NCCR international trade IP9.

WORKSHOP ON LIABILITY AND REDRESS IN BIOTECHNOLOGY: IS THERE A NEED FOR HARMONISATION?

DATE: **16th May 2007, 1.30 pm – 5pm.**

Venue: World Trade Institute, Hallerstrasse 6, Bern 3102, Switzerland.

Contact: Sufian Jusoh, NCCR Research Fellow, email: Sufian.jusoh@wti.org

Dear Colleagues,

On behalf of NCCR IP9 (Biotechnology), I would like to invite you to attend and participate in the above workshop. The workshop will discuss several pertinent issues surrounding liability and redress arising from biotechnology related activities. Issues to be discussed at the workshop are attached with this invitation.

Several renowned experts in the field of liability and redress in biotechnology have confirmed their participation. They include:

- Dr. Philippe Cullet, Senior Lecturer in Law, School of Oriental and African Studies, London.
- Dr. Thomas Epprecht, Director and Expert, Emerging Risks, Swiss Reinsurance, Zurich.
- Mr. John Kelly, CEO, Moffat Dickson, Northampton, United Kingdom, formerly a CEO of a Japanese pharmaceutical company.
- Dr. Peter Mani, CEO, Tecrisk, Bern.
- Dr. Markus Schott, Advocate, University of Zurich.

Please confirm your participation by contacting Sufian.jusoh@wti.org. Many thanks and I am looking forward to seeing you at the Workshop.

Yours Sincerely

Sufian Jusoh

PROGRAMME

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Programme

1.30 – 1.45 p.m.	Welcoming Speech by Professor Dr. Thomas Cottier, Managing Director, World Trade Institute and Leader of NCCR IP9 (Biotechnology).
1.45 – 2.15	Liability in Biotechnology – Presentation by Dr. Philippe Cullet, Senior Lecturer in Law, School of Oriental and African Studies, London.
2.15 – 3.30	Discussion (please see the attached questions).
3.30 – 3.45	Coffee Break
3.45 – 4.00	Insurance and Biotechnology – Presentation by Dr. Thomas Epprecht, Director and Expert, Emerging Risk, Swiss Re.
4.00 – 4.45	Discussion (please see the attached questions)
4.45 – 5.00	Summary and Closing by Professor Dr. Thomas Cottier, Managing Director, World Trade Institute.

MAP TO THE WORLD TRADE INSTITUTE

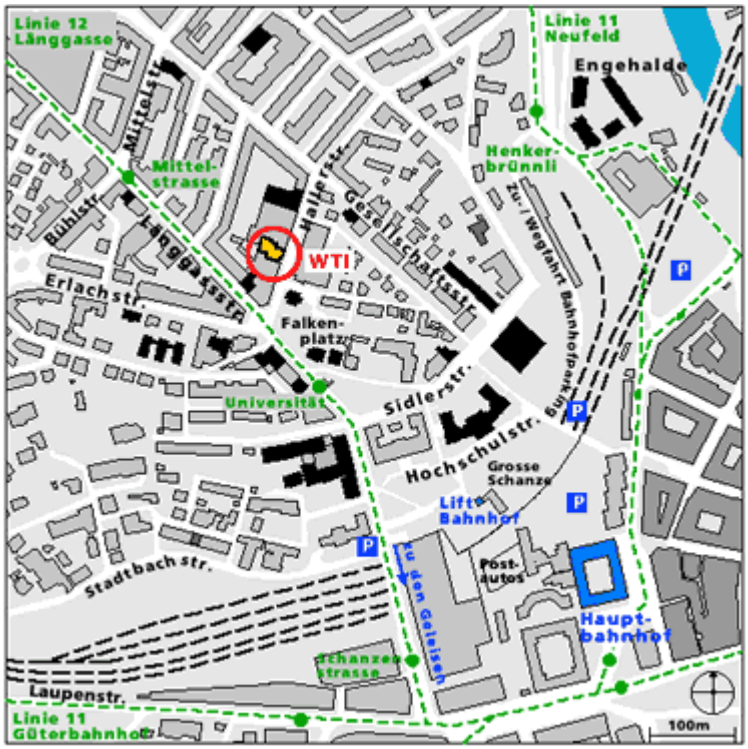
World Trade Institute

Hallerstrasse 6

CH-3012 Bern

Web: http://worldtradeinstitute.ch/

Plan du site:



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Introduction

Liability and redress in the context of biotechnology remains a relatively novel area at the international level and in most countries which are yet to adopt national rules.[1] This workshop will try to explore issues surrounding liability and redress in biotechnology. Those issues are not only limited to products based upon genetically modified organism, but should also cover wider scope such as pharmaceuticals and products from industrial biotechnology.

This workshop will be divided into two parts, Part 1 will discuss relevant issues pertaining to liability and Part 2 will address issues pertaining to redress.

1 Liability

Liability is an evolving concept, especially as it pertains to agriculture.[2] The key function of a liability regime is to determine who bears the risks of a particular activity. Four objectives should guide design of liability law:

- To provide compensation for victims.[3]

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1 Cullet, P., Liability and Redress in Biotechnology Towards the Development of Rules at the National and International Levels, COP/MOP 1 Biosafety Protocol, Background Paper IELRC Side-events on liability, February 2004, 1.

2 Phillips, P.W.B., *Agriculture: Farmers, Agrifood Industry, Scientists, Consumers,* Proceedings of the Canada-United States Law Institute Conference on Multiple Actors in Canada-U.S. Relations Cleveland, Ohio, April 16-18, 2004, 30 Can.-U.S. L.J. 273, 279.

- To incentivise operators to take due care.[4]
- To provide correct economic incentives for investment.[5]
- To act as deterrent regarding environmentally harmful activities, thereby fulfilling a preventive function.[6]

Liability is often conceived as a mechanism through which harm caused in the context of a legal or illegal activity can be compensated.[7] A liability regime gives rights to injured parties to sue those responsible for causing the harm, and impose obligations on others to limit the risk, mitigate the harm and provide redress. Liability law is often considered to be merely a mechanism for resolving disputes "ex post" and obtaining compensation after damage has already occurred.[8]

There are several issues relating to liability in biotechnology products:

1. There are three potential standards of liability to be considered: fault based liability, strict liability and absolute liability. Should the law relating to biotechnology liability be fault based or based on strict liability? What are the lessons to be learned from current domestic and regional legal framework such as those of the United States, England, the European Union, Germany and Switzerland?

2. Is there a need for a special rule for causation, especially in relation to fault based liability? The connecting issue is how to prove causation and what is the inter-relationship between science and law in proving causation? This is relevant especially in relation to the burden of proof and the burden to adduce evidence to support a particular contention.

3. The other question is the chain of liability. Who should be responsible and be liable for any losses? One of the important issues relating to liability, especially in relation to civil liability is the 'chain of liability'. One of the assumptions is that consumers or those who suffer damage from defective

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[3] Terry, S *The New Frontiers: Biotechnology Liability Law Reform*, Paper to the Biotechnology Law Conference, 20 February, 2003, 1.

[4] ibid.

[5] ibid.

[6] ibid.

[7] Cullet, P., note 1 above.

[8] Newell, P and Glover, D., Business and biotechnology: regulation and the politics of influence, IDS Working Paper 192, July 2003, 18.

product prefer to sue the richer person in the chain of liability. Examples of extended liability include the liability of retailers for design defects in the products the retailer sells, and the liability of waste shippers for leaks in the landfills that dispose of the shipper's waste.

4. In any liability system, whether it is fault based or strict liability, the defendant may be able to plead certain defences. What defences should be made available to a defendant? There are several defences available in the existing national regimes. One is the state of art defence. State of the art defence requires a demonstration that the technology available for the manufacture of a safer finished product with the same characteristics was not feasible. Other defences include contributory negligence, assumption of the risk and consumer product misuse defence.

5. The question of damage is also important. There are views that only consequential losses should be recovered by the claimant. The consensus is pure economic loss and remote losses and damages are not recoverable. However biotechnology liability may be wider than other forms of liability. There is an issue of genetic drift and in the Cartagena Protocol 2000 there is even a mention of social welfare issue. In Canada the case of *Monsanto* v. *Schmeiser* shows that a liability related to patent may also exist. What about damages to biodiversity? Thus, ultimately the question is, what kind of damages and losses should be excluded from this type of liability?

6. If the liability system is based on an international treaty, what is the basis of the liability? Is it going to be based on state responsibility? Is it going to be based on civil liability? Which one of the two concepts of liability will be more relevant and conducive in relation to biotechnology? There are lessons to be learned from existing international instruments. There are many instruments that have not come into force and in deciding the form of instrument, is it necessary to ensure that the instrument will finally be implemented?

7. In any cross border or international litigation, the question of the appropriate forum is always important. Claims for alleged damage from biotechnology may be brought before the national courts of the jurisdictions in which defendants and claimants reside. Where the claimant is based in one jurisdiction and the defendant in another, principles of international private law operates to ensure that claims recognized under national liability regimes also can be exercised in a cross-border context.

8. The other issue is that in cases filed in national courts involving parties from more than one country, principles of international private law will designate the substantive law to be applied in the case. The options are the claimant's law, the defendant's law, or the law of the place where the relevant act was done or the damage occurred. Which law should be the governing law?

9. Another important issue in relation to cross border or international litigation is the enforcement of judgement issued by the court. A judgement obtained by a claimant against a defendant would be meaningless unless such judgement can appropriately be enforced by the claimant to get the fruit of the litigation. The question is should any new international agreement introduce a comprehensive enforcement of judgement system? Or should the current system such as the bilateral recognition or regional recognition, e.g. Lugano Convention or Brussels Convention, be used to enforce such a judgement?

10. In relation to harmonisation of the law, there are views that the debate over the value of harmonising domestic regulatory policies has been a difficult one.[9] Advocates of trade liberalisation see domestic regulatory policies as possible impediments to free trade. Consumer and environmental groups argue against harmonisation.[10] In their view, the drive towards harmonisation restricts political sovereignty over domestic regulations, thereby making it difficult to adopt regulatory standards in areas such as environmental protection and food health and safety that are more restrictive than those of exporting countries.[11] Developed countries are concerned that harmonisation will force them to adopt the lower standards of other countries, developing countries are concerned that high standards in developed countries are barriers to developing country access to international markets.[12] Thus, should there be harmonisation of liability law in biotechnology? What are the arguments in favour of harmonisation? What are the arguments against harmonisation?

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9 Mayeda, G., Developing Disharmony? The SPS And TBT Agreements And The Impact Of Harmonisation On Developing Countries, JIEL 2004.7(737-764), 737

10 ibid.

11 ibid.

12 ibid.

2 Redress

Redress relates to the recoverability of damages or losses. It relates to compensation. The main redress available is recovery from insurance as tort is interrelated with insurance.

1. The main issue here is what is the attitude of insurance industry towards insurance of biotechnology products? This is because, 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. There is a view that for the insurance industry, genetic engineering is potentially one of the most particularly exposed technologies of the future.[13]
2. The other issue is what are the areas of liability recoverable or insurable? 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.
3. What influences the availability of insurance? There is a view that 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.[14]
4. There is another view that 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 c) that the limitation period is reasonably limited."[15] Is the standard of liability vital to the insurability issue?

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13 Epprecht, T., Genetic Engineering and Liability Insurance, The Power of Public Perception, Swiss Re, (Zurich: Swiss Reinsurance Company, 1998), 2.

14 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, 3.

15 Epprecht, T., "Cartagena Protocol on Biosafety: Insurance Industry and Art 27 (Liability and Redress) of the Cartagena Protocol" (Zurich: Swiss Reinsurance Company, 22 March 2002), 3.

5. Some international liability regimes[16] require the industry or activity being regulated to carry insurance or some other form of financial security. 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.[17] 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. Thus, should there be a compulsory insurance? What is the view of insurance industry on compulsory insurance?

6. 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.[18] 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. One example of compensation fund that has been implemented is that of the Marine Pollution compensation fund. The question here is, whether compensation fund would be an alternative to insurance? What are arguments for and against compensation fund?

7. A third alternative is that 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).[19] Should this option be considered for biotechnology liability?

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16 For example, Article 8 of the 1977 Convention on Civil Liability for Oil Pollution Damage resulting from the Exploration for and Exploitation of Seabed Mineral Resources17, 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.

17 Faure, M & Grimeaud, D, *Financial Assurance Issues of Environmental Liability* (Maastricht University, METRO & European Centre for Tort and Insurance Law, 2000), 147.

18 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 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.

19 Agriculture and Environment Biotechnology Commission, A Report By The Agriculture And Environment Biotechnology Commission Gm Crops, Coexistence And Liability November 2003, (London, DEFRA), 26.