; that is, to some types of direct damage to free resources of nature. Under the polluter pays principle, the operator of any facility which has caused ecological damage is obligated to take restorative measures, and to pay for them. However, the framers of the directive were aware that it is difficult to quantify damage to a resource of nature; thus, their concept focuses on restorative measures rather than on a monetary amount. The cost of such restorative measures is easier to estimate than a sum paid in “compensation”; and when the measures have been completed, their effectiveness can be verified. Additionally, measures need not apply in all cases strictly to restoring the resource of nature that was damaged, but compensatory or equivalency measures may be allowed.

This publication probably gives a fairly accurate picture of what the emerging environmental liability landscape will look like, at least within Europe, and we shall return to consider it in greater detail further below.

⁶ “Proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage”, available at http://europa.eu.int/eur-lex/e/com/pdf/2002/en_502PC0017.pdf

2 Legal situation

2.1 Overview

Public concern with the environment is increasing. Eco-catastrophes and pictures of dying animals and devastated landscapes have prompted greater efforts to call to account those who are responsible. Yet not infrequently, the legal situation has allowed the responsible party to escape paying compensation, even when its financial situation would have permitted this.

A series of industrial accidents in the 1980s⁷ triggered attempts to use civil law as an instrument for settling the liability question in cases where ecological damage resulted in traditional forms of secondary environmental damage: ie bodily injury or property damage. The objective of these efforts, grounded for the most part in strict liability, is to protect the property of damaged parties. In these cases, the damage involved a protected legal good, and could be quantified and indemnified according to the principles of legal liability.

In a second phase, it was lawmakers who addressed the problem of historical contamination by adding provisions on soil protection and pollution cleanup to existing environmental laws. Their purpose was to obligate the operators of industrial facilities and landowners to clean up any pollution on their property. These provisions, too, are based on property rights under civil law.

With pure, primary environmental damage, the situation is different, for it involves a free resource of nature which everyone has a right to use and benefit from equally. The principles of liability under civil law do not apply, because private property is not involved. However, special provisions under public law⁸ may empower the state, as trustee of all resources of nature, to require polluters to correct ecological damage or carry the costs for doing so. Police law provisions also make it possible to obligate potential polluters to install protections or to comply with minimum ecological standards.

Such regulations, however, solve only in part the problem of how to quantify ecological damage. Other approaches under discussion also include the *differential approach*, based on the difference in the value of a natural resource before and after a polluting event; and the *benefit approach*, where the yardstick is the future loss of benefits derived, in addition to restoration costs. Yet none of these methods can place a suitable value on a resource that is not used economically. No economic loss will result if a species "only" becomes extinct, a landscape is "only" spoiled or the quality of life is "only" degraded. Damage to such aesthetic, cultural or conceptual values is not quantifiable.

⁷ Examples: the Seveso accident in July 1976; the massive contamination of the Rhine after a chemical plant fire in Schweizerhalle near Basel in November 1986.

⁸ An example is Art 59, (Swiss) Federal Environmental Law: "The costs for measures taken by public authorities for the prevention of an immediately impending influence, as well as measures to define and correct the same, may be imposed on the polluter."

2.2 Individual countries

Germany

Germany's Bürgerliches Gesetzbuch (BGB, or civil code) and the environmental liability law harbour a liability gap, as they do not provide compensation for primary environmental damage. Indemnity may be demanded only for ecological damage that concurrently infringes on the rights of the individual. Here, however, the strict liability regime of the environmental liability act improves the position of the damaged party.

German public law on the environment contains no written general clause that gives blanket protection to all resources of nature. Environmental liability under public law is divided between laws at the land (state) level and the federal level.

France

French civil law does not mention liability for ecological damage. Liability is triggered only when an individual right is infringed, and economic damage results. If a resource of nature is the property of the state, the state can demand compensation for damage done to it: this is the case, for example, with areas in the public domain such as navigable rivers, the sea or the coast. The trend in case law is towards an expansion of civil liability which also covers most ecological damage.

Environmental law in France limits liability to the restoration of the affected resources of nature: the law does not recognise any more extensive liability.

Italy

In principle, Italian civil law covers primary environmental damage: in practice, however, such damage is only recorded when an individual right is infringed. On the other hand, case law gives broad protection to health as a personal right, and it also recognises the right to a healthy environment. There is an obligation to compensate the state for damage to any resource of nature used by the public.

Environmental law allows the state to require polluters to clean up any resource of nature that they have polluted. Certain older laws also mention the alternative of a fine in lieu of restorative measures.

UK

Civil law in the United Kingdom does not recognise any right to compensation for primary environmental damage, unless such damage concurrently infringes upon individual rights.

Environmental law does provide for ecological damage to be compensated, but only in areas covered by separate nature or wildlife protection laws. Soil protection laws, too, allow compensation for ecological damage. Responsibility for the pollution is determined by a sophisticated but cumbersome selection procedure.

US

In the United States, liability in connection with environmental impairment is regulated in various special laws. On the federal level, the most important of these are the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); the Oil Pollution Act (OPA) and the Clean Water Act (CWA). They also recognise primary environmental damage, referred to as “natural resource damages” or “NRD”. The NRD definition in CERCLA and OPA is very broad, covering the soil, air, water, groundwater, fish, fauna, flora and other resources. However, these resources are protected only when they are the property of – or administered by – the United States government, a state, a Native American tribe, or a local government. The CWA regulates the introduction of hazardous materials into navigable waters.

Normally, the law provides for NRD compensation as follows:

- restoration to the original (“baseline”) condition
- loss-of-use compensation for an impaired resource
- reimbursement of costs for investigating the damage

CERCLA focuses on cleaning up historical contamination. The Environmental Protection Agency (EPA) is assigned the task of discovering hazardous waste sites – ie those in need of cleanup – and announcing which parties are potentially liable. The agency then requires the cleanup of the site – or arranges itself for the cleanup to be carried out, with the cost then being recovered from the polluter. In most cases, these are the owners or operators of factories, shipping companies, warehouses, and waste treatment or disposal sites.

Figure 2:
Protected regions and resources

Responsibility/administrator	Examples of protected regions and resources
Department of Commerce (responsible under NOAA) ¹	<ul style="list-style-type: none"> ■ coastlines ■ threatened marine species ■ marine mammals
Department of the Interior (responsible under CERCLA)	<ul style="list-style-type: none"> ■ specified threatened species ■ specified marine mammals ■ migratory birds ■ national wildlife sanctuaries and fish spawning grounds ■ national parks
States	Natural resources – including ground and surface water – which <ul style="list-style-type: none"> ■ lie within the state’s borders or ■ are administered by the state such as state forests, parks and threatened species protected by the states
Native American tribes	Natural resources belonging to or administered by these tribes

¹ National Oceanic and Atmospheric Administration

Polluters carry unlimited liability for ecological damage to flora and fauna. This liability is retroactive: that is, US operators are liable for damage that occurred before CERCLA came into force. Furthermore, the application of “joint and several liability” means that each and every one of several polluters responsible is liable for the entire amount.

2.3 International regulations⁹

Environmental liability and the Council of Europe

The Lugano Convention¹⁰ was the first pan-European instrument for dealing with environmental liability. In addition to settling liability for the traditional classes of damage (harm to health or property, financial loss), it also addressed liability for primary environmental damage. However, the application of strict liability is limited: first, to the operators of facilities and disposal sites which pose a danger to the environment; and second, to the consequences of activities involving dangerous substances and organisms.¹¹

This liability expressly includes the costs for restoring any damaged resources of nature. Though it is left to national law to define the parties entitled to claim for damages, it gives recognised environmental organisations the basic right to obtain injunctions or administrative rulings that would obligate polluters to remediate the damage they have caused; however, this right may be restricted or vetoed entirely by national legislation. It also provides for financial guarantees.¹² To date, however, the Lugano Convention has not entered force.¹³

⁹ cf survey conducted on behalf of the German Federal Office for Environmental Protection "Ausgestaltung der Umwelthaftung in internationalen, europäischen und nationalen Haftungsregimen sowie Methoden der Schadensberechnung"; J. Kokott, A. Klaphake, S. Marr, September 2002.

¹⁰ More formally known as the "Convention on Civil Liability for Damages Resulting from Activities Dangerous to the Environment" of 21 June 1993, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/150.htm>

¹¹ According to the Lugano Convention's Art 2 para 7,

"Damage" means:

- a loss of life or personal injury;
- b loss of or damage to property other than to the installation itself or property held under the control of the operator, at the site of the dangerous activity;
- c loss or damage by impairment of the environment insofar as this is not considered to be damage within the meaning of sub-paragraphs a or b above provided that compensation for impairment of the environment, other than for loss of profit from such impairment, shall be limited to the costs of measures of reinstatement actually undertaken or to be undertaken;
- d the costs of preventive measures and any loss or damage caused by preventive measures, to the extent that the loss or damage referred to in sub-paragraphs a to c of this paragraph arises out of or results from the hazardous properties of the dangerous substances, genetically modified organisms or micro-organisms or arises or results from waste.

According to Art 2 para 10:

"Environment" includes:

- natural resources both abiotic and biotic, such as air, water, soil, fauna and flora and the interaction between the same factors;
- property which forms part of the cultural heritage; and
- the characteristic aspects of the landscape.

¹² The Lugano Convention's Art 12 describes the financial securities necessary to cover liability exposure: "Each Party shall ensure that where appropriate, taking due account of the risks of the activity, operators conducting a dangerous activity on its territory be required to participate in a financial security scheme or to have and maintain a financial guarantee up to a certain limit, of such type and terms as specified by internal law, to cover the liability under this Convention."

¹³ Nine states have currently signed the Lugano Convention, but none has ratified it (status: February 2003). Ratification by three countries is necessary for the convention to go into force.

*The Brussels Convention*¹⁴

The Brussels Convention makes ship owners liable for oil pollution. Liability, however, is limited to damage within the parties' territory or territorial waters. Closely associated with the Brussels Convention is the International Oil Pollution Compensation Fund, instituted by international agreement on 18 December 1971.¹⁵ Parties to the oil pollution liability convention are also members of the fund. Contributions to the fund are made by the oil companies in participating countries. These contributions depend on the amount of oil they transport by ship each year. The fund becomes active in cases where:

- the ship owner's liability is excluded
- the ship owner is not financially able to pay compensation
- the ship owner's liability is limited

According to the 1992 protocol, compensation up to 135 million Special Drawing Rights (SDR) may be paid: this is roughly the equivalent of USD 174 million. This maximum includes the amount that the ship owner must pay according to the "liability" convention.

The convention also allows claims for reasonable cleanup costs for the sea and the coast. These include personnel and materials costs for the cleanup, as well as costs for disposal and expert studies. Claims for individual property damage are also allowed. Financial loss due to pollution-impacted property (consequential loss) is always ground for a claim. The Brussels Convention includes all pure economic losses (such as reduced tourist trade) as a direct financial loss; indirect financial losses, such as those suffered by suppliers to the hotel industry, are not included. According to the convention's definition of damages, claims are admissible for all restorative measures needed to eliminate an instance of environmental damage. Thus, it can be assumed that the obligation to indemnify primary environmental damage has been recognised. Yet there is currently no obligation to pay compensation where restorative measures are not possible, or where they would be unreasonably expensive.

For its part, the fund accepts measures aimed at restoring a damaged resource of nature to its original condition; no compensation is provided for interim lost value, however.¹⁶ As impaired resources of nature often restore themselves, particularly after oil disasters, the fund's actions often reflect the opinion that additional restorative measures are not appropriate or necessary. In such cases, there is no obligation to pay compensation for any natural regeneration time that nature may need.

¹⁴ More formally, the "Convention on Civil Liability for Oil Pollution Damages", or CLC, of 29 November 1969; protocols in 1976, 1984 and 1992; amended 2000.

¹⁵ Seventy-two states have ratified the liability agreement, and 68 have ratified the fund agreement. The US is not among them.

¹⁶ Interim lost value: Some regimes (CERCLA in the US, for example) stipulate liability for ecological services lost during the time needed for the restoration of a damaged resource. This "interim lost value" must be compensated through financing measures on resources other than those the polluter damaged.

*The CRTD Convention*¹⁷

The CRTD Convention stipulates strict liability for damages arising from the transport of dangerous goods. The transport company is strictly liable for any damage occurring during transport, whether by road, rail or inland waterway. The liability amount is limited, however, and depends on the type of transport.¹⁸ The grounds for liability exclusions correspond largely to those of the Brussels Convention.

The convention stipulates liability covering the traditional types of damage including such pure financial loss as lost profits or income suffered by fisheries or the hotel industry. In addition, it also covers a polluter's liability for the primary environmental damage caused, as well as the costs for preventive environmental protection measures. However, where a resource of nature has been damaged, only the costs for restoration must be compensated: these costs must be reasonable, and they must be for measures actually carried out. Similar to the Brussels Convention (on oil pollution), the CRTD Convention does not stipulate liability where it is not possible to remediate the ecological damage: thus, not all damage to the environment entails an obligation to pay compensation. It is also unclear who is authorised to claim compensation for ecological damage not involving property.

The shipper is obligated to procure insurance or other financial guaranty to cover his liability when transporting dangerous goods within the territory of a party to the convention. Damaged parties notify their claims directly to the shipper's insurer.

*The HNS Convention*¹⁹

The HNS Convention is applicable to ecological damage within the territory of parties to the convention, but also in their territorial sea (200-mile zone) or exclusive economic zones. Liability for harm to health and property also extends beyond the territory of the parties to the convention, to include events aboard ships either registered in a country that is a party or authorised to sail under the flag of such a country. The HNS Convention is the practical framework allowing claims to be brought for damages occurring during the transport of dangerous goods at sea. The HNS Convention stipulates strict liability for the ship owner.

¹⁷ More formally, the "Convention on Civil Liability for Damage Caused during Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels" of 1989.

¹⁸ The CRTD Convention's Article 9 scales the amount of liability according to the type of transport and the damage:

1. The liability of the road carrier and of the rail carrier under this Convention for claims arising from any one incident shall be limited as follows:
 - a with respect to claims for loss of life or personal injury: 18 million units of account;
 - b with respect to any other claim: 12 million units of account.
2. The liability of the carrier by inland navigation vessel under this Convention for claims arising from any one incident shall be limited as follows:
 - a with respect to claims for loss of life or personal injury: 8 million units of account;
 - b with respect to any other claim: 7 million units of account."

¹⁹ More formally, the "Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea" of 1996.

It does not cover oil pollution damage coming under the Brussels Convention; otherwise, compensation may be demanded for ecological damage as well as for harm to health and property, provided that the relevant restorative measures have actually been carried out or are planned, and do not exceed a reasonable sum. This clause includes damage mitigation or avoidance measures and any losses or damage that such measures may entail. Also eligible for compensation are profits lost as the result of ecological damage. The convention does not compensate irreparable ecological damage.

In a measure intended to support these liability rulings, shippers are obligated to insure themselves to their limit of liability. In addition, the HNS Convention provides for a fund modelled on the International Oil Pollution Compensation Fund. Compensation claims may be notified directly to the ship owner's insurer or financial guarantor.

The Basel Protocol²⁰

The Basel Protocol is applicable only to damage deriving from international transports of hazardous wastes and their disposal.

According to the protocol, the producer or exporter ("notifier") carries strict liability for international transports notified to the affected states. The liability expires when the disposer has taken receipt of the waste. Without prejudice to the above, all parties carry strict liability for any non-compliance with the provisions of the protocol. The reasons for an exclusion of liability are by and large the same as those of other international liability agreements.²¹

Compensation may be demanded for primary environmental damage as well as for harm to health and property: However, the obligation to pay compensation is limited to costs that were or will be incurred in reversing the ecological damage. Claims may be raised for all lost profits from the use of a damaged resource of nature, including interest and other costs. In addition, it is possible to claim the cost of preventive measures made necessary by the transport and the dangerous nature of the waste being transported.

²⁰ More formally, the "Basel Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal" of December 1999

²¹ The Basel Protocol's Art 4 para 5 defines the justifications for an exclusion of liability as follows:

- "No liability in accordance with this Article shall attach to the person referred to in paragraphs 1 and 2 of this Article, if that person proves that the damage was:
- a the result of an act of armed conflict, hostilities, civil war or insurrection;
 - b the result of a natural phenomenon of exceptional, inevitable, unforeseeable and irresistible character;
 - c wholly the result of compliance with a compulsory measure of a public authority of the State where the damage occurred; or
 - d wholly the result of the wrongful intentional conduct of a third party, including the person who suffered the damage."

This strict liability is limited according to the amount of waste transported.²² The protocol requires a guarantee for the period of the liability from all parties exposed to strict liability under its provisions. Affected parties can satisfy this requirement by taking out insurance or similar financial guarantees. It is thus possible to address all claims directly to the insurer or guarantor.

*"Draft legally binding instrument on Civil Liability for Transboundary Damage caused by Hazardous Activities, within the scope of both Conventions"*²³

This agreement, which is basically a water protection protocol under the Helsinki Convention, should be mentioned in connection with internal waterways. The convention itself, formulated by the UNECE (United Nations Economic Commission for Europe), only treats liability very tentatively.

In July 2001, however, meeting jointly, the parties to the Helsinki Convention and to the Convention on the Transboundary Effects of Industrial Accidents decided to draft a protocol covering liability for transboundary environmental damage under both conventions. A committee was formed with the assignment to produce a draft for approval by mid-2003.

This protocol is designed to close one of the widest gaps in international environmental law. The Helsinki Convention itself aims at offering protection against transboundary environmental damage deriving from changes in the condition of transboundary waters. Whereas the protocol on civil liability will also cover such transboundary water damage, it will require an additional trigger: a cause, in the form of an industrial accident that occurred as the result of a hazardous activity. The protocol will apply to those nations who are parties both to the Helsinki Convention and the Convention on the Transboundary Effects of Industrial Accidents, and to later signatory nations upon joining. Other states as well may put themselves under the protocol's jurisdiction, however.

²² The Basel Protocol's Annex B Art 2 defines the liability limits as follows:

"The limits of liability shall:

- a For the notifier, exporter or importer, for any one incident, be not less than:
 - i 1 million units of account for shipments up to and including 5 tonnes;
 - ii 2 million units of account for shipments exceeding 5 tonnes, up to and including 25 tonnes;
 - iii 4 million units of account for shipments exceeding 25 tonnes, up to and including 50 tonnes;
 - iv 6 million units of account for shipments exceeding 50 tonnes, up to and including to 1000 tonnes;
 - v 10 million units of account for shipments exceeding 1000 tonnes, up to and including 10 000 tonnes;
 - vi Plus an additional 1000 units of account for each additional tonne up to a maximum of 30 million units of account;
- b For the disposer, for any one incident, be not less than 2 million units of account for any one incident."

²³ Available at http://www.unece.org/env/civil-liability/documents/protocol_e.pdf. In the title, "both conventions": refers to the Helsinki Convention or "Convention on the Protection and Use of Transboundary Water-courses and International Lakes" of 17 March 1992; and the "Convention on the Transboundary Effects of Industrial Accidents".

The Helsinki Convention itself is aimed at any “significant adverse effect on the environment”, giving as examples “effects on human health and safety, flora, fauna, soil, air, water, climate, land and historical monuments or other physical structures or the interaction among these factors; they also include effects on the cultural heritage or socio-economic conditions resulting from alterations to those factors.” The draft protocol on civil liability contains an extended definition of damage as well.²⁴

In addition to harm to health and property, it states that financial loss deriving from harmful utilisation of the environment is also eligible for compensation. Compensation for primary environmental damage is also included: however, similar to many other international agreements, the protocol is orientated mainly towards the cost for restorative measures.²⁵ These must be reasonable and aimed at restoring clearly defined resources of nature. The protocol also regulates compensation claims for various other measures: prevention, mitigation, emergency. Costs for environmental cleanup are expressly mentioned as damage mitigation.²⁶ Compensation is made financially.

The protocol limits strict liability in keeping with the hazard potential represented by the activities or substances: the sums are 10 million Special Drawing Rights (SDR) for Category A and 40 million SDR for Categories B and C. This is roughly equivalent to USD 13 million and USD 52 million, respectively. The insurance or other financial guarantees, too, are limited on the basis of hazard potential. These limits are set at 2.5 million SDR and 10 million SDR, equivalent to USD 3.2 million and USD 13 million, respectively.

²⁴ Protocol of May 2003 Art 2 b:

“Damage” means:

(...)

- iii Loss of income directly deriving from an impairment of a legally protected interest in any use of the transboundary waters for economic purposes, incurred as a result of impairment of the transboundary waters, taking into account savings and costs;
- iv The cost of measures of reinstatement of the impaired transboundary waters, limited to the costs of measures actually taken or to be undertaken;
- v The cost of response measures, including any loss or damage caused by such measures, to the extent that the damage was caused by the transboundary effects of an industrial accident on transboundary waters.

²⁵ *ibid.*, Art 2 para 2 g:

“Measures of reinstatement” means any reasonable measures aiming to reinstate or restore damaged or destroyed components of transboundary waters to the conditions that would have existed had the industrial accident not occurred, or, where this is not possible, to introduce, where appropriate, the equivalent of these components into the transboundary waters. Domestic law may indicate who will be entitled to take such measures.

²⁶ *ibid.*, Art 2 para 2 h:

“Response measures” means any reasonable measures taken by any person, including public authorities, following an industrial accident, to prevent, minimise or mitigate possible loss or damage or to arrange for environmental cleanup. Domestic law may indicate who will be entitled to take such measures.

Liability under international law

Under customary international law, there is an obligation to pay compensation for transboundary environmental damage. Because countries comply with this obligation in large degree, it is generally recognised as a standard of international law. "Transboundary environmental damage" refers to damage that is caused in one country or in a zone under its control (either an economic zone or on the continental shelf) and leads to damage in another country. Shared resources such as transboundary waters play a prominent role here, which explains the large number of agreements on the protection of particular rivers.

The extent to which liability exists for transboundary environmental damage was long a matter of dispute, and indeed, practice in this area tends to be very cautious. Many treaties and agreements contain only tentative liability clauses, and in some cases, liability for primary environmental damage is expressly excluded.

Normally, ecological damage is not caused by the state and its bodies, but by private parties. Basically, the state is not obligated to answer for the behaviour of these parties: it does, however, have an obligation to monitor and to prevent, and must sanction any environmental impairment with relevant national legislation, and monitor compliance with this legislation. When a private party causes ecological damage, in most cases this is because the state has failed in its duty to monitor, thus becoming guilty of infringing international law. In many areas, environmental liability under international law is complemented by civil liability conventions. There is disagreement as to whether strict liability should be applied to ecological damage in addition to the fault-based liability under international law. However, international law knows no form of liability that would go beyond the traditional classes of life, health, property and financial loss.

There is a lack of agreements that address ecological damage globally. Most such agreements focus on a single path through which pollution is propagated. Hence, the fundamental principles of international law are virtually the only comprehensive rules that apply to environmental liability. However, this does mean that fault-based liability, at least, is recognised in cases of transboundary damage; and today, practice has basically come to include primary environmental damage as part of this. The amount of compensation usually depends on the actual cost of restorative measures, as there is no consensus on other (economic) methods of assessing ecological damage; however, there is no obligation to pay compensation if no specific restorative measure is suitable to correct the damage. Also, any compensation amount is usually subject to negotiation: thus under customary international law, compensation in full is not usually paid.

Environmental liability in the European Union

In October 1989, the European Commission of the then-European Community (EC) first issued a "proposal for a regime for Civil Liability for Damage caused by Waste". As modified in 1991, the proposal stipulated strict liability for polluters and equivalent persons. Ecological damage, defined as "a significant physical, chemical or biological deterioration of the environment" was included. The proposed liability regime protected as a public good all resources of nature not considered to be property. This provoked lively opposition from the waste disposal industry. Thus, the proposal for a liability regime was not debated in the Council. Only the waste directive was accepted, which applied the polluter pays principle to waste disposal costs. This directive obligates the member states to ensure that waste is recycled or disposed of in an environmentally friendly manner, and to forbid unsupervised waste storage, dumping or disposal. No specific liability regime is currently planned.

Draft directives for waste disposal sites, brought forward in 1991 and again in 1993, also failed to gain approval. The modified 1993 proposal applied the polluter pays principle to disposal-site environmental damage. It would have obligated operators to pay for correcting any environmentally harmful effects caused by operations at their sites, making them strictly liable under civil law for any damage caused. Waste disposal companies also had to provide guarantees and contribute to a cleanup fund. As finally passed in 1999, the directive on waste disposal sites does mention the polluter pays principle, but contains no concrete liability provisions. Rather, member states must ensure that the operator covers all of a waste disposal site's costs for set-up, operation, closure and postclosure, for a period of at least 30 years.

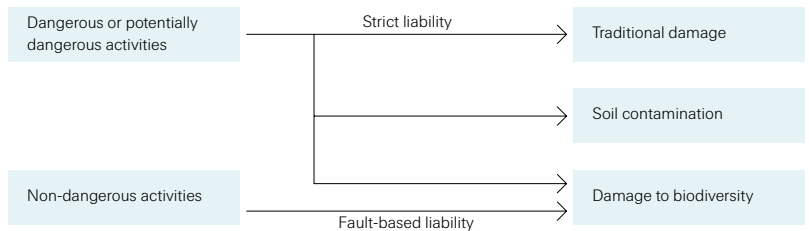
On 14 May 1993, the European Commission presented its "Green Paper on remedying environmental damage", which stated that implementation of the polluter pays principle was dependent on liability under civil law. At the same time, it was recognised that the paper had shortcomings: for example the definition of environmental damage; the demonstration of a causal connection; the calculation of a compensation amount; and the question of insurability. One question was touched upon only briefly: Who has the right to demand compensation for damaged resources of nature that are not private property? To avoid a liability gap, the suggestion was made to extend the right to sue to environmental protection organisations.

Subsequently, the Environment Commission of the European Union (EU) commissioned various studies. The “Study of Civil Liability Systems for Remedying Environmental Damage”²⁷ described the current liability regime in various countries of the EU and their experience with these arrangements, as well as experience with “Superfund” legislation in the US. The study on the “Economic Aspects of Liability and Joint Compensation Systems for Remedying Environmental Damages”²⁸ investigated the economical impact of liability and compensation systems under civil law, as well as methods for determining purely ecological damage. The “White Paper on Environmental Liability” of 9 February 2000 incorporated the results of both studies as well as various commentaries on the Green Paper.

The White Paper was to answer the question as to how the polluter pays principle could best be implemented as one of the EU Treaty’s most important environmental principles. The studies showed that all EU member states had already introduced national systems of environmental liability covering the traditional classes of damage. Legislation had also come into force concerning the liability for and the cleanup of contaminated sites (historical pollution). However, the individual national systems had given no extensive consideration to primary environmental damage: ie damage to nature at large.

The White Paper suggested the following principles for a future EU liability regime: Strict liability should apply to activities potentially dangerous to the environment. Commonly accepted defences must be recognised. Finally, the plaintiff’s burden of proof must be somewhat alleviated. Both types of damage were to be included: traditional (harm to health and property; financial loss) and ecological (historical pollution, damage to biodiversity). There was to be an obligation that compensation sums paid by the polluter should in fact be spent on environmental restoration. Interest groups should now have the right, in lieu of the public authorities, to ask courts for injunctions to prevent damage (or avoid further damage) to the environment. Financial guarantees should provide cover for liability exposures.

Figure 3:
Environmental liability overview according to the EU white paper



²⁷ McKenna & Co, London, available at <http://europa.eu.int/comm/environment/liability/background.htm>

²⁸ ERM Economics, London, available at <http://europa.eu.int/comm/environment/liability/background.htm>

Based on reactions to the White Paper and on additional studies, the EU Commission, in January 2002, presented its “proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage”, mentioned above in connection with the polluter pays principle. Its goal was to prevent ecological damage and – where such damage occurs nonetheless – to settle questions of liability and ensure that the damage is remediated.²⁹

Provisions in detail

The proposal is based on a liability regime under public law: that is, only the public authorities are entitled to bring compensation demands against polluters. Below is a partial list of the provisions in the proposal:

- Public authorities are obligated to initiate specific measures for remedying ecological damage.
- Strict liability applies to certain occupational activities presenting a potential hazard for the environment; for other activities, fault-based liability applies.
- Public authorities are obligated to demand that operators initiate appropriate cleanup measures, or to initiate them themselves.
- Cleanup measures are measures to restore the environment to its natural condition.
- Defences include force majeure, emissions and events specifically authorised under a permit, war, development risk,³⁰ intervention by third parties, and activities conducted in accordance with compulsory orders issued by a public authority.
- Liability is not retroactive.
- The liable party is the polluter, or the party performing dangerous activities.
- Joint and several liability shall not apply. Where an operator can demonstrate the extent to which damage can be attributed to his activity, he will carry only this share of the damage.
- This provision shall not apply to ecological damage resulting from diffuse pollution which is not clearly attributable, and for which it is not possible to demonstrate a causal relationship between the damage and the activities of individual operators.
- The question of whether to require insurance or other guarantees on an obligatory basis for certain activities is left to the member states.

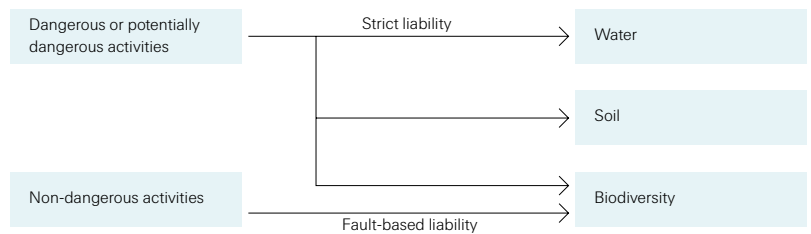
²⁹ In the “Proposal for a directive ...”, Art 2, para 1, no 18, we read:

“Environmental damage” is:

- a Damage relating to biodiversity, ie any damage seriously affecting the favourable preservation of biological diversity;
- b Damage to waters, ie any damage with deleterious effect on the ecological status, ecological potential and/or chemical state of waters, so that this status will deteriorate or might deteriorate so as to necessitate allocating them to a lower category of Directive 2000/60/EG. This type of damage does not include deleterious effects as described in Art 4 para 7 of Directive 2000/60/EG;
- c Widespread damage, ie any damage that, due to contamination of soil or subsoil, causes a serious, potential or actual danger to human health.

³⁰ Emissions or activities which were not considered harmful according to the state of scientific and technical knowledge at the time the emission was released or the activity took place.

Figure 4
Environmental liability overview according
to the proposed EU directive



A comparison of the EU Commission proposal with the existing legal situation in the individual member states reveals the following:

- Several environmental areas are already completely regulated. These include soil protection (historical pollution),³¹ water, protection of nature, waste (disposal sites, incinerators, etc), classified installations (eg IPPC, Seveso), dangerous activities/substances, air pollution and air quality, genetically modified organisms, agriculture and forestry, fisheries, and regional planning.
- In contrast, damage to biodiversity and compensation for interim losses are new for most countries, and the directive requires stricter legislation in these areas.
- Various, sometimes radically different approaches have been used, based on civil law and public law. The directive focuses on the operators in control of dangerous activities, whereas most member states concentrate on the polluter and/or the owner of a contaminated site.
- Introduction of the directive will cause overlaps with existing rules, and may lead to various compatibility problems.

Parliamentary discussions in the member states still show considerable disagreement in certain areas, above all on rules covering the admissible defences (particularly development risk and compliance with official permits and restrictions) as well as the obligatory financial securities for liability exposures (insurance or bank guarantees).³²

However, too extensive a liability for ecological damage could make it impossible for private insurers to continue to offer traditional insurance solutions, given the situation in the capital, insurance and reinsurance markets.

³¹ France: Waste and classified installation act, 1992; The Netherlands: Soil Protection Act, 1994; Belgium: Flemish Soil Cleanup Decree, 1995; Italy: Ronchi Decree/Waste Management Act, 1997; Germany: Soil Protection Law, 1998, Water Resources Management Law, 1959; Spain: Law on Waste, 1998; Sweden: Art 10 Environmental Code, 1998; Denmark: Contaminated Soil Act, 1999; United Kingdom: Part IIA Environmental Protection Act, 1990/1995/2000, WRA 1991, CROW Act 2000, Finland: Art 12 Environmental Protection Act, 2000

³² Status: Spring 2003. Also under discussion is the phased introduction of obligatory insurance according to industrial activity.

3 The insurance market

The major insurance concern with regard to environmental impairment (note a subtle shift of terminology here) is to cover legal liability for the following:

- bodily injury, property damage and financial loss to third parties resulting from ecological damage
- costs for mitigation and restoration measures, including cleanup of the insured's contaminated land
- pure environmental impairment, ie damage to the paths through which pollution is propagated (air, water, soil) as well as damage to biodiversity and to other resources of nature

Based on underwriting considerations, insurers make the following distinctions:

- third-party claims for compensation under civil liability law versus claims by the insured
- sudden and accidental environmental damage (due to failures) versus gradual contamination due to the normal, undisrupted operation of a facility
- contamination that is known at the time the cover is agreed (known historical pollution) versus unknown historical pollution and future pollution
- contamination at the insured site versus contamination elsewhere

The insurance products and solutions developed in respect of these criteria can be categorised as follows:

Environmental (impairment) liability (EIL) insurance

This product insures traditional claims: third-party liability for bodily injury, property damage and the resulting financial loss as well as – in some cases – named pure financial losses. Such policies may insure events due to sudden failure and/or gradual events, according to their individual wording. Separate cover for environmental impairment liability (EIL) is usually necessary because the general liability covers for businesses often exclude claims for environmental impairment.³³

First-party cleanup cost insurance (unknown historical pollution conditions or future pollution)

This policy covers the insured's costs for the restoration of contaminated land belonging to him. Such cover is usually offered as a floater on a fire insurance policy, eg to cover decontamination costs as the result of a fire or other sudden, accidental event. However, liability solutions are also available which cover costs arising from gradual contamination of a site as well.

³³ An exception is Switzerland: see Art 6, General insurance conditions, Swiss Insurance Association.

Cleanup cost cap insurance (known pollution conditions)

This insures additional costs arising due to unexpected or undiscovered contamination, or changes in regulations – as well as natural events – that lead to the cleanup budget being exceeded. Prerequisite for this cover is an approved cleanup plan with a verified cleanup budget.

Contractors pollution legal liability insurance

This product covers, for example, the legal liability exposure of specialist companies involved in performing cleanup work.

Motor insurance, marine insurance

These policies cover liability for environmental damage associated with the transport of hazardous materials.

In addition to these conventional products, some alternative covers are offered. These are mainly alternative risk transfer and alternative risk financing (ART and ARF) solutions as follows:

Finite insurance

This product transfers the cleanup costs for contaminated land from the owner to the insurer. The insurer will take over the cleanup of the site, up to the sum insured agreed upon. "Loss portfolio transfers" are another way of quantifying liability for damages associated with environmental damage and selling it to an insurer.

Captive insurance

This self-insurance – configured as an ART solution – allows the company to carry risks itself that are uninsurable or insurable only under unfavourable conditions. Normally, it is only large corporations that are able to use this method.

3.1 Overview: insurance for ecological damage liability in Europe and the US

Analysis of the various European insurance markets reveals no insurance products providing comprehensive cover for environmental impairment, either within the EU or elsewhere within Europe. This applies both to sudden and accidental environmental impairment, and to that caused by harmful emissions during an industrial facility's normal operation. It applies as well both to historical pollution and to new or as yet undiscovered pollution. The main concern in Europe is with future ecological damage, where the discussions regarding CERCLA focus on historical pollution.

Germany

Interest in Germany focuses on the Environmental Liability Insurance Model ("Umwelthaftpflichtversicherungs-Modell", or "UHV-Modell"). It covers bodily injury or property damage – and in some cases financial loss – due to liability claims under civil law, as well as loss prevention costs. It does not insure claims brought by way of public law or by the authorities, and there is no cover for claims arising from ecological damage.

There are also insurance concepts that are keyed to the laws on soil protection: these cover the cleanup of historical as well as new pollution. However, with the exception of fairly usual provisions included in fire covers for insuring the cleanup of a site subsequent to a fire, all of the above are niche products.

France

In France, all liability for claims arising out of environmental impairment is insured by the French environmental insurance pool "ASSURPOL", as conventional liability covers normally exclude such claims. ASSURPOL offers insurance protection against environmental impairment claims for bodily injury or property damage, and certain kinds of financial loss; no claims arising from primary environmental damage are insured.

The Netherlands

In the Netherlands, liability policies for businesses exclude all claims (with the exception of bodily injury) arising from environmental impairment. A separate environmental damage policy ("Milieu Schadeverzekering" or "M.S.V."), on the market since 1998, offers additional insurance coverage for cleaning up contaminated soil on sites (belonging either to the insured or to third parties), or bodies of (surface) water. Ecological damages are explicitly excluded.

UK

Liability insurers in the United Kingdom cover bodily injury and property damage as the result of unexpected environmental impairment. There is normally no insurance protection for damage in connection with gradual environmental impairment. No cover is offered for primary environmental damage.

Sweden

Bodily injury and property damage due to operational disturbances are covered under liability policies, similar to the UK. Cover for claims arising from gradual environmental impairment is also offered, but in a separate policy; this cover is limited to bodily injury and property damage, however.

There is a special insurance solution for cases where the polluter responsible for cleanup under environmental law has become insolvent. Such a cleanup is covered as an "urgent measure" for the prevention of bodily injury, property damage or environmental impairment. According to the wording of these policies, they do insure some primary environmental damage to a very limited degree: to the amount spent to prevent impending bodily injury or property damage.

Switzerland

Insurance cover in connection with environmental impairment is limited to legal liability for bodily injury or property damage due to a sudden, accidental event. Also insured are measures for avoiding impending insured damage to persons and property. Primary environmental damage and gradual environmental impairment do not come under the normal liability covers for businesses.

US

The commercial general liability (CGL) policies currently in use absolutely exclude damage in connection with environmental impairment. Special complementary covers are offered, but these are also limited: to claims following a sudden and accidental occurrence. These covers use wordings which either list the accidental events ("named perils clause") or "simulate" an event by means of a "time-based clause". Claims in connection with "natural resource damages" (NRD) are not excluded absolutely, but in practice – given the volume of the US liability insurance market – they play only a small role.

On the one hand, activities falling under the OPA or CERCLA (the Oil Pollution Act or the Comprehensive Environmental Response, Compensation and Liability Act, respectively) are not insured under CGL covers; on the other hand, any attempt to cover cleanup costs for the insured's site and primary environmental damage in addition to traditional claims would exhaust the normal sums insured under such policies which are usually modest.

Special covers designed for CERCLA exposures are difficult to obtain due to strict insurability requirements, cover exclusions and high premiums. The focus of these policies is on bodily injury, property damage and site cleanup.

3.2 Alternative provisions

Instruments such as sureties, joint sureties and bank guarantees provide certain alternatives to traditional insurance products. The authorities now accept sureties and bank guarantees as assurances that a company is financially able to shoulder its liability with regard to any waste disposal site cleanup that may become necessary (for example under Art 59a of the Swiss Environmental Law). In recent years, developments and events in the environmental area – notably, legislation on historical pollution – have raised another problem: solvency.

The number-one criterion for the approval of any guarantee has become the solvency of the company applying for it; and though in the past real estate was routinely accepted as collateral for a surety or guarantee, further conditions are necessary to secure such an agreement today.

One very basic problem lies in a peculiarity of damages arising in connection with environmental impairment: the consequences of an event normally affect both the industrial facility and the land on which it stands. For example, if water used for fire fighting contaminates an industrial site, it could mean that this land, used as collateral for a guarantee instrument, will lose the greater part of its value. The situation is similar when systematic soil testing, mandated under soil protection legislation, reveals a site as contaminated: here, too, the resulting loss of value could mean that a guarantor who had accepted the site as a pledge would find himself in a perilous situation.

Banks factor all these eventualities into their decisions. A site's potential to cause environmental damage is now a part of their risk analysis, and this explains why it is more difficult than ever to procure a surety or bank guarantee in return for pledged real estate.

4 The insurability of liability for ecological damage

4.1 The underwriting prerequisites for insurability

The prerequisite for insuring environmental liability is a clear set of criteria which would allow the underwriting risk to be calculated reliably. This applies particularly to the severity of damage, its type (bodily injury or property) and the trigger (insurance cover only for accidental events, or limited cover for gradual events as well, or full cover). Also, it must be accepted that insurance cover will never be congruent – will not be a “neat fit” for the legal liability: though increasing experience will allow liability and cover to approach each other, there will always be gaps between the two. Cover will never be given for intentional pollution, for example, and there will always be differences with respect to types of damage, triggers or sums insured. Also – particularly in the environment area – the risk of change, in its technical, scientific and economic aspects, has taken on forms that make adaptation particularly difficult for the insurance industry. We know little or nothing about the effects that many substances have or will have on our environment, for example.

Thus, the underwriting criteria for insurability are as follows:

- *Assessability*: It must be possible to quantify the probability that damage will occur, as well as its severity, in order to calculate the potential exposure and the premium necessary to cover it. In addition, it must be possible to allocate damage to a particular insurance period.
- *Randomness*: The time at which an insured event occurs must not be predictable, and the occurrence itself must be independent of the will of the insured.
- *Mutuality*: A large number of endangered parties must join together to carry the hazard jointly.
- *Economic efficiency*: Private insurers must be able to charge a premium commensurate with the accepted risk; a premium that allows them to write insurance profitably over the long term.

Assessability

To assess the probability and severity of an occurrence, insurers depend on their experience and statistics from the past. With environmental impairment, it is necessary to distinguish between two areas when assessing the occurrence probability.

The likelihood of primary environmental damage that is sudden and accidental can usually be determined using statistics available to insurers (on explosions or fires, for example). Then, by factoring in knowledge about legal liability, statutory regulations on the design and operation of industrial plants, and the properties – chemical, physical, biological – of known substances, insurers can arrive at a fairly accurate picture of the risk they are underwriting. The “joker” in such considerations is the risk of change, and this should not be underestimated. New knowledge is surfacing all the time as to the effect of various substances on human health. Normally, such uncertainties are accounted for by adding a surcharge (“loading”) to the premium; yet if a factor is new or unfamiliar – or when it represents a new category, such as ecological impairment – calculating its probability is more difficult, even if it is the result of a sudden or accidental event. In the past, such damage has just not been insured. Insurers have little or no experience – ie statistics – for this kind of loss, and it is presently almost impossible to calculate an “adequate” premium.

Where an “event” does not originate in a sudden or accidental occurrence, things are more complicated. Here, the insurer is dealing with emissions that accumulate gradually in the course of an industrial plant’s normal, undisrupted, authorised operations. At first, the “event” which causes the damage is not recognised as such; and for this reason, it cannot be allocated to a definite point in time. Normally, the threat to human health results from the slow accumulation of toxic substances in a propagating medium such as groundwater. Here, insurers do not have the necessary statistical data (or “experience”), because such events have until now been excluded from insurance cover, and thus are not included in loss statistics. They also lack knowledge as to the effect of many substances on the environment and this, too, makes it more difficult to assess environmental risk. An example are “endocrine disruptive” chemicals – substances that alter the hormonal balance of organisms when their concentration in nature reaches a certain level. If it ever becomes possible to prove that these substances also affect the hormonal balance of humans, and if it becomes possible to determine unequivocally their source, this will have unpredictable consequences for the economy. If, for example, it can be demonstrated that contraceptives have a definite effect on the hormonal balance of fish, who should be made responsible for the ecological damage? Is it the consumer, or the pharmaceutical company who produced the medicament, or society in general that would be responsible for ecological fallout such as a fall in fish populations or the loss of a species? And what would happen if it was demonstrated beyond any doubt that human reproduction was also affected?

Figure 5
Loss events

Cause	Effect	Examples
Sudden	Sudden	Explosion releases toxic gas cloud: residents poisoned, evacuation of area necessary
Sudden	Gradual	Explosion causes leak in pipeline: toxic substances contaminate drinking water, residents poisoned
Gradual	Sudden	Corroded gas line allows gas to escape: ensuing explosion results in several fatalities
Gradual	Gradual	Waste water gradually contaminates drinking water, residents poisoned

In addition to the risk of change, which is now factored into premium calculations, the inclusion of liability for primary environmental damage would aggravate the insurers’ situation.

The question of assessing the severity of damage is even more complex. Despite an abundance of statistical data, there is still considerable uncertainty in estimating the amounts that will be awarded in future for bodily injury claims, for example – due to cost trends in the health care sector. Similar uncertainty attaches to estimating the cleanup cost for contaminated waste sites: methods are changing, costs are rising. Ecological damage presents an even more formidable challenge: at present, it would be entirely impossible to estimate the cost of measures to restore environmental quality. Not only is there is no legal basis for judging liability and calculating damages: even more critical is the lack of statistical data for estimating the extent of such damage.

In contrast, the next two prerequisites of insurability mentioned above – randomness and mutuality – should pose no particular problem in the ecological damage area.

Economic efficiency

Long-term profitability is not the only issue in calculating an adequate premium: statutory solvency requirements also play an important role. The law requires insurers to charge premiums that, in light of underwriting know-how, are adequate to cover the risk. For the reasons mentioned, this is hardly possible for ecological damage using the traditional underwriting methods.

Placing an upper limit on strict liability could be helpful; however, it would be difficult to avoid misunderstandings that such a limit was identical with the sum insured that insurers make available (product liability law; environmental liability law). Insurers must be able, too, to provide these amounts (despite the limited amount of capacity in the finance, insurance and reinsurance markets).

4.2 Compulsory insurance: a magic formula for financial security?

The reasons why compulsory liability insurance has been introduced in Europe can be summarised as follows:

- Isolated, simple events may lead to a serious single bodily injury (activities such as the use of motor vehicles or the provision of healthcare).
- A single event may harm many victims and lead to series of claims (activities such as handling toxic substances, manufacturing medicines, organising dangerous sport events, the nuclear generation of electric power or operating pipelines).
- Some events may cause substantial financial loss (activities such as those exercised by attorneys, notaries, tax advisors, real estate agents, architects or travel agents).

The insurance industry attempts to offer insurance solutions that are congruent with the relevant laws (examples: motor liability insurance; environmental liability insurance; professional liability insurance for attorneys and notaries; insurance solutions for nuclear power plants). In certain cases, it is difficult to provide the sums insured that the lawmakers require ("unlimited" motor liability in Europe, for example).

Insurers should encourage lawmakers to consider the following conditions of insurability when mandating new forms of obligatory insurance:

- The risks to be insured must be homogeneous. Motor insurance, for example, is said to be homogeneous because of the very large number of motor vehicle operators who represent essentially the same type of risk. With liability insurance for ecological damage, this is not necessarily the case. Should only those companies carry insurance that use specified hazardous materials, or should all commercial operations be insured?
- Only a statistical sample with a sufficiently large number of insurance policies will allow meaningful assessments and realistic calculations. Where significant statistical data is lacking, new insurance products will suffer from uncertainty with regard to risk analysis and premiums.
- It is politically desirable for a number of insurers to offer such products, in order to avoid monopolies.
- The insured parties must be in a position to pay the premium required for the mandated cover. Obligatory insurance is useless if companies must shut down their operations because they are unable to pay an adequate premium.

- The decision as to what insurance cover can be offered in each case – and if any can be offered at all – must be left entirely to the insurer: he must be free to reject certain risks.
- Likewise, it must be recognised that the calculation of a premium adequate to the risk is the insurer's domain: the government should not prescribe premiums.
- If a risk is not insurable, either objectively or subjectively, special arrangements (eg financial guarantees) must be made.
- The public authorities must set up offices to monitor the insurance solutions proposed to fulfil statutory requirements.

Introducing obligatory insurance for ecological damage liability would solve none of the problems described above. The main difficulty would be the lack of statistical data for calculating loss frequencies and severities. In addition, the exercise of a particular activity should not depend solely – or even mainly – on having insurance cover: this puts insurers in the position of a policeman, and this is not their job. Hazardous activities should not be approved only because the activity is insured: in the environmental area, the necessary level of safety can be only ensured by fulfilling an entire catalogue of preventive measures.

5 An insurability concept for ecological damage liability

5.1 The scope of cover

What is needed in order to develop an insurance solution capable of transferring all risks associated with ecological damage? Due to the many areas of uncertainty that remain and the many open issues, this question is far from simple. Nonetheless, we will attempt to consider below the most important elements in any future solution.

Covering claims deriving from civil law and public law

Ecological damage (according to our definition of the term: primary as opposed to secondary environmental damage) impacts those free resources of nature that belong to no one but exist for the common good, such as open bodies of water, nature preserves, or even free-living flora and fauna. As the current liability regime under civil law is not particularly suitable as a tool for their protection, it is not surprising that the EU³⁴ would prefer to use strict liability under public law to address this problem. An added advantage to this approach is that it does not further aggravate the liability situation under public law: the EU proposal is based largely on existing provisions that most European countries have already written into their public (police) law (with the exception of interim losses). These provide authorities with powerful means of intervening to protect free resources. Where there is danger either to the public or to legally protected resources of nature, public authorities may mandate measures to prevent or clean up ecological damage. If the polluter is unable to perform his obligations – or refuses to do so – the public authorities may, within reason, arrange for third parties to carry out the necessary measures; and the polluter must then pay the cost.

It may be said that the general trend in the environmental protection area is for private and public law to merge. Any forward-looking insurance concept must rest on a principle allowing it to cover all environmental liability claims, whether they derive from civil law or public law.

At the same time, the insurer's concept must distinguish clearly between two types of potential loss under public law: liability for damage, on one hand; and fines and penalties on the other. These last two must be rigorously excluded: insurance cover must not extend to infractions of penal law!

³⁴ Again, in its "Proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage"; cf Chap 1 above, and Chap 2 above, section on "Environmental liability in the European Union".

Concentrating on restorative measures

Under new environmental legislation, the lawmakers' fundamental concerns are to protect biodiversity and designated nature preserves, mainly through a focus on preventing or remediating ecological damage. Thus, an insurance concept should cover the cost of measures set in motion either to prevent impending ecological damage or restore already impaired resources of nature to their original or "baseline" condition. The environment is considered to be restored when damaged habitats, contaminated soil or polluted bodies of water have regained their baseline condition. We also speak of measures aimed at correcting primary environmental damage as "primary restoration".

Limiting insurance to the tangible components of ecological damage

What is "tangible" ecological damage? What ecological damage is "intangible"? Consider the following structure:

- all ecological damage (containing tangible and intangible components)
- damage to designated, protected resources (containing tangible components only)
- damage to biodiversity (basically intangible, although the actual, underlying damage to flora and fauna are tangible).

The "tangible component" of ecological damage relates to defined, quantifiable, but free (ie ownerless) resources of nature: water, soil, air, flora and fauna.

Opposed to this tangible component is "intangible" ecological damage: impairment of intrinsic values which are much more difficult to quantify in concrete fashion. These might include landscapes, an area rich in biological varieties, or a particular panorama or view.

Risk transfer solutions for ecological damage focus primarily on the tangible component. This is fortunate, because it means that from an underwriting (as opposed to a legal) standpoint, there is – regarding water and land damage – no fundamental difference whether the damaged resource is private property or free; or whether a claim arises from a damage suit under civil law, or from a mandated cleanup under public law. Just as the insurance industry offers products for bodily injury, property damage and financial loss, it has also developed extensive concepts for the tangible area (at least) of primary environmental damage: covers ranging from prevention or mitigation costs to cleanup costs (for sites belonging to the insured). At present, these covers are still tailor-made; they are not volume products. Yet the know-how gathered in past years can be used to develop these tested cover concepts further.

It is possible to develop procedures for evaluating the tangible component of ecological damage; and they will be necessary, mainly to evaluate and quantify the cost of restorative measures.

5.2 Primary restoration: damage, options, the need for cooperation

The prime concern of all parties (the authorities, the [insured] plant operator who is liable, as well as the insurer) is to restore the damaged resources to as near their original condition as possible, as rapidly and efficiently as possible.³⁵ It should be in the interest of all parties to avoid the delay and expense of litigation, and cooperation must also be made a prerequisite of the insurance concept.

As the goal is to restore the protected resource, allowing it to be used and enjoyed by the public, the issue is not to determine a sum that the damage is “worth”, but rather to determine the qualitative nature of the damage, and how much it would cost to restore the original condition – or to approach it as nearly as possible. The cost of these measures, then, is the restoration cost. In recent years, the cleanup of contaminated industrial sites has provided a store of know-how that permits such costs to be estimated.³⁶ The type and degree of contamination determines the cleanup method; the method, in turn, determines almost exactly the cost of cleaning a ton of soil. Replanting or reforestation costs, too, can be determined with a fair degree of accuracy.

We should note here that insurers are still far from being able to calculate a fair and adequate premium for covering any one of the innumerable potential losses that might materialise. This requires much more statistical material than is currently available. Nonetheless, we might ask the question:

What might the concept for such a restoration plan be?

Such a concept would comprise several phases in which the damage would be evaluated, options considered, and measures selected and implemented. These phases will be discussed below.

Determining and evaluating the damage and its severity

The point of departure for determining the damage is an assessment of the protected resource’s “baseline condition”: its condition before being affected by the damage. Such a report describes the resource’s type and quality as well as any ecological functions or “services” that it may have provided. Then, each effect produced by the damaging occurrence on the resource and the ecological services it provides is identified and quantified.

³⁵ Such resources may include habitats and species protected by EU directives the Habitats Directive of Annex 1 of the Birds Directive – as well as nature or wildlife sanctuaries established under national law.

³⁶ In isolated cases, experience has been gathered also in cleaning up contaminated bodies of water (eg the Rhine after the Schweizerhalle fire). Special attention should be given to the regenerative potential of flowing bodies of water.

Figure 6:
Services potentially provided by wetlands

Ecological benefits	Benefits for residents
Geological, hydrological <ul style="list-style-type: none"> ■ groundwater regulation ■ groundwater source ■ cleansing function ■ flood alleviation ■ shoreline and river bank stabilisation 	Leisure <ul style="list-style-type: none"> ■ swimming, beach use ■ fishing, hunting ■ boating ■ wildlife observation
Habitat for flora and fauna <ul style="list-style-type: none"> ■ Grasses, bushes, trees ■ Place for indigenous animal species (birds, fish) to live and multiply ■ oxygen production 	Commercial benefits <ul style="list-style-type: none"> ■ fish farming ■ drinking water resource ■ hydroelectric power ■ agriculture, forestry
Ecological integrity <ul style="list-style-type: none"> ■ regulation of climate and air quality ■ conversion of pollutants 	Health <ul style="list-style-type: none"> ■ recreation ■ enhanced air and water quality

Perhaps the most fundamental issue is to decide whether the effects of the damage are reversible at all: this question is decisive for any subsequent restoration programme.

The decisive question with regard to any possible liability is whether there is significant damage: if there is none, no restorative measures are necessary. Damage is significant if it worsens the favourable conservation status³⁷ of a habitat protected in the EU's "Habitat" directive or "Birds" directive,³⁸ or of a nature sanctuary designated by national law.

The following criteria can be used as measures of whether the damage is significant:

- qualitative environmental standards for water and air pollution, with threshold values for unacceptable levels
- the degree, duration and extent of the exposure
- the answer to the question as to whether the harmful influence is reversible or not
- the sensitivity and rarity of the affected resources

In the case of the "Natura 2000" sites, one measure of severity is whether the damage has a negative effect on the ecological integrity³⁹ of the protected site.

³⁷ According to Article 1 of the Habitats Directive,

The conservation status of a natural habitat will be taken as *favourable* when:

- its natural range and areas it covers within that range are stable or increasing, and
- the specific structure and functions which are necessary for its long-term maintenance exist and are likely to continue to exist for the foreseen future, and
- the conservation status of its typical species is favourable...".

³⁸ The full titles are "Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora", and "Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds". Both are available at <http://europa.eu.int/comm/environment/nature/legis.htm>

³⁹ The integrity of a NATURA 2000 site has been defined in the UK (UK DoE, 1994) as the coherence of the site's ecological structure and function across its whole area, or the habitats, complexes of habitats and/or populations of species for which the site is or will be classified.

Defining the options

Once it is clear that significant damage has occurred and that a remedy is possible, the next step is to define the goals and develop options for a programme that – ideally – will restore the damaged habitat to its baseline condition.

Under the “Proposal for a Directive...”, any liability is dependent on significant damage or on an unfavourable influence on the ecological integrity of a protected Natura 2000 habitat. Whenever possible, the damaged resource should be restored by assisting the natural processes of regeneration.⁴⁰ A large variety of restorative measures are possible; we will describe only three general categories.

No intervention

In extreme cases, the best decision may be to let nature take care of itself: that is, to restore or regenerate the damaged resource on its own. This option might be the only reasonable course when a resource (or habitat) is particularly sensitive – to heavy machinery or other physical disturbance, for example – or are simply inaccessible.

It may be that certain vegetation will react negatively to the chemicals (detergents or emulsifiers) that would ordinarily be used to clean up an oil spill. For this reason, it may be better to forgo using them and wait for natural influences to break down the oil in their own good time.

Limited intervention

Limited measures are used where the goal is to assist or accelerate the natural regeneration of damaged resources. These may include planting trees, shrubs or grasses that will attract a variety of animal species. Together, all of this will improve the ecological structure. A further example is the planting of special grasses in the restoration of dunes along the coasts. Such grasses stabilise the ecology and prevent wind erosion.

Complete restoration

In cases where an event has caused a complete collapse of the ecological system, more extensive measures are necessary. These might include the cleanup of pollutants, the substitution of clean soil, or the replanting and re-population of the area’s life forms. To date, such radical restoration programmes have been quite rare: the restoration of a complete ecosystem is a complex and difficult task, and there is a danger of “over-restoring”.

Successful examples of complete restorations include gravely damaged sections of rivers. In such cases, the correct mix of flora, fauna, water quality and flow velocities can be reconstructed fairly well.

Progress towards the defined restoration objective must be monitored continually. Methods range from very low-tech to aerial or satellite imaging, and must be appropriate to the individual situation.

⁴⁰ “Proposal for a Directive...”, Article 3.

Selecting the measures

After the various restoration measures have been determined and listed, a selection must be made. Simple, powerful criteria have been defined to steer this process.⁴¹ A cost-effectiveness analysis ensures that the most efficient measures are chosen; a cost-benefit analysis ensures that the benefit will exceed the cost for all measures implemented.

From this description of the process, it should be clear that the individual process steps leading to the selection of the restoration measures can be successful and efficient only when all parties cooperate purposefully from the very beginning. Such cooperation is an important pillar of the insurance concept, and it bears repeating here that it should be made obligatory for all those involved.

⁴¹ For example, in the "Proposal for a directive...", Annex II para 3.2.1, we read:
"Once the competent authority has developed a reasonable range of restorative options, it shall evaluate the proposed options based on, at a minimum:
1 The effect of each option on public health and safety;
2 The cost to carry out the option;
3 The likelihood of success of each option;
4 The extent to which each option will prevent future damage, and avoid collateral damage as a result of implementing the option; and
5 The extent to which each option benefits each component of the natural resource and/or service."
See also Annex II para 3.2.2: "If several options are likely to deliver the same value, the least costly one shall be preferred."

5.3 Compensating interim lost value

In addition to liability for restoring damaged resources, the "Proposal for a Directive..." makes polluters liable for the "interim losses": the accrued value of the ecological resources or services lost due to ecological damage, from the time of the event until the affected resources are fully restored.

Such compensation always implies a form of substitution of one resource for another, whether calculated in terms of another ecological resource or of cash value. The EU Commission must further elaborate both the basic concept as put forward in the "Proposal for a Directive..." and the cash valuation methods to be used to quantify these interim losses.

Another type of compensation might be to exchange resources impaired or lost today for improved resources or services in the future. Such compensatory measures might have to be implemented at another location as well; or they may have to generate an ecological service that is completely different from the one lost.

Due to the many variables, it is not currently possible to quantify such compensation. Thus, in this area – in contrast to primary restoration – we find that one of the basic prerequisites is still lacking for an insurance solution with full risk transfer.⁴² In addition, the capital that the insurance industry furnishes should be used exclusively to restore the protected resources to their full ecological function.

⁴² In the US, measures taken under the NRDA (Natural Resource Damage Assessment) taken to compensate for interim lost value are divided into four categories:

- same resource, same quality, comparable value
- same resource, same quality, no comparable value
- same resource and quality
- neither resource nor quality is comparable

"Category 1" measures are the optimum to be worked toward and implemented, while "Category 4" measures cannot be recommended. "Category 1" measures are also known in the US as the "service-to-service approach": put simply, this means that interim lost value is compensated through equivalents. For the other categories, the "value-to-value approach" or the "value-to-cost approach" is used. These approaches use monetary evaluation methods that are quite controversial in academic and scientific circles. Certainly one of the more contentiously debated of these is the "contingent valuation method", whereby the value of a resource – where market data is unavailable – is assessed using specially developed surveys of the populace.

5.4 The necessity of a causal and temporal context

Even though the “Proposal for a Directive...” has a strong public-law orientation, it leaves intact several familiar civil liability components. For example, liability for any damage to a protected resource always depends on the insured operator being engaged in a specific industrial activity; and in order to trigger the cover, there must be a sufficient causal connection.

The proposal’s Annex 1 contains a list of activities particularly dangerous to the environment: for these activities – and for no others – strict liability is stipulated.

Two points have yet to be included in the “Proposal for a Directive” in clear and unequivocal form: the requirement of a reasonable causal connection; and a clear statement as to which party or parties (the public authorities?) is responsible for providing the proof of such a connection.

An extremely important aspect – particularly in light of the latency problem that generally pervades environmental impairment liability issues – is the definition of a time frame allowing damage to be allocated to a definite time, and thus to a definite insurance period. The issue here is to fix the point of the damaging occurrence on the time axis as clearly and unequivocally as possible.

For the insurance concept that we are attempting to elaborate here, we consider the manifestation (or discovery) of (impending) damage during the term of insurance as the trigger principle that would come closest to producing the desired result.

The issues of the time frame and trigger are closely connected with the need to clarify and define cover for ecological damage. The central challenge here is to eliminate “the phenomenon of the gradual” as a potentially powerful loss generator: both for environmentally dangerous activities in the past which may have deposited a legacy of historical pollution; and for such future activities that could lead to similar pollution years from now.

The “Proposal for a Directive...” explicitly excludes retroactive liability. This means that the new liability regime will only apply to those environmentally dangerous activities or exposure increments that begin after it comes into force and are registered under it. There is no liability for historical pollution, and this is a major liability prerequisite for insurability.

Assuming that this proviso is upheld, the introduction of a “time-based clause” into the prospective insurance concept should render it much more congruent to the liability regime under the new proposal.

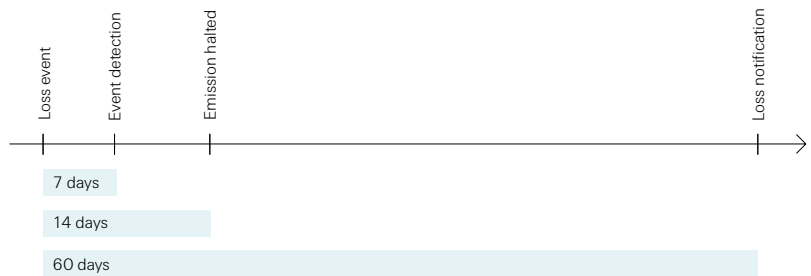
A suitably formulated clause governing future ecological damage will “compress” time, thus eliminating “the phenomenon of the gradual”. The avoidance of this problem, which has long made environmental losses difficult to quantify, should further encourage development of a risk transfer solution.

The clause provides cover for ecological damage in cases where the insured operator of a plant becomes aware, within a specified, relatively short period, that environmentally harmful substances are escaping; the polluting event as well must not extend beyond a limited period. In addition, the insured operator is obligated to notify the insurer within a specified period of any emissions, and provide certain details as soon as these have been ascertained.

Such clauses do not exclude gradual causation as such from the cover; rather, it compresses the time frame of the covered event. This avoids the dreaded case where the cause of the pollution – and the trigger for the cover – lies far in the past.

The intention is to cover only events that the insured becomes aware of within a week at the most, and which he must report to the insurer within a specified interval: 60 days, for example.

Figure 7:
Period of validity



The decisive point is to eliminate the latent claim element. This is accomplished by defining clearly and unequivocally the beginning of the causal event: that is, the emission of the environmentally harmful substances.

This point in time is not to be determined by scientific or technical means – for example by using analytical methods to detect and register substances. A slightly different wording of the clause would allow unknown historical pollution to be brought into the cover as soon as the scientific or technical state of the art improves to the point where the insured is able to detect the long-existing pollutants. Thus, the time it is first possible to detect an omission objectively must not be considered as the start of the emission from the point of view of the cover.

5.5 Integrating the cover concept into the current product range

Due to the complexity of the ecological damage problem and the associated underwriting process, an assessment of each separate, individual risk by a specially trained, competent underwriter is an absolute necessity. Ideally, this process should be combined with the existing processes for underwriting environmental impairment liability.

Ecological damage covers should have their own conditions, premiums and sums insured. However, depending on market preferences, they could either become a component of an environmental impairment liability insurance, or be offered as a new stand-alone product.

6 Conclusions

In the past, the insurance industry has repeatedly proven that it adapts its concepts and products to its clients' changing needs. In doing this, it makes an important contribution to the development of society itself.

The same applies to environmental risks, which are continuously evolving in response to legal, technical, social and political change. For these risks, insurers have already brought out new or extended covers – first party cleanup cost covers and cleanup cost overrun covers, to name only two examples.

The area represented by the tangible component of ecological damage is similar: an insurance solution could be elaborated despite the fact that the prerequisites for insurability – assessability, randomness, mutuality and economic efficiency – are only partially given.

The new liability regime is only a matter of time. The question now becomes: For which areas within this new liability regime does the insurance industry want to develop covers to offer its clients?

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Genetic engineering and liability insurance The power of public perception

Developments in genetic engineering are changing the risk profiles of the pharmaceuticals, agricultural and nutritional sectors permanently. Genetic engineering has triggered a worldwide discussion on public acceptance, which will not leave the insurance industry unaffected. When assessing the future risk profile, the decisive element is not whether genetic engineering is dangerous, but how dangerous it is perceived to be. Industry and insurance share the responsibility of helping to shape society's changing values.



Do new technological advances mean “business as usual”?



Origami, the Japanese art of paper-folding, brings a simple piece of paper to life.

For an insurer, thinking the unthinkable and quantifying the unquantifiable would mean being in a position to predict the risk potential of new technologies without any claims experience. Because this is an impossible task, the insurance industry has reacted uneasily towards genetic engineering risks.

At the outset, new technologies, such as genetic engineering, are lacking in familiar advantages and disadvantages. There are no means for comparison and as a result, hopes and fears are boundless, and potential uses and supposed damages are initially unquantifiable. For the insurance world, a lack of clear loss experience and means for calculation culminates in the fundamental question of the insurability of such risks. If the risk profile of an insured sector is undergoing permanent change, there is need for action.

Has the insurance industry been too careless?

The fact is that genetic engineering is insured under the many existing liability insurance policies of large industrial enterprises. Only a handful of markets define special covers or even exclusions for genetic engineering applications. This creates the impression that many insurers treat genetic engineering as a simple continuation of industrial activity using different gradually developing means. Is the insurance industry perhaps being too rash in its dealings with genetic engineering? How risky is liability insurance business involving genetic engineering in reality?

When dealing with new technologies, it is important to distinguish the scientific and technical risks from cultural and societal influences. With regard to the technical risk, the industry maintains – and quite rightly so – that its applications have so far not brought about any accu-

mulation of losses. For a long time, genetic engineering has therefore been seen as gentle and environmentally friendly. Genetic engineering applications will hardly lead to catastrophes such as those in Bhopal or Schweizerhalle. However, changing societal values and a constant increase in the importance of our environment pose the likelihood of new types of loss patterns, which may lead to far-reaching changes in the risk profile in general and not just that of the environmental risk.

New technologies create new realities

In product liability, it will not be possible to simply transfer loss experience from conventional products to transgene ones, since many of these products are aimed at new markets and consumer groups. Consumers' cost/benefit analyses are therefore the decisive risk characteristic of genetic engineering for the insurance industry. If we compare medical applications of genetic engineering to genetically modified foodstuffs, the different risk perceptions and propensity become particularly clear.

New technologies create new realities far removed from the world we trust. This makes us wary and cautious, not only ordinary citizens and politicians, but also actuaries and reinsurance underwriters. Since there are few experience values available for the risk profile of this new technology, the profitability of liability insurance business is dependent on whether the right assumptions were made in assessing future loss scenarios.

The controversy surrounding genetic engineering and its consequences for the insurance industry

Risks of change

In liability insurance, many losses only become apparent many years after cover has been granted. Long latent claims are very dangerous for the insurance industry, because the type and extent of the risks cannot be predicted. These risks of change are characterised by an imbalance between the risk premium and the actual claims expenditure.

For the insurance industry, genetic engineering is potentially one of the most particularly exposed technologies of the future. This is not only because the loss experience necessary for traditional insurance models is unavailable, but also because the euphoria, which once accompanied and spurred each advancement, has hit a crisis. The widespread scepticism towards a mechanised society increasingly associates scientifically complex developments with a massive potential for destruction. This also holds true for genetic engineering, which is approaching the point at which intellects differ on the sense and nonsense of technical development.

“Nip it in the bud” seems to have become the motto for many people. They feel that their personal rejection might have an immediate effect on the development of genetic engineering. It is certainly advisable to question in depth and at an early stage the possible negative consequences of technological progress. However, opportunities are often lost as a result. Frequent demands for absolute

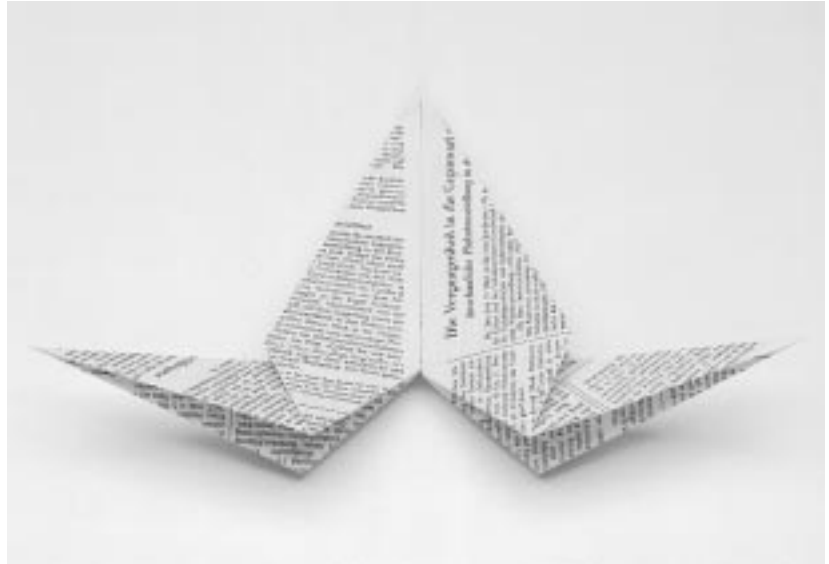
safety, controllability and reversibility cannot be fulfilled and represent a failure to appreciate the fact that new technologies not only solve problems but also create new ones. The less acceptance the public shows towards new risks, the less trust is placed in the means to deal with them and the greater the likelihood that the possible negative consequences of each new technology will become a problem for the insurance industry.

Unknown development

The insurance industry does not perceive genetic engineering risks as clearly definable, but primarily as part of an uncertain societal development. As long as a consensus is reached on what a loss is, what value it can be attributed and how it can be replaced, the insurance industry is happy to perform its traditional role. However, the more disagreement there is about the basic prerequisite of insurability, the more insurance companies consider themselves unable to fulfil their function as a risk carrier.

If the development of the socio-political and socio-economic environment is uncertain or does not proceed as expected, this is known as the socio-political risk of change. Genetic engineering is a prime example. Which is why the insurance industry should pay it particular attention.





How risky is the insurance of genetic engineering risks? One answer is clear from what we have seen so far: insufficient loss experience and changing societal values are reflected in a risk of change for which no quantifiable elements are available.

The level of acceptance and the forces changing it, as well as the growing distribution of transgene products for highly sensitive consumer areas form the main elements of this risk of change. These elements are subject to rapid changes:

- Socio-political and cultural elements. Genetic engineering provokes debate in wide circles. In German-speaking countries and in northern Europe in particular, sensitivity is high and risk acceptance low. The issue forms the main subject of discussions on structures and values. It is a public issue.
- Socio-economic factors. The pharmaceuticals, agricultural and nutritional sectors are growing disproportionately in the area of genetic engineering ap-

plication. Their products are winning over new markets where reactions from consumers are quite different and cannot be predicted.

- Genetic engineering is on the point of becoming omnipresent: genetically engineered applications and products will penetrate above all areas such as health, nutrition and the environment, which are particularly sensitive because they are essential to everyday life.
- The time factor: fundamental values, laws and risk acceptance are subject to constant change which has no predictable direction or speed. This is particularly true of genetic engineering, because the future risk component is prominent. It represents a particularly exposed long-term risk.

How do public issues arise?

Public issues originate from pressure groups. They begin as printed matter and progress through public opinion to become political issues. Once they are on the political agenda it is only a matter of time before laws and legal decisions are amended.

In the medium term, only one thing is certain, namely that genetic engineering will remain a public issue. The insurance industry is therefore faced with two fundamental tasks: selecting and influencing risks. In other words: risk management and issue management. Traditionally, the insurance industry is involved in identifying risks and assessing them technically. What is new is the approach to viewing the elements of a risk landscape as a whole and using them as the central theme.

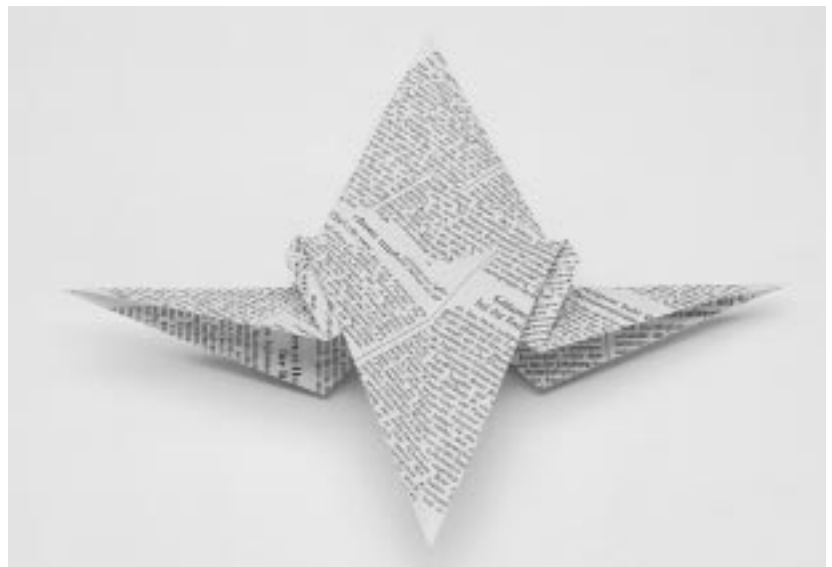
Where is the need for action?

Issue Management involves the early recognition of signals from a sensitised public and an analysis of the effects on one's own company. In the case of genetic engineering, Swiss Re is in the process of identifying where the strongest signals are coming from, because this is where the need for action is greatest. Such signals are, for example, stricter liability provisions, a legal obligation to be in-

sured or the threat of legal proceedings; these are all signals with immediate consequences for the insurance industry.

Even if individual insurance companies are able to "accurately" calculate and obtain their premiums for the expected expansion of their services, no such high level of insurance cover will reduce the risk potential posed by genetic engineering nor can it influence the character of the risk. Risk potential and risk profile are subject to the influence of changing values and acceptance, the particular characteristics of this risk of change.

This may cause conflict for the insurance industry, primarily with public opinion and, in the event of a loss, with their industrial clients. However, insurers will be harming themselves, and not least the insured community, if they decide to wait and see what happens.



The unresolved issue of xenotransplants

Surgically, it would be possible to transplant animal organs to patients, in the same way as human organs are transplanted, as a means of overcoming the chronic shortage of donor organs. The only obstacle is the immediate rejection of non-human transplants. One solution proposed by genetic engineering, which has been widely discussed, would be the transplantation of animal organs which have been implanted with human gene information. This would reduce the likelihood of rejection by the recipient's body.

The donor organ may not however be the only thing transplanted. Animal pathogens, primarily herpes and retroviruses, could also be passed on to humans, and theoretically adapt themselves. If the medical and research industries were not already aware of this danger, humanity could be confronted with a new form of illness which would be hard to limit to those individuals initially affected. From an insurance point of view this would be a loss series which could turn not only the health insurance system upside down.

For whom the bell tolls ...

Some risks defy our powers of imagination. It is not always risk-related factors which are at the fore, as can be seen from the following example: in the eyes of the general public, xenotransplantation (ie the implantation of transgene organs from animal donors in humans, see left) is not as controversial because of the known medical risks as it is because of ethical or animal-protection reasons. In individual cases, many a patient would be faced with a dilemma which would be too ambivalent to cope with: Faced with possible death as a result of organ failure, would he rather live as a chimera with the heart of a pig, or die "ethically intact"? Does he consider the possible dangers to his fellow human beings, or does he put his own family first? In other words, new opportunities such as xenotransplantation not only solve problems, but create new ones.

Acceptance is usually also in conflict where technical advances are polyvalent. This makes it all the more astonishing that in the area of medicine especially, an area where risks and opportunities are more closely related than in the foodstuffs sector for example, there is a surprisingly high level of acceptance (cf "Eurobarometer survey").

Ambivalent acceptance

A national referendum was held in Switzerland in June 1998 on amending the constitution to include a far-reaching ban on genetic engineering. The referendum was prompted by opponents of the science, whose campaign was based on the rejection of transgene foodstuffs. Supporters of genetic engineering fought their campaign above all with medical arguments. The result of the referendum confirmed the general consensus of opinion throughout Europe: 2 to 1 against a general ban. One simplified conclusion is that, whilst most people support medical applications of genetic engineering, a substantial minority rejected transgene foodstuffs so strongly that they also include medical uses in their ban. This is despite the fact that there are scarcely any scenarios to confirm an acute risk to humans and the environment from transgene foodstuffs. The small amount of damage caused by genetic engineering to date and the scenarios with the largest risk potential originate from the medical world.

Ambivalence is particularly discernible with genetically engineered foodstuffs: each slice of "Swiss cheese" contains a pinch of a slaughtered calf. This comes from the stomachs of suckling calves; approximately one knife point of lab ferment can be recovered per animal. This lab ferment (chymosin) is an enzyme which coagulates milk, a process which is vital in the manufacture of cheese. It is also possible to produce chymosin using micro-organisms genetically modified with the relevant calf gene. More than half the hard cheeses in the United States are produced using this transgene enzyme.

Eurobarometer survey

At the end of 1996, approximately 16 000 EU citizens were surveyed on their attitude towards genetic engineering. The most important findings of the survey were:

1. Genetic engineering applications were rejected if they did not correspond to the moral code of the consumer. Ethical and moral attitudes have a veto effect on acceptance.
2. The level of support or rejection for the different areas of application depends primarily on the subjective benefit to consumers, and only secondarily on the risk perception. Exception: In the case of transgene foodstuffs, the need for safety is paramount.
3. The EU citizens' growing knowledge and ability to differentiate may not lead to more acceptance but at least to more decisive behaviour and opinions.
4. Trust is placed neither in risk experts nor in national governments. People tend to favour the institutions with the least to gain. Political parties are never trusted, but environmental and consumer organisations (in the case of transgene foodstuffs) and doctors (in the case of xenotransplants) are.

Vegetarians and animal-rights groups like the slogan "vegetarian cheese". In northern Europe, however, the introduction of a transgene lab ferment has not been accepted. Individual cost/benefit considerations only fall in favour of transgene products if the benefit can be felt by the person and corresponds to his/her own system of values.

Experience gained with exotic natural products such as kiwis or avocados shows that, despite frequent cases of allergies, no relevant liability claims are made. However, because alternatives of at least the same quality are available in sufficient quantities for most genetically modified foodstuffs, the possible allergic effects of transgene vegetables or cereals are discussed much more frequently – and correspondingly overestimated – than those of exotic fruit.



In case of doubt – against the defendant ?

Allergic reactions to transgene food components which up to now have not been contained in trusted foodstuffs are basically possible. Lawsuits from persons suffering allergies to "genfood" are therefore conceivable. Although such cases will be rare as a result of extremely comprehensive tests (and on an individual basis would perhaps be analytically difficult to prove), they may grow on a global scale to a size of relevance to the insurance industry. Even if a lawsuit is by no means a guilty verdict, Anglo-Saxon legal systems in particular offer consumer groups sufficient opportunity to put pressure on the industry and insurers. In this regard, the cost of defending unjustified claims is a familiar, but rapidly growing problem which the insurance industry faces.

In other words, the possibility of legal action is primarily, but not only, a question of acceptance and less one of the risk effectively taken. Against this backdrop, it is possible for insurers to offer cover for genetic engineering risks for as long as individual companies have to compensate for individual losses. It must not be a task of the insurance industry, however, to satisfy claims which stem from a change in societal values. This risk is the manufacturers' business risk.

Case against the US Environmental Protection Agency – storm in a tea cup or the calm before the storm?

The US Environmental Protection Agency (EPA) was threatened with a precautionary suit in autumn 1997 by a coalition of consumers, environmental protectionists and ecological farmers, because they had allowed genetically modified cereal to be planted. These plants produce a transgene toxin fatal for pests. The plaintiffs feared that the bacteria toxin, directly employed for biological pest control, would at some time no longer be effective against pests, because the genetically modified cereal could spur the pest to develop its own resistance.

Europe, America, Japan – not so different after all

The number of Europeans who associate genetic engineering with apocalyptic perceptions is diminishing, as shown by several studies published recently. The large number of citizens who at the outset basically rejected genetic engineering are today much more pragmatic and willing to differentiate. This development is being accompanied by a strict legislative process which may be able to contribute to calming fears. Is it safe to sound the all-clear? No, because there are still feelings of mistrust. Even a relatively small loss could tip the balance of opinion.

What is the situation in the United States, a country which pampers to plaintiffs? The acceptance factor seems to be less of a problem here than in Europe. American consumers are much more open to experiments and willing to test “novel food”. However, the proposal of the US Department of Agriculture to allow the label “organic” to be used for transgene products as well met with such strong opposition that the plans had to be abandoned. Similarly in Japan, consumers reacted anxiously to transgene soya in their food and, according to a survey, demanded its immediate declaration on packaging.

It is irrelevant whether a lobby uses the legal system to exert pressure or whether a large part of the population are sceptical, as long as no serious claims for compensation result. However, a relatively small number of opponents or alleged injured parties might be sufficient to cause considerable problems for genetic engineering companies or licensing authorities in the shape of high claims for compensation (see “Case against the US Environmental Protection Agency”).

Reasons for legal action

What is the key problem from the point of view of legislation and jurisdiction? The more people can gain from society viewing genetic engineering as dangerous, the more the socio-political risk of change will increase, ie the risk of the rules being changed halfway through the game. Arguments used in the risk debate by lobby groups are only partially based on scientific findings. Liability claims are founded on conceivable, but barely demonstrable risks. The more complex the material, the more suited it is to lawsuits with an insufficient basis of proof directed at making individuals rich or gaining political advantage.

The reverse trend in the burden of proof, which is being increasingly stipulated in European legal systems, has for many years been part of a legal development which is moving away from tort liability to strict liability. This trend of broadening liability accentuates the problem of serial and long latent claims considerably. The Anglo-Saxon notion of class actions is particularly suited to claims directed at political effects or solvent defendants. If potential plaintiffs are no longer required to furnish proof of negligence or neglect, claims for compensation can be expected to increase.

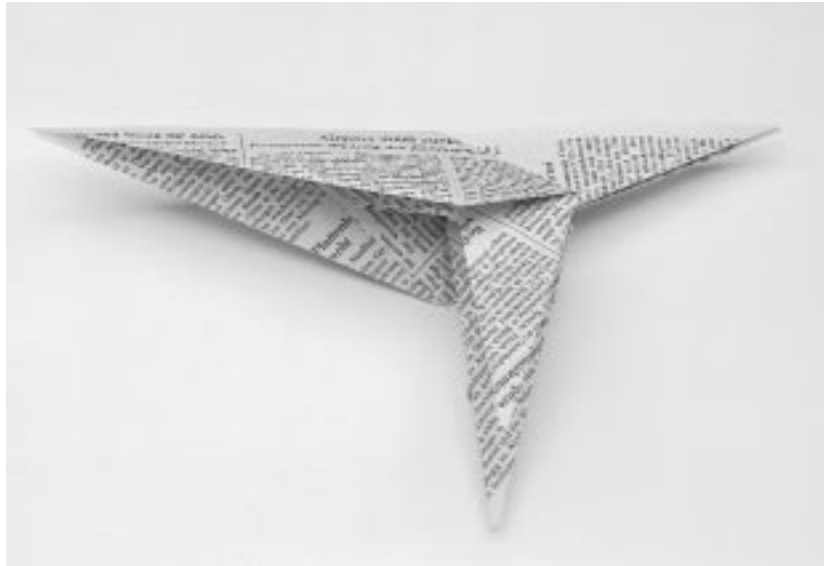
The risk thus stems not from the risk of genetic engineering *per se*, but from the plaintiffs and their motives and finds expression in the courts' decisions. In other words, in dealing with the “genetic engineering” risk, the decisive factor is not whether genetic engineering is dangerous, but rather how dangerous it is perceived to be.

No effect without cause?

In the olden days, a cause was understood to be an event that always, without exception and without doubt brought about a specific effect. "Common sense" and our sense of right and wrong are clearly characterised by this way of thinking. The obviousness of this view can mislead people into digital conclusions, whereby it must be possible to answer everything with yes or no.

To make the party responsible for damage liable for compensation, tort law demands a verifiable causal link between the cause and its damaging consequences. The task of reaching a decision is made difficult if a possible cause cannot be proven or ruled out without doubt. Even more so because the modern scientific concept of causation is based on probability considerations.

Allowing causes with low probability as a reason for liability would mean introducing presumed liability, which is primarily still inadmissible according to current legal opinion. However, where is the border between pure presumption of cause and the adequate causal link required by law? Influenced by the changing scientific concept of causation, this is a recurring topic of socio-political debate and thus an important component of the risk of change.



Fear is always real

The interface between scientific analysis and legal assessment requires an evaluation in the philosophical sense. The law is caught in a dilemma between the need for individual protection on the one hand and the interests of society as a whole on the other. The question repeatedly arises as to whether it is fairer to make a party suspected of being responsible liable than to leave a possible injured party without protection. This is difficult to resolve legally. Wherever claims are asserted, the law must preside and ensure justice and equality.

However, societal processes also attribute subjective values to scientific findings. This is particularly the case if science and society can no longer find common ground, a primary reaction to which are defence and fear of the unknown.

Whenever we, as humans, are confronted by the unknown we search for explanations and develop mental models. These

exist only in our heads and, although they are only phantoms, they are an expression of our fears and as such are very realistic. However unrealistic or immeasurable a danger may be, the fear of it can be very real. Wherever there is fear, humans seek safety and protection. Can the genetic engineering industry provide this safety, and can the insurance industry offer the necessary protection?

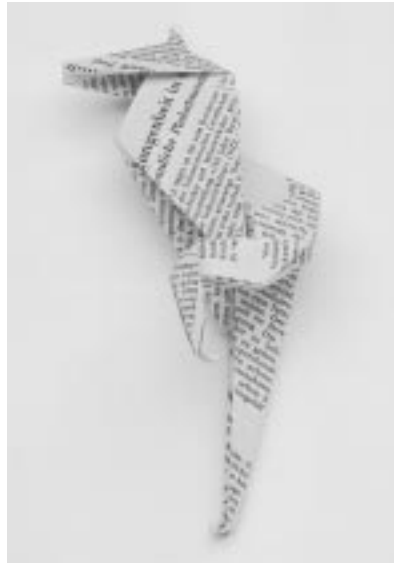
Psychological motives and emotional criteria are legitimate, but can they be permissible in the case of legal assessment of benefits and damages? In a society of pluralistic values the danger of this segregation becoming blurred can never be ruled out. Yet another element of the socio-political risk of change.

The underwriting maxim

Traditional insurance business is based on empirical values. Those risks whose presumed loss extent is limited for the insurance industry and for which the possible loss scenarios are available are insurable. This knowledge of previous loss experience must also reflect future realities as accurately as possible. Risks such as these are only really insured in the long term if they are potentially profitable to the insurance industry, and the insureds are able to protect themselves from the right hazards at the right price.

The underwriting maxim states that future expected claims payments must not be allowed to exceed on average the earned premiums minus costs incurred. For the insurability of a risk, therefore, it is not the extent of danger which is decisive, but the predictability and calculability of the costs triggered by a loss.

Like all other profit-making companies, Swiss Re is keeping a close eye on the market and its environment. It is following the technological and societal change accompanying genetic engineering closely, and tries to implement findings into its market strategies as early as possible. Since the insurance industry's "business" is to accept risks in return for premiums, it must have a clear conception of the nature and size of these risks.



The risk profile of genetic engineering is extremely diversified and very difficult to anticipate. There is no clear conception of the risks accepted, so how can genetic engineering risks be insured?

It is currently not possible to give a direct answer to this question. A lot depends on whether consensus can be reached on the relevant loss scenarios in a dialogue involving the genetic engineering industry, society and the insurance industry. This will make genetic engineering risks more calculable and more interesting to traditional insurance models. From the point of view of the insurance industry, we are at present a long way off.

Today, we must assume that the one-sided acceptance of incalculable risks means that any participants in this insurance market run the risk not only of suffering heavy losses, but also of losing control over their exposure. If, for example, one single genetic engineering loss manifests itself not only at the seed manufacturer's, but also at the farmer's and the foodstuffs industry, different underwriting liability covers could be triggered simultaneously. A loss of the affected insurer's financial security would also have repercussions on the community of insureds not directly involved in the actual losses.

In an unsure, traditional insurance market, the insurance industry would normally protect itself from too large a loss by limiting capacities, establishing cover limits or adding exclusions. But this also restricts opportunities.

The long latent trap

If insurance protection is guaranteed at too low a premium on the basis of previous loss experience gained from a different technology, the insured will also enjoy protection for the increased risk of new types of products. These usually only lead to losses many years after they have been introduced onto the market.

New products are often used to tap into new markets. These markets and their consumers will initially act according to tried and tested models. As a result, losses which can be traced back to inadequate experience with unfamiliar products are almost pre-programmed. In the event of a loss, the insurer thus offers balance sheet protection from technological innovations, whilst any prospective profit goes entirely to the producers.

Alternative risk financing: the new opportunity

The mainly traditional, one-sided risk transfer to cover damages from genetic engineering is unattractive for the insurance industry and, despite current practice, is often not sufficient for the genetic engineering industry. So long as the risk profile of genetic engineering and thus the basis for liability claims are under discussion, the gap between the cover on offer and the cover required will drift rapidly apart. In addition, genetic engineering losses are the kind which have not yet, or only rarely, occurred and whose consequences are extremely difficult to predict.

As a result, an increasing number of alternative risk financing models are taking their place alongside the traditional forms of cover. These are tailor-made hedging instruments which are carried and financed jointly by the insurer and the insured. The binding principle behind this arrangement is care, in accordance with the principle of the "polluter pays". Such instruments are more suited for types of cover in the grey area between insurability and non-insurability.





The socio-political discussion centring on genetic engineering has so far been dominated by risk conflicts. The genetic engineering discussion therefore often focuses on the area of sensitising risk perception. Its basis is however an ideological conflict of goals, or conflict which is dictated by different interests. Fundamental questions on the development and structure are under debate. This puts genetic engineering in the area of conflict between risk and ethics, a situation in which hardly any other modern technology finds itself.

Successful companies are trying to support their corporate objectives by means of value management. They identify the importance placed on the different values of a pluralistic society, and what effect these values have on a company. Where no consensus can be reached, for example on how to deal with genetic engineering, they look to find a balance of interests and make a constructive contribution. The prerequisite for this is that basic questions are asked and the different interests are made public.

The constant conflict of goals inherent to a society of pluralistic values can paralyse development, not least if no adequate, long-term insurance cover is available. The insurance industry is therefore seeking dialogue with clients and those affected on the subject of genetic engineering. Risk-related information must be exchanged openly and differing values taken seriously.

A development of societal and legal frameworks unfavourable to genetic engineering could lead to insupportably high liability risks which cannot be carried by either the genetic engineering industry or the insurance industry alone. Despite differing motives, both industries hold joint responsibility for helping to shape the change in societal values.

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CARTAGENA PROTOCOL ON BIOSAFETY

Insurance Industry and Art 27 (Liability and Redress) of the Cartagena Protocol

Article 27 of the Cartagena Protocol on Biosafety records the intention of the Parties to the Cartagena Protocol to elaborate international rules and procedures with respect to liability and redress issues. In particular, it states 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, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavor to complete this process within four years.”

When it comes to securing liability, the question of insurability is posed. This article outlines some of the prerequisites of insurability with regard to biodiversity. These considerations have already been published partly in other contexts^{1,2}.

Prerequisites for a Successful Liability Regime

Prevention and precaution: One may argue that the pure existence of liability norms promotes safer behaviour of possible polluters. This is in reality only achieved when common principles to evaluate and to quantify damages to natural resources and biodiversity are adequately defined and firmly established. Unambiguous quantification rules constitute the basic requirement for a workable and effective regime in order to prevent damages to biodiversity.

¹ *Position Paper of the CEA* (Comité européen des assurances) re. the „EU White Paper on Environmental Damage“, Brussels, September 2000. In that paper the European insurers point out their position re. the crucial elements for the further development of environmental liability, including biodiversity issues. The proposals on environmental liability made by the European Commission in January 2002 are not suitable to change that position which holds true also for the Cartagena Protocol.

² Epprecht, T. *“Die Rolle der Assekuranz im Konflikt um die Gentechnik”*, in *“Risiko-Dialog – Von der Idee zur konkreten Umsetzung”*, Betty Zucker (ed.), IVW, University St. Gallen, June 2001. An english translation of that article has been made available for interested parties, title: *“What is a genetic engineering loss? – How the biotech risk conflict affects the frontiers of insurability”*.

Polluter pays principle: If prevention fails, there must be agreement on how and to which extent remediation is necessary and what redress is adequate. Talking about liability, it must also be clear who is the aggrieved (third) party entitled to receive financial compensation for damages that cannot be restored. Although the *polluters pays principle* is well recognised, it is difficult to embody in legal norms, foremost when such norms do not strictly follow the intention attached to this principle. In fact, frequently discussed *deviations from this principle* are for example the presumption of causality, the alleviation of the burden of proof and the application of the joint and several liability mechanism within one and the same group of enterprises.

Compensation of losses: The availability of financial guarantees in line with the envisaged liability regime is necessary to make any legal rule effective and workable. The party held liable must be in the position to carry the financial consequences of potential environmental risks. Preferably the liable party can transfer the financial burden to a risk carrier such as an insurer, in order to be in a position to really meet its obligations. However, this goal can only be achieved when the prerequisites of insurability are met. With respect to damage to natural resources or biodiversity, it appears very optimistic that insurance cover for this type of damage is likely to be granted in the near future.

The role of insurance

Should insurers contribute to preventing risk, or to enabling riskier behaviour? The answer is more mundane than one might expect, and also more obvious: insurance is there mainly to make risky activities possible by mitigating the possible consequences, that were unwanted but still occurred. A liability cover most directly benefits the policyholder: that is, the party who might cause the damage. This party purchases liability insurance so that a loss, if it materialises, will not endanger his economic existence or financial standing. Insurance compensates the claimant for the damage he has suffered – at least to the extent of the cover, and to the extent that the damage can be indemnified with money.

The role of insurance in society is thus more or less that of an overflow basin, into which premiums flow, and from which payments are taken for losses that occur despite every safety measure. Since insurance has enabled greater risk-taking, society has consciously discounted those risks which are insured and insurable: for example, society accepts motor vehicle risks and their price in terms of disabling injuries or fatalities (as a consequence of „non-standard operation“ and with effective balancing rules), or air pollution and damages to natural resources (due to „standard operation“ and without effective balancing rules). Some other risks are much less likely to be triggered, but are controversial. They are not insured, simply because only calculable, generally accepted, and compensatable risks are insurable.

Thus, for classical risk transfer (i.e. insurance) to work, there must be clarity as to what a loss is, which losses are considered acceptable, and who is the liable person. Risks that no one is willing to take are unacceptable: the associated losses cannot be indemnified with money and are thus uninsurable. Conversely, it must be possible to calculate the monetary value of an insured loss. This is because statutory liability – as the larger context for any insurance – implicitly assumes that risk exists and that risks are taken; and that, basically, these risks are accepted to the extent that the related loss is indemnified – or can be indemnified – with money at a certain cost.

Prerequisites for Insurability

To achieve insurability the following must be considered:

1. Insurability requires the **quantification of risk**. Only if this requirement is met can insurers calculate premiums and define adequate conditions including prevention measures. Liability to compensate damages to biodiversity must focus on compensating the **costs** for restoration of the impaired nature. Liability must not focus on the **value** of natural resources themselves, since they can't be quantified in monetary terms. **Penalties**, especially when unlimited, are not insurable, last but not least since insurance would undermine the purpose of a penalty. As long as intelligibility is lacking, insurance against biodiversity damages seems **impossible**.
2. Only **fortuitously** (involuntarily, unexpectedly) occurring adverse consequences of future activities with LMOs are insurable. To be insurable, these adverse consequences must occur **subsequent to the enactment** of a new legal regime. For consistency, the liability regime hence better only apply to damages that are caused after its enactment. Retroactive liability, foremost for already existing, but not yet discovered impairment of biodiversity at the moment of enactment, does not qualify for insurance coverage.
3. The same applies to the **limitation period**, the inception of which should be a well-defined event at a specific point in time, i.e. the date when the binding defined damage was **triggered**. The statutes of limitations generally are set for 10 years, which is a **reasonable period of time**. The longer the limitation period is, the more difficult identification of cause and effect are. Too long limitation periods (for example 30 years) mean that **inequitable** conclusions as to the identification of the actual polluter and the damaging effects are made. In addition, the potential to **misuse** such an extensive right is substantially increased, especially in combination with strict liability or a reversal of the burden of proof. Consequently, insurance coverage can't be granted for a whole generation's active lifetime.
4. Thus, judicial **certainty** and predictability must be achieved. In other words: the liability regime to be applied must become clear and **unambiguous**. Fault-based liability solutions promote insurability. If strict liability is put in force, insurability requires at least: a) that the claimant bears the **burden of proof** of causality (no reversal); b) that the insured is allowed specific defences beyond Act of God ("force majeure"), in particular the **state-of-the-art defence** and the **compliance-with-permit defence**; c) that the limitation period is reasonably limited.
5. With regard to causality, there must be a clear and **provable causal link** between cause and consequences, based on technical evidence and not on assumption and presumption. Furthermore, the damaging and injuring activities must be **directly attributable** to a specific identifiable legal entity, and also the injured party must be an identifiable legal entity of its own. Where there are **multiple** liable parties, each party should only be liable **in proportion** to its contribution to the damage (no joint and several liability).

6. Insurance must **not** be **compulsory**. First, mandatory cover does undermine the safety goals: a party who receives automatic, full insurance cover will **act more dangerously** than one who must compete for insurance cover by qualifying as a „good risk“. Second, understanding the principles of insurance means taking note of the fact that the insurance industry will not stand ready to cover every form of liability in full. Surely being granted within the borderlines of legal liability, insurance cover is further **limited by contract** to a well defined type of loss, for example product liability or environmental impairment liability, and the conditions under which a covered loss must occur. As a rule, measurability is imperative, which only makes it worthwhile to offer coverage.

The business principle of insurance

Assuming freedom of contract, which is a fundamental right in a free market, the insurer will always choose the clients to whom cover is offered, as well as the conditions. Thus, insurers will for example always put a limit on the amount that can be claimed for any kind of policy. They also will exclude losses from cover as long as they are impossible to quantify, such as the value of impaired biodiversity itself.

A risk's insurability is not a question of how large a *potential* loss may be, but primarily a question of whether it is calculable: that is, whether the probability of occurrence and the size of the *average* loss are known. It depends in addition on the funds available, on the possibility of diversifying the risk elsewhere, and on an adequate premium. Thus, when insurers say „yes“ or „no“, they do not deliver a verdict of „good“ or „bad“, but decide whether accepting a risk is an attractive proposition – or not. Nor does it matter, in an insurer's risk evaluation, whether a risk is large or small: large risks, such as aircrafts, ferry boats, oil platforms or water dams, are insurable, if the cover granted can clearly be defined.

Conclusion

When offering insurance cover, the basic question is whether the risk can be calculated. If not, the cover is limited until it can be. Yet, the more limitations that are placed on a cover, the farther it will fall short of the legislator's goal of *protection* and *precaution*. Thus, if the insurance industry is to help society reach its protection goal, the statutory framework must be shaped so that it will still be possible to put a monetary value on all *liability* risks. Unfortunately, current legislative trends largely ignore this. With their increasing blurring between civil liability and criminal law, legislators run the risk that substantial gaps will open between their protection goal and the extent of insurance cover effectively being offered.

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ECONOMIC COMMISSION FOR EUROPE

**MEETING OF THE PARTIES TO THE
CONVENTION ON THE PROTECTION
AND USE OF TRANSBOUNDARY
WATERCOURSES AND
INTERNATIONAL LAKES**

**CONFERENCE OF THE PARTIES TO
THE CONVENTION ON THE
TRANSBOUNDARY EFFECTS OF
INDUSTRIAL ACCIDENTS**

**Intergovernmental Working Group
on Civil Liability**

Second meeting

Geneva, 4-6 February 2002

Working paper*
MP.WAT/AC.3/2002/WP.4
CP.TEIA/AC.1/2002/WP.4

ENGLISH ONLY
31 January 2002

**COMMENTS ON THE
DRAFT LEGALLY BINDING INSTRUMENT ON CIVIL LIABILITY FOR
TRANSBOUNDARY DAMAGE CAUSED BY HAZARDOUS ACTIVITIES, WITHIN THE
SCOPE OF BOTH CONVENTIONS (MP.WAT/2002/2 - CP.TEIA/2002/2)**

Submitted by Swiss Re

I. General remarks

1. From the reinsurance point of view, we welcome the idea of a uniform regime on civil liability for damage resulting from transboundary effects of industrial accidents on transboundary watercourses and international lakes within the member states of the Economic Commission for Europe. We support the results of the first meeting and we agree, in general, with the solution formulated in the above document. There are, however, some concerns about the consequences for the insurance industry and we have to express our reservations on some specific provisions.

* Apart from minor editorial changes, this working paper is reproduced in the form as received by the secretariat.

2. The insurance landscape within the member states of the Economic Commission for Europe is not standardized but rather heterogeneous. This is true for civil liability insurance for enterprises in general and particularly for civil liability insurance for damage as a result of environmental impairments. There is a well developed insurance penetration in industrial countries (e.g. Germany, France, Switzerland). On the other hand in some countries, which do not fulfill the development of industrial countries in technical, social and legal areas, a civil liability insurance system is not in place or is only partially developed. In some countries there are no civil liability insurance solutions available because the prerequisites for insurability (e.g. up-to-date technical standards regarding the installations, processes and use of hazardous substances) are not given and it would appear that these requirements will not be fulfilled in the near future. This could lead to differences in the economic competition within the member States.

3. Liability insurance companies are private organized enterprises. Contrary to public or non-profit institutions and organizations, the insurance companies as well as other financial institutes and the industry in general, target economic goals. Insurance solutions have to achieve a certain yield. Therefore, only risks fulfill the minimum insurance requirements (e.g. big number of uniform risks, calculation of frequency and severity) are insurable. This is true in respect of known damage (e.g. bodily or personal injuries, third party property damage). It is extremely difficult to estimate the consequences of new damage, for example 'ecological damage' or too broad formulated liability conditions, and thereby provide an insurance solution.

4. We strongly support the introduction of uniform legal regulations within the member States in respect of the construction and use of technical installations, use of hazardous substances, permission for business and the like, which help to avoid the occurrence of environmental impairments. These preventative measures have a large impact on the position of the insurance industry regarding the civil liability regime and the subsequent insurance solutions.

II. Remarks on art 2 'definitions b) damage'

5. The insurance industry has developed instruments which allow the calculation of specific types of liability and, therefore, the insurability of these is given. This is true for bodily or personal injuries ('loss of life or personal injury') and third party property damage ('loss of, or damage to, property other than held by the person liable in accordance with this protocol'). In respect of pure economic damage ('Loss of income directly deriving from an economic interest in any use of the environment, incurred as a result of impairment of the environment, taking into account savings and costs') insurance protection is not in place or is only partially available. The costs for the prevention of resulting damage (bodily or personal injuries and/or third party property damage) after the occurrence of an environmental impairment are also partially insurable ('the cost of preventive/mitigation measures, including any loss or damage caused by such measures, to the extent that the damage results from the transboundary effects of an industrial accident on transboundary watercourses and international lakes'). In general, pure ecological damage ('ecological damage', the cost of measures of reinstatement of the impaired environment, limited to the costs of measures actually taken or to be undertaken') are not insurable. The use of traditional insurance instruments is not possible. There is no experience available which allows the calculation of frequency and severity of ecological damage.

III. Remarks on art. 4 ‘strict liability’

6. The liability limitation should also be available for the operator of the industrial facility. Therefore, subparagraph 2 should be changed as follows ‘...shall attach to the owner/**operator** of the industrial facility...’.

7. The implementation of a joint and several liability regime may inhibit the development of insurance products. We strongly support a liability regime where the owner/operator of the industrial facility would only be liable proportionally for the damage they cause. Therefore subparagraph 3 should be cancelled.

IV. Remarks on art. 10 ‘time limit of liability’

8. The absolute period of limitation of 10 years is in accordance with most national liability regimes. The introduction of a relative period of limitation of 5 years is, however, new. Usually the relative period of limitation is between 1 and 3 years (e.g. product liability regimes). Experience shows that there is normally no problem for the plaintiff to claim compensation within 1 year from the date the claimant knew or ought reasonably to have known of the damage and of the person liable. There is no need to implement a special relative period of limitation of 5 years. On the contrary this could lead to the danger that the subject of the liability no longer exists. The unnecessary blocking and reserving of capital for damage for more than 1 year prevents investments and, therefore, economic development. Therefore subparagraph 2 should be changed as follows ‘...brought within **one** year from the date the claimant knew or ought reasonably to have known...’.

V. Remarks on art. 11 ‘insurance and other financial guarantees’

9. In principle civil liability insurance is a suitable instrument for providing financial guarantees for the insured for damage as a result of environmental impairment, which fulfil the prerequisites of insurability. On condition that the insurance companies have the right to decline insurance for risks, which do not fulfill the technical standards and the insurance prerequisites (e.g. ecological damage), liability insurance could provide financial guarantees. As mentioned above art. 11 should be changed as follows ‘...guarantees covering their liability under article 4 **for damage mentioned in article 2 Ziff.2a lit. (i) and (ii)** for amounts not less than ...’

10. The implementation of the right to claim directly from the insurance company is problematic. This instrument is useful in cases where the subject of the liability could be lost by the accident, for example in motor liability insurance, and where claiming for liability could be more difficult or impossible. But this is not the case in respect of damage as a result of environmental impairment. The polluter’s identity would be known and a claim could be made against it. The task of liability insurance is the financial protection of the insured (not the plaintiff) for the negative consequences of a liability claim. Such a right to claim leads to a change of the intention of liability insurance. The liability insurer or any person providing financial guarantee should take over the role of the polluter and is suddenly subject of a claim. That is a new situation

for the insurer and changes the function of insurance. We strongly recommend not to implement such a right to claim. Such a right to claim is not necessary and therefore we recommend to cancel subparagraph 2.

ECONOMIC COMMISSION FOR EUROPE

**MEETING OF THE PARTIES TO THE
CONVENTION ON THE PROTECTION
AND USE OF TRANSBOUNDARY**

**WATERCOURSES AND
INTERNATIONAL LAKES**

**CONFERENCE OF THE PARTIES TO
THE CONVENTION ON THE
TRANSBOUNDARY EFFECTS OF
INDUSTRIAL ACCIDENTS**

**Intergovernmental Working Group
on Civil Liability**

Fourth meeting
Geneva, 2-4 September 2002

Working paper*
MP.WAT/AC.3/2002/WP.15
CP.TEIA/AC.1/2002/WP.15
ENGLISH ONLY

2 September 2002

**Comments to article 11 of the draft legally binding instrument on civil liability
(Working paper submitted by Swiss Re)**

I. General remarks

The analysis of the insurance situation in the member states of both conventions shows that, even in the well developed insurance markets, there are no insurance products available which provide coverage of the whole extent of the envisaged liability regime. This is especially true in respect of the remediation/restoration of environmental impairment ('cost for reinstatement of the environment', 'ecological damage', 'biodiversity damage') as well as in respect of pure economic losses. In some countries, however, insurance coverage for the liability for bodily injuries and property damages as a result of a sudden and accidental environmental impairment is available.

* This document has not been formally edited.

In respect of the general situation we have to realize that there is no established insurance market in 54% of the member states of both conventions.

In more than 60% of the member states there is no mature liability insurance market and in 63% of the member states the insurance industry only provides an insurance coverage for liability claims for bodily injuries and property damages as a result of a sudden and accidental environmental impairment (e.g. industrial accident).

Moreover, even in the insurance markets world-wide there are no insurance products available on a standard basis and in a standard format providing explicit coverage for the remediation/ restoration of environmental impairments (e.g. watercourses), for ecological or biodiversity damages.

Today there is no market for liability insurance for ecological or biodiversity damages.

II. Reasons

The insurability of risks is only given if the following necessary criteria are fulfilled:

- **Accessibility**
The probability and severity of losses must be quantifiable
- **Randomness**
The time at which the insured event occurs must be unpredictable and the occurrence itself must be independent of the will of the insured
- **Mutuality**
Numerous persons exposed to a given hazard must join together to form a risk community in which the risk is shared and diversified
- **Economic feasibility**
Private insurers must be able to charge a premium which is commensurate with the risk.

Clearly, ecological damage risk does not readily meet all of these criteria. Available data from past events reveals little about the future risk. The tremendous loss potential hampers diversification. And finally, with the apparent uncertainties regarding the risk quantification, the economic feasibility of the business is extremely doubtful.

Insurability is the result of a complex decision-taking process by the insurers that involves several individual considerations. The essential precondition for any risk to be insurable is that the insurers must be able to make realistic reliable estimation of the claim amount to be paid out over a specific period. Any injury, damage or loss to be compensated must be quantifiable in terms of money in line with a priori established and known criteria. The insurer has to be able to estimate the probability of any loss and also the severity of the loss. This process results in the willingness of many, few or no insurers to provide coverage.

Even in the well developed liability insurance markets the insurers have difficulties in estimating the probability and severity of the liability for bodily injuries and property damages as a result of environmental impairments.

The probability of industrial accidents regarding **known** industrial activities, types of installations, processes and substances could be estimated due to the experience of the insurers as well as the consequences of the established situation regarding awareness of the claimants or the liability regime. The estimation of changes e.g. new industrial activities, new processes, new substances or changes in respect of the awareness of the public iro environmental matters, changes of the liability legal system or changes in the decisions of courts is quite problematic.

The estimation of the severity of the **known consequences** of substances to the human health or established soil remediation processes for known substances/pollutants is also possible due to past experience. Nevertheless problems arise in respect of the estimation of the severity of unknown consequences of substances to human health e.g. the effects of genetic modified organisms on human health, new scientific results as well as new soil remediation processes due to new scientific results, new substances/pollutants, changes in the remediation and waste legislation and the like. We have to bear in mind the fact, that we still know relatively little about the possible impact many materials and substances have on the environment. Many which today are still considered harmless may soon turn out to be harmful (risk of change).

Due to the fact that insurers currently do not have sufficient experience (as well as of the industry, legislator and science) in respect of the remediation/restoration of the environment as such (e.g. watercourses, biodiversity), the insurance industry is not in a position to offer any coverage for this class of damages.

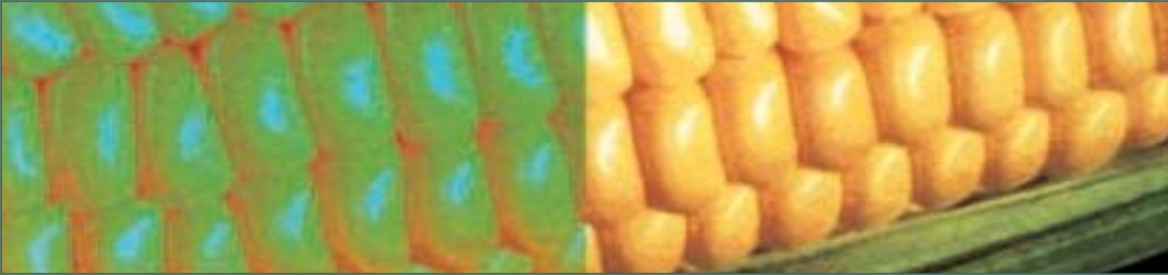
In addition to the above mentioned factors for insurability there is another important point to mention. Insurers being forced to offer insurance for which they have little experience could come into conflict with regulators because supervisory authorities generally require that insurers are able to calculate the adequate premiums for a risk. This is not the case in respect of remediation/restoration of environmental impairments.

The implementation of a compulsory insurance regime, however, does not solve the above mentioned problems regarding quantification of the probability and severity of an environmental damages.

III. Consequences

The insurance industry is generally willing to develop insurance products as far as the prerequisites for insurability are fulfilled. Today in respect of the envisaged regime the above mentioned prerequisites are only given for liability for loss of life or personal injury respectively for loss of or damage to property as a result of an industrial accident.

Pure ecological damages (e.g. restoration of the environment, biodiversity damages) as well as pure economic/financial losses are not insurable because the relevant statistical data is not available or the risk of change is too vague.



Genetic engineering and liability insurance The controversy on GMOs continues

Reprint from SITC ReView No. 17 July 2003

Thomas Epprecht
Swiss Re



The controversy on GMOs continues

The worldwide discussion on genetic engineering will not leave the insurance industry unaffected. The issue is not whether genetic engineering is in fact dangerous, but how dangerous it is actually considered to be.

Commodity handling, harvesting and the rest of the production chain is highly efficient. However, the agri-food chain is ill-equipped when it comes to ensuring 100% segregation of GM from conventional crops.

The conflict surrounding genetic engineering in the agricultural and nutritional sectors has roots in the food crisis caused by mad cow disease (BSE). “Unknown long-term effects” have become a major concern in connection with BSE, which was the result of an unnatural production process and has subsequently posed a danger to human health. Not surprisingly, as food scandals become more commonplace, other industrial methods used in today’s food

production are being lumped together in the same group and categorised as “bad” or “harmful”.

From mad cow to mad corn?

Consequently, “unnatural” foods – genetically modified organisms (GMOs) first amongst them – are uniformly perceived as potentially dangerous. As a result, the mass production system used in current food processing has been called into question.

This will keep agricultural applications of genetic engineering in the headlines for a while to come, presenting a challenge not only to the biotech industry, but also to the insurance sector.

However, GMOs have never posed a problem like BSE, and any comparison is rationally unjustifiable. Nevertheless, this wariness must be factored into evaluations of the (liability) risks associated with genetic engineering, since it reflects a growing sensitivity to this issue. Under pressure from strong demand for total safety, the biotech industry has focused on the technical mastery of risk at a high level. It was confident for a long time that the general public would honour these efforts with increased trust – and that this would suffice to keep legislation and insurability unchanged.

Unfortunately, current legislative trends largely ignore the fact that insurability requires a predictable quantification of risk and that legal liability is a conceptualised societal agreement on acceptable exposure to risk. For some lawmakers, though, no safeguards are safe enough, reflecting society’s ambiguity and scepticism towards any risk associated with this novel technology. Thus, there is a continuous need for dialogue on technological prospects and the ongoing goals of protection and precaution. Enabling activities associated with acceptable risk and providing monetary compensation for damages sustained are, after all, the key functions of the insurance industry.

Lawsuits

Although the use of genetic engineering in foodstuffs does not seem to increase the potential for bodily injury or property damage, commingling of bulk agricultural commodities with GMOs is prone to lawsuits. In fact, one can assume that costs arising



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Swiss Re will be holding an International Biotechnology Forum from 3 to 4 November 2003. For more information, please contact the author.

from tainting losses will be enormously higher than those caused by negative health effects due to GMO consumption.

The StarLink™ case

In September 2000, Genetically Engineered Food Alert (GEFA), a coalition of food safety and environmental organisations active in the US, claimed that traces of genetic material from StarLink corn (see box: StarLink™) had been found in corn tortillas. After further tests confirmed the presence of the ingredient StarLink, Kraft Foods – the manufacturer of the taco shells under investigation – immediately recalled some 2.5 million packages of their US-supermarket “Taco Bell” brand. Later, many other food producers joined the voluntary recall campaign, removing from the shelves about 300 products made with the suspect yellow corn flour.

The StarLink case illustrates just how unpleasant the GMO issue can get. The case raised fundamental questions about identification of GM crops and their segregation from conventional crops. That – even more than the unproven suspicion that StarLink contains a potential human allergen – is what caused the actual loss. This goes to show that, if society as a whole is ambivalent about a risk and the distance is too great between acceptance and non-acceptance, it is difficult to calculate the exposure for the insurer.

StarLink corn entered the food supply chain after the involved US authorities (EPA, FDA and USDA*) had issued a split approval, permitting its use for animal feed and industrial use, but retaining clearance for human consumption. As long as StarLink had not been approved for human consumption, its use in foodstuffs was impermissible.

Commodity handling, harvesting, shipping, storing, manufacturing and marketing system is highly efficient. However, the agri-food chain is ill-equipped when it comes to ensuring 100% segregation of GM from conventional crops: only a few kernels in loads of other types of corn can render entire loads unfit for consumption.

The StarLink case was not only limited to massive recalls throughout the US. It also damaged export markets such as Japan and Korea, countries which considered rejecting US corn altogether. Food manufacturers, farmers, grain dealers, grocers, retailers, mills and consumers pointed the finger at one another, as well as at Aventis, for causing a number of problems ranging

from operational disruptions and loss of profit to alleged allergic reactions and general health impairment (see Production chain chart).

Although the entire harvest was repurchased and no persistent negative impact on human health has been proven to date, this USD one billion case was the most costly economic loss in recent genetic engineering history.

The ProdiGene case

The convergence of “red” (pharma) and “green” (agricultural) biotechnology could aggravate the commingling issue greatly. A recent USD 3.75 million loss (to date) was generated by ProdiGene, a Texas-based biotech company that had sown GMO corn – containing a pig vaccine – on a trial basis in Nebraska. The planting was conducted in the summer of 2001 with approval by the US Department of Agriculture (USDA). The following year, edible transgenic soy was sown in the same fields. After harvesting the soy, it was found to be mixed with the previous year’s corn containing the pig vaccine. The commingling, probably due to remaining scattered corn seeds on the fields, was only detected in the warehouse. Subsequently, the entire storage of potentially contaminated soybeans had to be burned.

Increased frequency?

GM agricultural products approved for general use can also trigger claims if these products are detected where they shouldn’t be found. For example, in a case which made headlines in Switzerland, farmers had to destroy entire poultry stocks because their hens inadvertently had been given GM feed. This meant that the hens’ eggs, though intrinsically unaltered, could no longer be sold as purely organic eggs.



The USD one billion StarLink case was one of the most costly in recent genetic engineering history.

What is genetic engineering?

Genetic engineering – also referred to as gene technology, recombinant DNA technology or modern biotechnology – is a cross-sectorial laboratory technique applied in life science, whereby DNA sequences of genetic material from one species can be spliced into the DNA of another to introduce specific novel traits. Always performed with existing genes, the primary goal of this “copy/paste” technique is to utilise the function of a protein which is encoded by the transferred gene.

In agriculture, genetic engineering is commercially used to broaden conventional breeding techniques and to improve yield by transferring specific genes, eg for resistance to pests, herbicides and diseases. In livestock, it has been experimentally applied to increase growth of hatchery-bred salmon. In the pharma industry, genetically-modified micro-organisms or cell cultures are used to produce active proteins, such as insulin or hormones, otherwise occurring in the human body. Other applications allow the production of live vaccines by means of a targeted weakening of the disease-causing genetic properties. None of these applications creates an entirely new organism, however.

* Environmental Protection Agency, Food and Drug Administration, and United States Department of Agriculture.

In a similar case, pigs raised in accordance with organic criteria were fed soy meal from Argentina. The GM content in the soy meal was erroneously measured at below the legal tolerance limit of 3% for fodder. In fact, it was later discovered that the soy meal contained more than ten times the GM content than originally measured.

Contamination losses on the rise

These examples illustrate that both the insurance and biotech industries are ill-prepared for claims due to commingling which can trigger several different underwriting liability covers simultaneously. No doubt, it is virtually impossible to prevent a certain amount of contamination at some stage in the production chain. Cross-pollination with other, related crop varieties also may occur. Pollen does not respect demarcation boundaries, and agricultural mass production methods are not designed to distinguish between GM and non-GM products.

To achieve complete segregation during every step of the agri-food chain, all machines and handling equipment used from harvest to production, as well as all the transport and storage facilities, would have to be isolated or cleaned thoroughly every time a given farmer switched from GM crop to conventional crop.

Clearly, modern agricultural production methods have their price. Yet the agricultural sector is not in a position to satisfy conflicting interests simultaneously. It cannot produce large quantities of food both cheaply *and* quasi-naturally without becoming embroiled in a conflict of goals, particularly when the agricultural industry is global and incompatible production philosophies co-exist in close proximity.



After tests confirmed the presence of the ingredient StarLink, Kraft Foods immediately recalled some 2.5 million packages of their "Taco Bell" brand.

The role of insurance

A fundamental question then arises: should insurers contribute to preventing risk *or* to enabling riskier behaviour? Largely, insurance is available to make "risky" activities possible by mitigating the possible negative consequences which might occur. Statutory liability – the larger framework for any insurance – implicitly assumes that risk exists and that risks are taken and that, basically, these risks are acceptable as long as any related loss can be indemnified at a certain cost.

Does this also hold true for the commingling issue? Society's zero-risk mentality and the genetic engineering industry's claims of zero risk to individuals create a dilemma. For classical risk transfer to work, there must be clarity as to what a loss is and which losses are considered acceptable. However, the continuing genetic engineering conflict indicates that society is still undecided about what a loss is, how that loss should be compensated and what cases society is prepared to accept.

At the same time, some parliamentarians and interest groups pin their hopes on insurers, confident that insurance will be able to provide even



Genetic engineering in agriculture is used mainly in soy, corn, cotton, canola/rape seed and potato crops.

greater security. Compulsory insurance to the full extent of legal liability, for example, is no solution: a party which receives automatic, full insurance cover will live more dangerously than one which must compete for insurance cover by qualifying as a “good risk”.

Full insurance cover for “outlaw” incidents turns the entire idea of insurance on its head. When legislation is driven by the desire to escape a risk entirely, it virtually condemns the risk as unacceptable. Thus, insurers will have to be cautious and shape their covers so that they will not be left holding such liabilities, especially since several bills on genetic engineering currently under scrutiny (primarily in European countries) reflect the desire to avoid risk altogether.

Underwriting measures

Ambiguous risk perception, not quantifiable and inevitable commingling losses, call for underwriting measures. Thus, Swiss Re has introduced standard GMO clauses for facultative and treaty business that limit coverage to bodily injury and property damage. Thereby, covered losses must directly result from the genetic changes of the GMOs, which also must be handled in accordance with labelling prescriptions. In effect, the Swiss Re GMO standard clauses address the crop tainting issue appropriately in excluding the cover for blending and contamination losses, pure financial losses and ecological damage. These underwriting measures become even more important when food production and pharmaceutical agent generation in plants will increasingly overlap.

Society and the business principle of insurance

Assuming freedom of contract, which is a fundamental right in a free market, insurers can always choose the clients they wish to cover and determine the conditions. As a rule, they are well advised to exclude those liabilities from cover that are impossible to quantify, such as the value of impaired biodiversity itself or pure financial losses which can

result from commingling of natural quality crop with genetically modified crop.

Insurers make business with calculated risk; playing judge is not their job. Thus, when they choose to provide coverage or not, the issue is not to deliver a verdict of “good” or “bad”, but to decide whether accepting a risk is an attractive proposition. If the risk cannot be calculated, the cover is then limited. Yet, the more limitations that are placed on a cover, the further it will fall short of the legislator's goal of protection and precaution.

Therefore, if the insurance industry is to help society reach its protection goal, the statutory framework must be shaped so that it will still be possible to put a monetary value on losses subject to liability.

Thomas Epprecht, Swiss Re

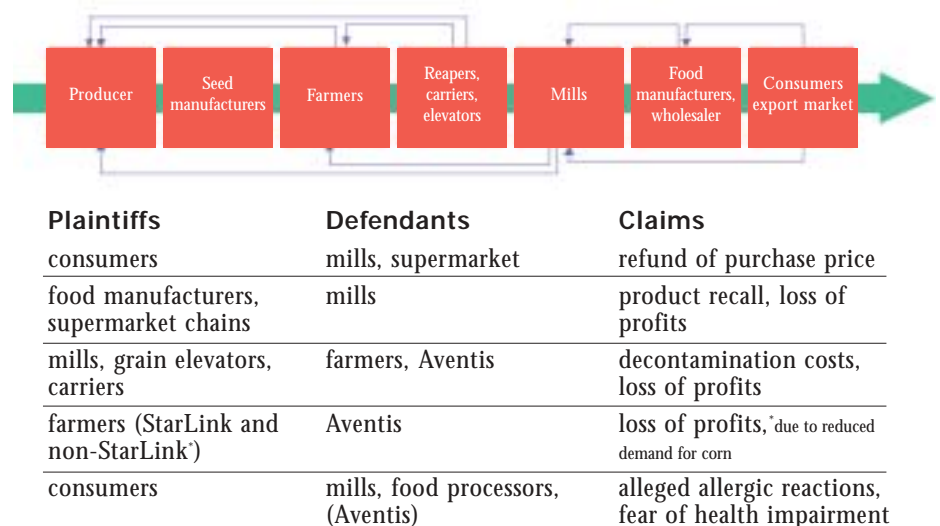
StarLink™

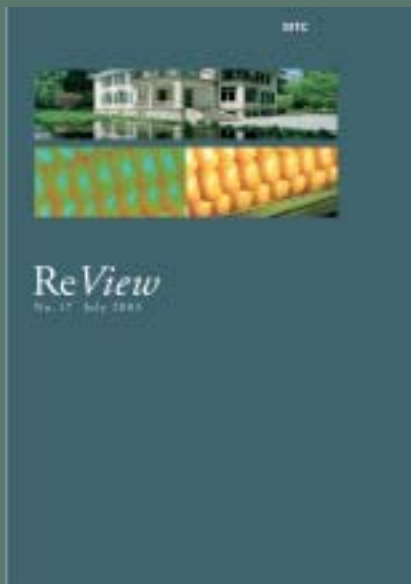
StarLink is the trademark for a variety of genetically altered corn produced by Aventis, which sold its CropScience Division to Bayer in late 2002. StarLink is a variant of *Bt* corn, so called because the gene (*Cry9C*) used to modify the corn stems from *Bacillus thuringiensis*, a soil borne bacterium. The gene product (*Cry9C* protein) acts as a built-in biopesticide, controlling the European corn borer, a major pest otherwise kept in check by chemical insecticidal sprays. StarLink also contains a second gene produced by Aventis, which makes the plant tolerant to a particular herbicide.

The approval for StarLink was limited to use as animal feed and in industry

(eg for producing alcohol), since the *Cry9C* protein was suspected of possibly triggering allergic reactions. For that reason, the US Environmental Protection Agency (EPA) adopted a cautious approach, giving it only partial approval and requiring further allergy testing. The *Bt* toxin in StarLink is broken down more slowly than the biopesticide in some other (fully approved) *Bt* corn variants, and although not much is known about exactly what triggers allergies, scientists do know that some natural allergenic proteins are retained longer in the digestive system and are not broken down quickly. However, StarLink's allergenicity has yet to be proven.

Production chain and the lawsuit in the StarLink case





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23 May 2005

**"Availability of financial security to cover liability resulting from the transboundary movement of living modified organisms (LMOs) and the prices at which such financial security is available".
General considerations provided by Swiss Re on demand of the Secretariat CBD**

1. Introduction

The CBD Secretariat kindly invited Swiss Re to participate in the first meeting of the Ad Hoc Open-Ended Working Group of Legal and Technical Experts on Liability and Redress under the Cartagena Protocol on Biosafety (UNEP/CBD/BS/WG-L&R), taking place in Montreal on 25–27 May 2005. The Working Group is seeking first-hand information regarding the "availability of financial security to cover liability resulting from the transboundary movement of LMOs and the prices at which such financial security is available"¹.

Regrettably, Swiss Re is unable to participate in the meeting due to the short notice. An in-depth written comment would also require more background information and more time. As the CBD Executive Secretary outlined in Chapter III of his note of 4 November 2002,² the final extent of liability is composed of many elements, and these are what decide the insurability issue. These elements are not yet sufficiently elaborated to allow us to make a conclusive statement.

However, the following general considerations, as well as the attached papers on similar matters may provide some indications as to what the limits of insurability may be. We refer particularly to our statements on the "Kiev Protocol"³ regarding the crucial question of environmental damage and compensation for financial losses in a situation where transboundary damages occur.

1. _____

¹ Paragraphs 88, 89 and 117b (iv) of the Report of the Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, 24 Feb 2005.

² CBD: Identification of Issues Relating to Liability and Redress for the Damage Resulting from the Transboundary Movement of LMOs, Note by the Executive Secretary, 4 Nov 2002.

³ For more detailed information see references [1] and [2].

2. Are the “Basel Protocol” and “Kiev Protocol” appropriate examples?

In its report, the Technical Group of Experts explicitly makes reference to the “Basel Protocol” on “Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal”, and poses the question whether an obligation to ensure financial security could be imposed analogous to this Protocol. During the elaboration of both the “Basel” and the “Kiev” Protocols, Swiss Re pointed out – in an opinion that concurred with that of European insurance associations – that the liability regimes under these respective Protocols are not favourable to the development of insurance solutions to provide full liability cover.

Indeed, today’s insurance market would tend to reinforce the concerns expressed in the past, and neither Swiss Re as a leading reinsurer, nor any of the major direct insurance companies provide cover for liability as defined in these Protocols.

3. Liability framework and insurability

One reason behind the lack of insurance cover for these “Protocol” liabilities may be that too little regard has been given to the basic nature of insurance companies: they are private enterprises, and must target economic efficiency as a goal. Therefore, for a risk to be insurable, the associated exposure to liability and claims must be transparent, or calculable. Any liability that goes beyond measurable or generally accepted risk must therefore be considered as uninsurable.

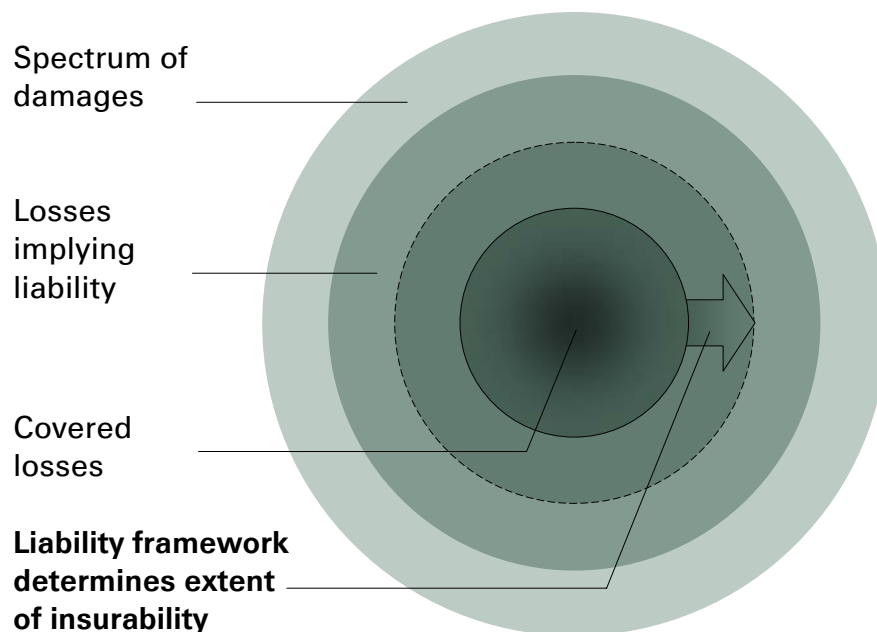


Fig 1: A clear and practical liability framework promotes insurability



The defining elements of liability exert a crucial impact on insurability as well⁴, and thus for liability to be well defined, and risks made insurable, these elements must be defined and, where necessary, delimited as well. They include the following concepts:

- damage and loss
- loss categories (bodily injury, property damage, environmental damage, financial loss)
- acceptable impact (including thresholds)
- exemption from liability
- limitation periods
- burden of proof
- beneficiary
- claimant.

The basic course is set by the liability standard chosen and the parties held liable.

4. Role of insurance and compulsory insurance⁵

Insurance enables society as a whole and a policy holder in particular to take greater risks. A risk should be taken only when it is acceptable – that is, when it is unlikely that the risk will materialise, although it might. Acceptability is a precondition for liability, since liability implicitly assumes that risks exist and that (acceptable) risks are taken. In exchange for the “licence” to take a risk, liability functions as a corrective in case a loss occurs.

When a risk manifests itself in a loss, insurance can only pay indemnity in the form of money. Therefore the only risks that qualify as insurable are those that are generally accepted, and about which there is consensus as to the value of a damaged entity and the way a loss can be compensated.

Obviously, it is always the liable party that must financially compensate any damages it caused. It can attempt to pass this obligation to an insurer, but because the freedom of contract applies, insurance companies have the right to either underwrite insurance cover – or decline it. Where legislators demand compulsory insurance⁶, the requirement binds only the liable party: ie the insurance companies may still limit or decline cover. In cases where a potentially liable party cannot get the required cover (or cannot afford the premium), the compulsory insurance mandate will work to restrict the company's activities, limiting its market access. Regulators should take this aspect into consideration carefully.

5. Basic principles of insurability

The basic underwriting criteria that determine insurability include the following:⁷

- Assessability (measurability, quantification)
- Economic efficiency (profitability)
- Randomness (fortuity)
- Mutuality (solidarity)

1. _____

⁴ Elements of a liability regime that may either leverage or counteract insurability are outlined in references [3] and [4] p 3.

⁵ For more detailed information see reference [4], pp 2 and 4.

⁶ For more detailed information see reference [3], chapter 4.2 (p 30f).

⁷ For more detailed information see reference [3], chapter 4.1 (p 27ff).



Assessability is a function of both the frequency and severity of risks that manifest themselves as losses. It is a key criterion since an insurer must be able to quantify the probability of a possible damage, as well as its consequences in order to calculate the potential exposure and the necessary premium. One thing currently impossible to quantify is the value of impaired biodiversity.

Economic efficiency: In order to write insurance profitably over the long run, private insurers strive for charging premiums commensurate with the accepted risks. When selecting the risks he wants to cover, an insurer must take into consideration the expected variation, any trends, the legal certainty, and the potential claimants' behaviour. The insurers' preference towards allocating his capital in light of profitability is also a consequence of statutory solvency requirements which oblige insurers to calculate net premiums that are adequate to the risk exposure. Thus, the requirement for solvency, ie economic efficiency, is an element that also needs to be considered by legislators.

Randomness: An event is considered fortuitous or random if at least the point in time and occurrence of the damage are unpredictable: It must be impossible for the insured party's intention to influence the occurrence of a loss event. For example, where genetically modified seed is unlawfully commingled with conventional seed, it may remain unclear to what extent such an event stems from attempts to cut costs along the distribution chain, and to what extent it happened fortuitously. Thus as a rule, pure financial losses are excluded from insurance cover.

Mutuality: This basic principle of insurance expresses the joint effort and common will of a large number of insured parties to carry a hazard jointly. Particularly with compulsory insurance, a large number of insureds is required – the large majority of which do not cause losses. Motor vehicle insurance or health insurance are good examples of this. On the other hand, the more a liability regime targets a few industrial operators, the more unbalanced a risk portfolio becomes. This affects both insurability and premium.

6. Summary: Availability of financial security and prices

- Availability of financial security: Taking the example of the Basel Protocol and environmental damages, general liability insurance policies presently available on the market normally exclude pollution risks resulting from the transport of dangerous substances. As a general rule, cover is either fully excluded or – with regard to the extent of legal liability – very limited.
- Compulsory insurance / financial guarantees: This would hardly result in additional offers of insurance cover, in particular not to the full extent of the stipulated liability. Note: "compulsory" just means that the liable party must buy insurance cover or ensure other financial guarantees: it never means that insurers must actually provide cover.
- "Prices": Premiums depend on the individual risk and associated exposure, the individual contract and the extent of cover provided by individual insurer(s) to single insured parties. A general answer is impossible, and price calculations here – because the losses do not occur in statistically significant numbers – cannot be compared with "mass products" such as motor vehicle liability insurance and the like.



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- [2] Economic Commission for Europe, Intergovernmental Working Group on Civil Liability; Comments to article 11 of the draft legally binding instrument on civil liability; working paper (MP.WAT/AC.3/2002/WP.15 and CP.TEIA/AC.1/2002/WP.15) submitted by Swiss Re; 2 Sept 2002
- [3] The insurability of ecological damage; Swiss Re technical publishing series (2003)
- [4] Cartagena protocol on biosafety; Insurance industry and Art 27 of the Cartagena Protocol; workshop paper submitted by Swiss Re to the Meridian Institute ICCP-3 side meeting in The Hague, 22 Mar 2002

8. Selected Swiss Re publications on the subject of biotechnology⁸

- [5] International Biotechnology Forum – Conference report; Swiss Re Center for Global Dialogue (2003)
- [6] Genetic engineering and liability insurance – The controversy on GMOs continues; Swiss Insurance Training Centre, ReView No. 17 (2003)
- [7] Genetic engineering and liability insurance – The power of public perception; Swiss Re (1998)

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⁸ can be ordered from www.swissre.com or are available via the Secretariat CBD