ROYAL NORWEGIAN MINISTRY
OF THE ENVIRONMENT

Dr. Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, QC, H2Y 1N9, Canada

Your ref	Our ref	Date
	200501695-/CLI	5 JUN 2012

Comments from Norway on Notification 2012-016

Dear Dr. Ferreira de Souza Dias,

Notification 2012-016 invites

> *"other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that were considered for the identification of such living modified organisms.*

In our response to this notification, the Norwegian authorities would like to share some views on

- The case-by case principle of risk assessment under the Protocol
- Inductive generalization from non-existent or negative evidence (including the lack of positive evidence)
- The legal implications of the assertion "not likely to have adverse effects" under the Protocol

1. The case-by case principle of risk assessment under the CPB

The Cartagena Protocol on Biosafety, Annex III paragraph 6 states that *"Risk assessment should be carried out on a case-by-case basis."*, and in paragraph 9 it states that *"Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:"*. This includes paragraph 9(h) *"Receiving environment. Information on the location, geographical, climatic and*

Postal address
PO Box 8013 Dep
0030 Oslo

Office address
Myntgt. 2
postmottak@md.dep.no
www.miljo.no

Telephone
+47 22 24 90 90
Vat no.
972 417 882

Department for Nature Management
Telefax
+47 22 24 95 60

Our officer
Casper Linnestad
+47 45895

ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment."

The different receiving environments of an LMO, including the same geographical area in different seasons or years, may vary in important ways. For example, land use patterns, physiological or reproductive responses under different environmental conditions are well documented. Social, cultural and land management issues related to the receiving environment make a priori predictions of "not likely to have adverse effects" difficult.

A priori determination of an LMO not likely to have adverse effects may undermine the case-by-case principle of risk assessment outlined in Annex III of the Protocol. An assertion of "not likely to have an adverse effect" may be assumption-based, rather than evidence-based and therefore lack sufficient analytical rigor to be of value in upholding the objectives of the Protocol.

2. Inductive generalization from non-existent or negative evidence (including the lack of positive evidence)

The inductive inference of using past generic knowledge or experience on any LMO and applying it to novel cases has its limitations for science-based analyses of non-likelihood of adverse effects. Any assertion of non-likelihood of adverse effects that is science-based should provide statistical support with appropriately adjusted error rates for capturing small but important effects and is necessary to uphold any assertion of no effect. That is, the absence of evidence of harm is not the same as evidence of lack of harm. Hence, scientifically sound conclusions of likelihood may not be drawn and logically derived from the current state of knowledge.

We are unaware of any experience with LMOs to date that would provide credible scientific evidence, or verifiable criteria, to establish the non-likelihood of adverse effects. Such information would further be required to show relevance to risk appraisal in the given context. Empirical scientific evidence to date, and particularly the lack of verifiable absence of adverse effects, does not at present support a conclusion of low likelihood of adverse effects.

Probabilistic inference of likelihood is probably not a valid line of argumentation with the terms and central objective of the Protocol *"to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."* (Article 1 of the Protocol).

3. The legal implications of the assertion "not likely to have adverse effects" under the Protocol

In our view, an assumption-based conclusion of "not likely to have adverse effect" does not provide any exclusion for instance for a product developer who would still bear liability in the event that this assumption was erroneous or that the product lost efficacy and caused damage.

Conclusion

Information leading to a conclusion of a LMO "not likely to have adverse effects" may undermine the case-by-case approach of risk assessment under the Protocol. In the case of loss of efficacy or damage resulting from a LMO, a developer will still be presented with legal liability. Further considerations on this topic by Parties would require a stringent process to determine the relevance of such a request (*the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*) to meeting the objectives of the Cartagena Protocol on Biosafety.

Yours sincerely,

Birthe Ivars
Deputy Director General

Casper Linnestad
Senior Adviser, National Focal Point
for the Cartagena protocol