

Template for comments on the Study on Financial Security Mechanisms under the Nagoya-Kuala Lumpur Supplementary Protocol

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Comments on the text and Appendix		
Page #	Line in text	Comment
0	0	<p>The study is well written, and as thorough as possible given the paucity of experiential data, of relevant literature and of any evidence of damage to biological diversity caused by LMO's. It is clear, factual, objective and balanced.</p> <p>That said, there are at least two points that should be discussed:</p> <p>The first relates to the obligations of Parties with regard LMO's within their territory. As in 17 other instances in the NKLSP, the determination of financial security mechanisms is a matter for "domestic law". This is important, because it emphasizes two fundamental obligations of the Parties:</p> <p>1) The BSP tasks Parties to conduct a thorough risk assessment of an LMO before the Party allows transboundary movement into or intentional release of an LMO in that Party State. That risk assessment will assess the potential for adverse environmental impacts of that LMO within that Party's territory. If properly done, then the probability and hence the risk of such potential adverse impacts should be effectively mitigated or even eliminated, significantly reducing the need for the creation or implementation of financial security mechanisms dedicated to LMO impacts of biodiversity.</p> <p>2) Most, if not all, Parties already have in place laws or regulations governing the right to conduct various businesses within that Party State. Since the Party assesses the risk of and controls the transboundary movement or intentional release of each LMO, that Party is best positioned to ensure that its domestic business laws require adequate capitalization and financial capacity, if any, may be appropriate for any enterprise engaged in the development or release of an LMO to address the risks to biodiversity posed by that LMO. Moreover, when a Party determines that a particular LMO, or a set of activities with LMOs generally, does not pose potential risk to biodiversity based on its risk assessment process, it may be unnecessary to provide for strict capitalization and/or financial capacity requirements.</p>

		<p>The second is the inappropriate and irrelevant discussion of the “liability” for the unintended presence of genetic material from an LMO in non-LMO crops or plants, which the authors recognize, but nevertheless raise it repeatedly with examples because of the lack of experience or literature regarding the effects of LMO’s on biodiversity. It is appropriate to briefly recognise the issue, but it should be made clear that this is not relevant in the context of damage to biodiversity. Its prevalence in this report implies that GM crop farming itself is damaging to biodiversity, or non-GM farming systems are being confused with biodiversity. If there is a lack of literature or studies relevant to the topic, then other irrelevant LMO-related “liability” issues should not be used to fill that gap. The paucity of information reflects what we have repeatedly emphasised: in over 30 years since the introduction of LMO’s into the environment, and in annually increasing plantings, there has never been a single credible allegation of damage to biological diversity resulting from an LMO, and hence, no “liability and redress” per the NKLSP. This is evidence of the effectiveness of LMO risk assessment and risk management procedures, and also of the low probability of adverse environmental impacts they present. We also emphasise that the unintended presence of LMO genetic material is not harm <i>per se</i>, but rather the result of different choices in farming practices, with any resulting “harm” is not only purely economic, and any resulting “harm” is not only purely economic, but the result of voluntary participation in markets that have decided to exclude LMOs from their products for reasons of personal preference. Damage to biological diversity on the other hand can be real harm that must be measurable and significant to require response, and the determination and quantification of such harm is necessarily daunting and complex.</p>
7	4	<p>“Modern biotechnology” is a defined term, and that definition is important to the implementation of the CPB, so should be in quotation marks.</p>
7	5	<p>Article 27 of the CPB does not “mandate” the <i>negotiation</i> of rules and procedures for liability and redress, but rather the “appropriate elaboration” of such, taking into account extant international law. In fact, the NKLSP leaves the elaboration of such rules and procedures to domestic law.</p>
7	Fn2	<p>To be complete and unbiased, reference should also be made to the CropLife International/Global Industry Coalition <u>Implementation Guide to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety</u>, September 2012 (copy attached)</p>
7	13	<p>The Study should note that the right to provide for financial security in domestic law must be consistent with rights and obligations under international law.</p>
7	Fn7	<p>To be complete and unbiased, reference should also be made to the CropLife International/Global Industry Coalition <u>Implementation Guide to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety</u>, September 2012 (copy attached); particularly since the authors state that all relevant literature has been included.</p> <p><u>This is appropriate given that, as noted by the authors (e.g. page 8 lines 12-22), much of the discussion on this topic concerns agricultural uses of LMOs. .</u></p>
8	4	<p>“advantages” <i>not</i> “advantageous”</p>

8	15	As noted, above, the <i>allegations</i> of “damage” to non-GM farmers are <i>not</i> relevant to actual damage to biological diversity. This should be stated. They do not constitute damage or harm, but rather derive from potential economic loss resulting from philosophical differences and voluntary participation in markets that have decided to exclude LMOs from their products for reasons of perceived consumer preferences.
8	22	The NKLSP focuses <i>solely</i> on damage to biological diversity, and is neither applicable to nor relevant to alleged damage to farmers. Line 22 replace “ <i>rather than</i> ” with “ <i>and not</i> ”.
8	30	Financial security should not be viewed as a mechanism to protect against “risk” in the abstract, but rather, as a potential risk management mechanism after conducting a science-based and hypothesis driven risk assessment that considers the likelihood and consequences of exposure, in terms of harm. Either low probability or trivial harm results in minimal, perhaps even <i>de minimis</i> risk.
9	4	As noted in the general comments, above, the potential for insolvency of an operator is also a function of the Party’s duty under domestic law to regulate permission to conduct business in a particular field, taking into account appropriate capitalization, if any.
9	11, <i>et. seq.</i>	Legislators also govern the risk assessment (and potential mitigation) of the effects of an LMO prior to movement or release; and the determination of whether an operator is allowed to engage in business activities involving LMO’s.
10	18	Replace “ <i>demand</i> ” with “market demand” or “operator need”
11	9	As noted above, there is no property damage. Corn with the adventitious presence of LMO genetic material is still corn, with no phenotypic or nutritional difference. There are only allegations of economic loss stemming from voluntary participation in markets that have decided to exclude LMOs from their products for reasons of perceived consumer preferences. There are zero reported instances of harm to biodiversity after three decades of extensive consumption of LMO plants. Delete “ <i>thus leading to property damage for a farmer</i> ”
11	20	Replace “ <i>can appear</i> ” with “ <i>could hypothetically appear</i> ” The damage referred to is hypothetical, not actual.
11	21	Replace “ <i>can cause harm</i> ” with “ <i>could hypothetically cause harm</i> ” These harms have not been demonstrated.
11	24	Delete “ <i>caused by LMOs</i> ”
11	25	Replace “ <i>leading to</i> ” with “ <i>that could lead to</i> ”
11	29	Risk should be correctly defined: “Risk” is <i>not</i> merely the probability that a harm will occur, but rather a function of both the likelihood and consequences of exposure to an identified and hypotheses-driven harm. Either low probability or trivial harm results in minimal, perhaps even <i>de minimis</i> risk.
11	30	Replace “ <i>probabilities are</i> ” with “probabilities and potential magnitude are”
12	1	Replace “ <i>The uncertainty</i> ” with “ Further, The uncertainty ”
12	2	Delete “LMO” in “...concerning the LMO impact of civil liability regimes on LMO’s and operators as they...”
12	5 <i>et. seq.</i>	The statements by Swiss Re with regard to risks of allergenicity, fitness and impacts of wildlife are <i>incorrect</i> . National risk assessment

		processes carefully assess each of those risks and resulting authorizations for movement or release consider and mitigate, if needed, potential risks in these areas. Swiss Re is correct that the risks posed by LMO's are very low.
12	10	Edit text: "respect to the scope of magnitude of potential damage."
12	11 et. seq.	This general statement should be deleted or justified with more recent scientific evidence. It is not the technology used to develop an LMO that determines its potential risk. In agriculture there is scientific evidence to support the contrary view, with increasingly sophisticated biotechnological tools allowing for greater precision, and consequently uncertainty and complexity may indeed be reduced.
12	27	Replace " <i>demand</i> " with "market demand" or "operator need"
14	14	Edit text: "...information with respect to the <u>probability</u> risk and also..."
15	12-13	Are there any real examples indicating demand or supply?
16	4	Restate or clarify the meaning of "equally covering".
16	6	Delete " <i>that</i> " prior to " <i>calculating</i> "
16	15 et. seq.	Much of this paragraph is irrelevant content, and confusing the discussion of inter-farmer/producer allegations of harm with damage to biodiversity is particularly inappropriate. The clear and extant impact of the former issue on insurability of LMO's can and should not be implied to the latter. Potential damage to biological diversity is specifically assessed and regulated, and there has never been an allegation of such harm.
17	18	Is the risk really <i>new</i> ? Is there really <i>little known</i> ? This is not really the case – the limited information is simply a function of the "risks" not being demonstrated despite three decades of GM crop cultivation. The report could mention here the impact of the lack of history or evidence of damage on insurability.
18	8-9	The "Guidance" should not be referred to – it has not been formally adopted or endorsed by Cartagena Protocol Parties. Instead, in this context of "standards", the authors could recognise that LMOs are highly regulated by governments. The Cartagena Protocol obligates its Parties to conduct a risk assessment, consistent with the framework set out in Annex III, before taking decisions on LMOs. This is for the purpose of assessing the risk of potential adverse impacts on biodiversity. The Cartagena Protocol also requires its Parties to impose risk management measures to the extent necessary to prevent such potential adverse effects. In their domestic implementation of the Cartagena Protocol, Parties develop biodiversity policy that defines protection goals according to their priorities and circumstances. The level of regulation applicable to an LMO will reflect the acceptability of the assessed level of risk with respect to those protection goals.
18	18	Legislators also govern the determination of whether an operator is allowed to engage in business activities involving LMO's.
19	22	Further emphasizing the duty of the Party to regulate the conduct of business in the field of LMO's to verify, as necessary, that operators are adequately capitalized and have sufficient assets.
21	26 et.seq.	Again, further emphasizing the duty of the Party to regulate the conduct of business in the field of LMO's to verify, as necessary, that operators are adequately capitalized and have sufficient assets.
26	4	Delete the extra "an".

26	Box 5	<p>It should be noted earlier in the discussion that the Compact is not a true pooling or risk sharing agreement, but rather a hybrid in which the members define and finance the process for access to response costs, but the risk and funding of response costs are not shared and are more akin to self-insurance.</p> <p>We note that this is the only relevant existing mechanism specifically addressing damage caused by LMOs to biodiversity, and its membership consists of the largest developers of GM crops, which much of this discussion is focussed on. However, this mechanism is only briefly mentioned in Box 5 and not at all referred to in the main body of the text. In comparison, the irrelevant topic of “property damage” to non-GM farmers is given extensive attention in this report.</p> <p>Line 10: insert “...<i>largest agricultural LMO developers</i>...”</p>
26	28	Insert text: “...the memberships goals [for the availability of insurance and of broad access across the industry to response costs] will be difficult...”
27	13	Delete “ <i>and complicated (often new)</i> ”
27	18	Edit text: “... <i>Ex ante</i> only information is <u>only</u> needed on to establish the relative contribution ...”
28	Section 3.4.5	It should be noted that risk-sharing could be orchestrated by a trade association which could also establish industry best practices for various segments of operators. An example for agricultural LMOs is the Excellence Through Stewardship program (excellencethroughstewardship.org). Such an approach could be triggered or supported by government regulation.
30 31	27-33 1-12	<p>Again, confusing the discussion of inter-farmer/producer allegations of harm due to adventitious presence and different farming practices with damage to biodiversity is irrelevant and particularly inappropriate. This is not a form of “environmental harm” (as referred to on page 31, line 13), and by repeating this the authors are implying or asserting their own opinions that GM farming is itself environmentally harmful compared to non-GM farming practices – this is not the scope of this report, nor can such views be scientifically justified.</p> <p>The allegation of economic loss to a non-GM farmer’s crop cannot be compared in any way to the creation of and magnitude of a fund to compensate for the potential costs of response measures for damage to biological diversity. These “economic losses are the result of voluntary participation in markets that have decided to exclude LMOs from their products for reasons of perceived consumer preferences.</p>
31	13	It is inappropriate to suggest that the preceding discussion of funds to compensate farmers for alleged economic crop value loss is “environmental harm”.
35	8	Replace “ <i>losses</i> ” with “ <i>damage</i> ”
35	Box 9	Line 22 – what is the “risk” in this example? This is not about biodiversity and is an irrelevant example.
36	1-2	The fund referred to as an example does not concern relevant “damage”.
37	26	In considering mandatory financial security, it should be noted that the mechanisms for accident and consequent damage from oil pollution and nuclear power are known and understood, while the mechanisms and damage to biological diversity from LMO’s are speculative, such risks are thoroughly assessed and considered to be very low and have not materialized into even an allegation of harm to biodiversity.

38	20 et. seq.	This section discusses the costs of damage prevention. As mentioned previously, LMOs are highly regulated. The release of a GM crop into the environment requires regulatory authorisations, and ongoing regulatory compliance requirements and product stewardship. The NKLSA applies to authorised uses, as well as unauthorised and illegal. Authorised uses involve extensive risk assessments by many regulatory authorities worldwide, and these require scientific and technical data that is generated over several years of testing at significant cost (e.g. see https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/). Is this economic investment factored into considerations of “damage prevention” and “incentives”? Further, the different routes to damage – authorised, unauthorised and illegal – are not separately considered in this report, however the potential for each will impact “incentives” as there will be different regulatory consequences.
42	5 et. seq.	It is <i>not</i> necessary for self-insurance to work that reserves or assets would have to be set aside, as long as the operator has sufficient reserves or assets to pay the response costs in the event that the operator’s LMO actually causes damage to biological diversity. That can be verified by regulation and regulatory review of proof of financial wherewithal such as that described in Box 2 on p 20 and in p 20 FN 77.
42 & 43	Secs. 4.4.2 & 4.4.3	These discussions of social and environmental impacts of self-insurance highlight the need for adequate policies related to LMO’s, but do not support a conclusion that mandatory financial security should be required as a matter of course or as a condition on the right to do business in the field of LMO’s under the Party’s business law. For any insurers, it does suggest the need for adequate regulation and oversight of these entities, including adequate proof of financial wherewithal such as that described in Box 2 on p 20 and in p 20 FN 77.
45	16	The term “victims” is inappropriate. Better: “Costs of restoration...”
46	12 et. seq.	That is not correct: The Compact is exactly such a mechanism created and implemented by the major developers of agricultural plant biotechnology.
47	6	Edit text: “...where <u>the regulator or an insurer</u> monitors...” “...the activities of <u>the fund contributor or the insured</u> ...”

Please submit your comments to secretariat@cbd.int by **25 June 2020**.