

## Summary of Results

### *Chapter 1: The Emergence of Self-Spreading Biotechnology*

1. Molecular biotechnology has made significant advances in the last decade, especially because of the emergence of *genome editing* techniques like CRISPR, which make it possible to modify the genome of living organisms on the level of individual *base pairs* (or ‘letters’) of DNA. Compared to conventional techniques of genetic engineering, genome editing is not only more precise, versatile, and cheaper to apply, but also allows inducing genetic modifications without inserting foreign genetic material into the target organisms.<sup>1</sup>
2. Genome editing techniques also enable the development of various types of *self-dispersing* biotechnology, which refers to modified organisms capable of quickly dispersing through populations of wild species or crop plants in already-planted fields. This includes engineered gene drives, which bias the Mendelian rules of inheritance in favour of the genetic modification they confer. Gene drives could be used to confer new traits to natural populations, but can also be used to inhibit the reproductivity of organisms and thereby suppress populations of species, potentially to the point of extinction.<sup>2</sup>
3. So-called *horizontal environmental genetic alteration agents* (HEGAAs) might even be capable of genetically modifying organisms within the same generation, which would make it possible to confer new traits on existing crop plants.<sup>3</sup> Besides, genetically modified viruses can be used for many different interventions, including the suppression of plant pests or as ‘transmissible vaccines’, which move through populations like pathogens but confer immunity rather than causing disease.<sup>4</sup>
4. The emergence of self-dispersing techniques is likely to signify a megatrend that will vastly change the *modus operandi* of biotechnology. In contrast to conventional genetic engineering, where modifications are made under controlled conditions in a laboratory, the emergence

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1 Chapter 1, section B.

2 Chapter 1, section C.

3 Chapter 1, section D.

4 Chapter 1, sections E.I. and E.II.

of self-dispersing biotechnology implies that genetic modifications are carried out directly in the living target organism without human intervention. However, the ecological effects of these techniques have not yet been sufficiently scrutinized, and there is a substantial likelihood that they will be released into the environment before the risks are fully understood. This poses considerable challenges to existing scientific conventions, but also to the law.<sup>5</sup>

*Chapter 2: Concepts and Terms Relevant to Transboundary Harm Caused by Biotechnology*

5. While most national biosafety regimes apply to ‘genetically modified organisms’ (GMOs), international law generally refers to ‘living modified organism’ (LMOs). It is widely assumed that both terms are synonymous, although more recent genome editing techniques challenge the existing definitions of both terms under the various instruments.<sup>6</sup>
6. Generally, LMOs can give rise to personal injury, property damage, and economic loss, which is often referred to as ‘traditional damage’ because its compensability is universally accepted. In addition, damage may also be caused to common goods, such as the environment itself and biological diversity. While it is widely accepted that expenses incurred to mitigate environmental damage are recoverable, it is controversial whether any sustaining damage to the environment *per se* is subject to financial compensation. Besides, uncontrolled transboundary movements of LMOs must be distinguished from harm that occurs after an organism was deliberately imported into the receiving state and subsequently released there.<sup>7</sup>
7. The terms *responsibility* and *liability* are used inconsistently in international law dealing with the consequences of transboundary harm. The present study refers to ‘responsibility’ as the legal consequences that arise from unlawful conduct, whereas ‘liability’ is used to denote an obligation to rectify damage, regardless of whether this obligation results from responsibility or from a legal rule providing for liability regardless of wrongdoing.<sup>8</sup>

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5 Chapter 1, section F.

6 Chapter 2, section A.

7 Chapter 2, section B.

8 Chapter 2, section C.

8. The ‘polluter-pays principle’ provides that the costs of pollution or environmental degradation shall be allocated to the actor who causes the harm and draws the benefits from the harmful activity. However, from the perspective of international law it is not entirely clear whether the principle directs liability only to the *operators*, which means the person in actual control of a hazardous activity, or also to the state under which jurisdiction the activity is conducted.<sup>9</sup>
9. Since states are generally reluctant to accept liability for hazardous conduct carried out by private actors within their jurisdiction, international law often provides for *operator liability*, which denotes the liability of private actors implemented under national law adopted in accordance with international treaty obligations and enforced by national judicial and administrative systems.
10. Operator liability usually takes the form of ‘civil liability’, which denotes a legal obligation to pay monetary compensation. In contrast, ‘administrative liability’ refers to requiring the operator to take ‘response measures’, which means tangible action to contain, mitigate and remediate the damage.<sup>10</sup> Most liability regimes usually distinguish between ‘fault-based liability’, which attaches to some form of wrongful or negligent conduct, and ‘strict liability’, which arises regardless of such fault and is often imposed because of the inherent hazardousness of an activity or substance.<sup>11</sup> However, since non-state operators are not subjects of public international law, their liability must usually be implemented by states. This may pose obstacles in a transboundary context since states are under no general obligation to recognize and enforce foreign judgments.<sup>12</sup>
11. Besides the operator, accountability for transboundary harm may also be imposed on the so-called *state of origin* (or *source state*), which refers to the state under whose jurisdiction the activity that has caused the damage is carried out. In principle, it is undisputed that a state is internationally responsible for transboundary harm that results from a breach of its international obligations aimed at preventing such harm. Arguably, international responsibility may also be incurred by a failure to implement international obligations to provide for the liability of the respective operators which have caused the damage. Beyond that,

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9 Chapter 2, section D.

10 Chapter 2, section D.

11 Chapter 2, section E.

12 Chapter 2, section F.

however, it is controversial whether the state should also be *liable* for transboundary harm for which it is not *responsible*.<sup>13</sup>

*Chapter 3: The Regulation of Biotechnology in International Law*

12. At the global level, the most relevant instrument regulating the development and transboundary movement of LMOs is the Cartagena Protocol on Biosafety. The Cartagena Protocol is wide in scope and applies to organisms modified with genome editing techniques even when the technique employed does not – unlike conventional methods of genetic engineering – involve the (permanent) insertion of foreign genetic material into the target organism.<sup>14</sup>
13. The Cartagena Protocol is primarily concerned with ensuring that products of modern biotechnology that are permitted under the jurisdiction of one state and that are, in principle, freely available in international markets, do not cause harm to the environment of other states. To this end, the Cartagena Protocol establishes a detailed procedural framework for ensuring that each party can take sovereign decisions on whether to allow the import and environmental release of LMOs in its territory. At the same time, the Cartagena Protocol contains no material provision outlining under what circumstances an import should be allowed, subjected to conditions, or denied entirely.<sup>15</sup>
14. A significant challenge to the effectiveness of the Cartagena Protocol's consent mechanism is the fact that its applicability depends on the exporter's (stated) intentions about whether or not an LMO will be released into the environment once it has been imported into the receiving state. Apart from situations of a genuine subsequent change to the intended use, importers may exploit the 'contained use' exception to circumvent the AIA procedure. While this would not affect any domestic regulations applicable to a later release in the receiving state, a plausible motive could be to avoid more stringent requirements that apply in the state of origin. The responsibility to prevent such behaviour is shared by exporting and importing parties to the Cartagena Protocol alike. Exporting parties must ensure that statements about

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13 Chapter 2, section D.

14 Chapter 3, section A.I.

15 Chapter 3, section A.II.1.

the intended use are accurate, whereas importing parties should insist on the application of the AIA procedure – as implemented in their domestic law – whenever it appears possible or likely that an LMO initially imported for contained use will subsequently be released into the environment.<sup>16</sup>

15. The Cartagena Protocol also contains a range of provisions that apply regardless of whether an LMO is subject to a (deliberate) transboundary movement and thus regulated by the AIA mechanism, although they are largely free to decide how to regulate the development and use of LMOs in their own territory.<sup>17</sup> Moreover, states are required to cooperate, especially in sharing information about potential hazards originating from LMOs.<sup>18</sup>
16. In sum, the Cartagena Protocol is insufficient to regulate the use of modified organisms capable of self-propagation, including engineered gene drives and modified viruses, that have a high likelihood of spreading across political borders.<sup>19</sup> Article 25(2) is a notable exception because it imposes a strict obligation on the state of origin to dispose of an LMO illegally imported into another state. As the lawfulness of the import depends on whether the AIA mechanism, as well as the domestic laws of the receiving state, have been observed, this obligation is independent of any wrongdoing on the part of the state of origin. However, it remains questionable how this obligation can be implemented, especially when a (potentially self-dispersing) LMO has already been released into the environment of the receiving state.<sup>20</sup>
17. The liberty of states to decide for themselves whether they allow the import of LMOs into their territory may be considerably limited by international trade law, which provides that any restriction on international trade for the purpose of protecting the environment or human health must be based on scientific evidence about the risks that are to be averted. In contrast to the Cartagena Protocol, states are not allowed to invoke scientific uncertainty about risks as a reason to restrict trade, but only insufficient scientific information that prevents a scientifically sound risk assessment altogether. How WTO law can

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16 Chapter 3, section A.II.1.g).

17 Chapter 3, section A.II.2.

18 Chapter 3, section A.II.3.

19 Chapter 3, section A.II.2.a)cc).

20 Chapter 3, section A.III.2.c)bb).

- be integrated into the wider body of international law is still an unresolved question.<sup>21</sup>
18. Besides the Cartagena Protocol, the provisions on biotechnology contained in the Convention on Biological Diversity remain relevant, particularly for those states which have not ratified the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, which makes it difficult to assess compliance. However, programmes aimed at completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.<sup>22</sup> Moreover, the CBD and several other instruments require to prevent the spread of invasive species. It appears to be widely recognized that LMOs which may become invasive are covered by those provisions.<sup>23</sup>
  19. Despite the widespread and persisting disagreement about whether LMOs are – as such and inherently – hazardous, the international instruments concerned with plant and animal health, food safety, and international transport of hazardous goods recognize that LMOs (or GMOs) may indeed pose certain risks. Yet, these instruments take a more practical approach than the Cartagena Protocol by providing specific guidance on how to assess potential risks of LMOs in their specific context and on how to handle LMOs in ways that minimize these risks.<sup>24</sup>
  20. When a modified organism or pathogen causes a transmissible disease in humans, the WHO's *International Health Regulations* require the state where the outbreak occurs to speedily inform the WHO, which can then issue recommendations to the affected states on how to mitigate the outbreak, and to non-affected states on how to prevent an international spread. However, the recent experience of the COVID-19 pandemic has shown that compliance of both affected and non-affected states is still insufficient and inconsistent.<sup>25</sup>
  21. International law on biological weapons and the military use of environmental modification techniques as well as international humanitarian law also applies to recent advances in biotechnology, includ-

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21 Chapter 3, section C.III.

22 Chapter 3, section B.VIII.

23 Chapter 3, sections B.V, D, E, and G.

24 Chapter 3, sections D to H.

25 Chapter 3, section I.

ing self-dispersing modified organisms, although ensuring compliance with these provisions involves significant challenges.<sup>26</sup>

*Chapter 4: Prevention of Transboundary Harm from Biotechnology Under Customary International Law*

22. The general customary obligation of states to prevent significant transboundary harm applies to adverse transboundary adverse effects of LMOs in the same manner as it applies to other forms of transboundary environmental interference.<sup>27</sup> However, it only applies to unintended or accidental transboundary effects of LMOs but not to intentional transboundary movements. A general obligation to ensure that the prior consent of the receiving state is obtained prior to exporting an LMO, as set out in the Cartagena Protocol, is currently not part of customary international law.<sup>28</sup>
23. International responsibility for transboundary harm requires such harm to be 'significant', but it is doubtful whether this threshold is reached by the mere presence of an LMO in the territory of another state. It must be shown that the LMO causes 'real detriment' in the form of damage to persons, property or the environment. A large-scale influx of LMOs, e.g. caused by an invasive gene drive, is likely to be regarded as significant, especially when it has adverse effects on local ecosystems. Moreover, when the release of a particular LMO (or of LMOs generally) is illegal under the national laws of a state, that state cannot argue that an unintentional spread of that LMO into the environment of another state was insignificant.<sup>29</sup>
24. The obligation to prevent transboundary harm is only an obligation of 'due diligence', which means that a state must make reasonable efforts to inform itself about the factual and legal circumstances that relate to a proposed activity and take appropriate preventive measures in due time.<sup>30</sup> Hence, in order to establish a violation, a claimant would need to demonstrate that the responsible state has failed to employ due diligence and that this failure caused the occurrence of transboundary

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26 Chapter 3, section J.

27 Chapter 4, section B.II.

28 Chapter 4, sections B.III. and B.VII.2.

29 Chapter 4, sections B.IV. and B.VII.

30 Chapter 4, section C.

- harm. Ultimately, this will require an *ex post* determination of what measures would have been appropriate in the individual case from an *ex ante* perspective.
25. When knowledge is insufficient, the precautionary approach lowers the evidentiary threshold for requiring preventive measures. As a result, states can be required to take preventive action already when there are indications, albeit no proof (or scientific certainty), that an activity might lead to significant transboundary harm. However, the precautionary approach does not result in a reversal of the burden of proof; a state invoking the precautionary principle still must adduce enough evidence to establish at least a *prima facie* case.<sup>31</sup>
  26. While the substantive content of due diligence remains rather vague, the corollary procedural obligations are more specific. In particular, the obligation to carry out an environmental impact assessment is universally recognized, and the adequacy of such assessments is increasingly subject to legal review by international courts and arbitral tribunals.<sup>32</sup> The documentation prepared during an EIA procedure can be regarded as written evidence of the exercise of due diligence, as it commonly includes a description of the potential impacts of the proposed activity as well as of the required prevention and mitigation measures. At the same time, the greater level of detail in the procedural manifestations of prevention has often led international jurisprudence to focus on procedural aspects while applying less scrutiny to the question of whether the substantive obligation to prevent harm has been observed.
  27. Because the obligation to act with due diligence is not an ‘obligation of result’, the mere occurrence of transboundary harm does not *per se* indicate a violation.<sup>33</sup> *Vice versa*, however, international jurisprudence seems to consider it a prerequisite of a breach that harm has actually occurred.<sup>34</sup> Nor are violations of procedural duties, in the view of international jurisprudence, evidence *per se* of a breach of the substantive obligation to prevent transboundary harm. However, procedural duties should be seen not only as independent obligations but also as expressions of the substantive obligation to prevent harm. That is, breaches of procedural duties imply that a state has also disregarded its

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31 Chapter 4, section B.VI.

32 Chapter 4, section D.II.

33 Chapter 4, sections E.I.

34 Chapter 4, sections E.II.

substantive obligation to employ due diligence, regardless of whether harm has already been caused.<sup>35</sup>

28. To date, no state has ever claimed a breach of international law for adverse transboundary effects caused by LMOs uncontrolledly entering its territory. In light of recent advances in developing self-dispersing biotechnology such as engineered gene drives, such claims are likely to arise in the future. However, it is doubtful whether customary international law is capable of preventing unilateral releases when the potential for a transboundary spread of the organism is controversial.<sup>36</sup>

### *Chapter 5: The International Governance of Engineered Gene Drives*

29. Since the first releases of engineered gene drives are expected to occur as soon as 2023, the debate about the international regulation of this emerging technology has gained speed and culminated in a first substantive decision on this matter by the parties to the CBD in 2018.<sup>37</sup>
30. The fact that the decision was carried by consensus by all states (except for the United States) gives the decision a high degree of normative authority. This is also because the decision does not attempt to establish new principles, but rather endorses the application of certain established rules of international law to the issue of gene drives.<sup>38</sup>
31. The decision calls on states to observe the precautionary principle. Contrary to what a few authors have contended, this cannot be used to justify premature releases in order to address other environmental threats that require rapid action. Instead, the precautionary principle calls for restraint in using gene drive techniques as long as their risks and benefits cannot be fully evaluated.<sup>39</sup>
32. The decision calls on states to consider releasing engineered gene drives only when three conditions are met: a scientifically sound risk assessment has been carried out; appropriate risk management measures are in place; and the free and informed prior consent of indigenous peoples and local communities has been obtained (where applicable).

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35 Chapter 4, sections E.III.

36 Chapter 4, section F.

37 Chapter 5, section A.

38 Chapter 5, section B.

39 Chapter 5, section C.I.

33. While these criteria had previously been recognized by the parties to the CBD, many questions remain regarding their consequences in the context of gene drives, and the benchmark for what constitutes the ‘best available technologies’ is currently not defined by the states but rather by the researchers involved in the development of gene drives. The same is true for the call to ensure the safety of gene drive in contained use, where the decision even suggests a level of international harmonization that actually does not exist.<sup>40</sup>
34. An issue left unaddressed by the decision is the potential of engineered gene drives to spread across borders. While the problem is broadly recognized in principle, the likeliness of such spreads will often create controversy between the state planning a release and potentially affected neighbouring states, which makes it difficult to agree on general rules.<sup>41</sup> Parties to the Cartagena Protocol should clarify that releases likely to result in a transboundary spread constitute ‘intentional transboundary movements’ that require the Advance Informed Agreement of the likely affected states prior to the release.<sup>42</sup>
35. The decision neither results in a moratorium of gene drive releases nor provides a comprehensive ‘checklist’ for future releases. Therefore, the decision should be seen as a carefully balanced compromise between both ends of the spectrum, which does not answer the question as to whether responsible gene drive releases are permissible under the current rules of international law.<sup>43</sup>

*Chapter 6: The Nagoya – Kuala Lumpur Supplementary Protocol on Redress and Liability*

36. The Supplementary Protocol is the first global agreement on liability for damage to a global common and the first global agreement providing for an administrative approach to liability, and the first global agreement dealing with environmental liability outside the context of maritime oil pollution and nuclear damage that has ever entered into force.<sup>44</sup>

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40 Chapter 5, section C.II.

41 Chapter 5, section D.

42 Chapter 5, section D.I.2.

43 Chapter 5, section E.

44 Chapter 6, section A.

37. The Supplementary Protocol provides for ‘administrative liability’. Instead of providing simply for the payment of monetary compensation by the responsible operators, the Supplementary Protocol stipulates that damage shall be prevented, mitigated and restored by implementing response measures. However, parties to the Supplementary Protocol enjoy too much leeway in implementing the administrative approach in their domestic legal and administrative systems. Apart from stipulating the primacy of prevention over restoration, and the primacy of restoration over compensation,<sup>45</sup> it does not define any specific criteria for what constitutes damage to biological diversity,<sup>46</sup> how to identify the liable actor, and what kinds of response measures should be taken. At the same time, it might be an inherent necessity of the ‘administrative liability’ approach to grant states a certain margin of appreciation, as it is not possible to pre-emptively regulate what measures will be required in individual cases of damage.<sup>47</sup>
38. With respect to personal injury and property damage, the Supplementary Protocol does not even attempt to harmonize substantive and procedural rules on civil liability. This takes account of the fact that states widely refuse to accept the harmonization approach, as aptly demonstrated by the numerous civil liability treaties that have failed to enter into force. Consequently, the Supplementary Protocol does not commit the parties to particular standards on civil liability but only stipulates a procedural duty requiring states to ‘aim’ for ‘appropriate rules and procedures’ in their domestic law.<sup>48</sup>
39. One of the most striking omissions of the Supplementary Protocol is its failure to address the transnational implementation of liability. Although it only applies to damage resulting from LMOs that find their origin in a transboundary movement, it remains silent on how to deal with situations in which the responsible operator is located in one state and biodiversity damage occurs in another. The Supplementary Protocol fails to address the issues that naturally arise in these situations, including jurisdiction, applicable law, and recognition and enforcement of judgments. Thus, the Supplementary Protocol only ap-

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45 Chapter 6, section C.IV.

46 Chapter 6, section B.

47 Chapter 6, section C.VI.

48 Chapter 6, section D.

- plies to transboundary situations but treats liability in these situations as if they were a purely domestic matter.<sup>49</sup>
40. It is doubtful that the Supplementary Protocol will be of particular use when self-dispersing biotechnology causes adverse transboundary effects. Although the Supplementary Protocol expressly applies to unintentional transboundary movements, it does not provide any means to deal with such situations. Unless the ‘operator which has caused the damage’ has assets in the affected state that can be seized to enforce liability, and in the absence of other instruments, a state facing adverse effects of an LMO that uncontrolledly entered its territory has no remedies to enforce the civil or administrative liability of foreign operators. In such situations, the only options are seeking civil law remedies in states where the responsible operator is situated or has assets, or invoking the international responsibility of the state that has authorized the release, provided it has breached preventive obligations under international law.<sup>50</sup>
41. While the lack of harmonization is a major shortcoming of the Supplementary Protocol, it is arguably also an important factor that allowed it to enter into force. However, it also demonstrates the low level of agreement among states about substantive standards for environmental liability in an international context. In any event, adopting instruments on transboundary environmental liability that do not actually address the challenges arising from transboundary situations will likely prove to be a Pyrrhic victory.<sup>51</sup>

*Chapter 7: A Private Liability Scheme: The ‘Biodiversity Compact’*

42. The Biodiversity Compact is a voluntary private compensation scheme under which six agricultural biotechnology corporations assume liability for biodiversity damage caused by any of their LMOs.<sup>52</sup> The Compact adopts the ‘administrative approach’ to liability followed by the Supplementary Protocol but specifies the modalities of liability in much greater detail.<sup>53</sup> It channels liability to a clearly identifiable ac-

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49 Chapter 6, section F.I.

50 Chapter 6, section H.

51 Chapter 6, section H.

52 Chapter 7, sections A and B.

53 Chapter 7, section E.

tor, and its binding arbitration mechanism provides means to enforce liability even when the liable party is situated outside of the state's jurisdiction.<sup>54</sup> Furthermore, due to its nature as a third-party beneficiary contract, the Compact also benefits those states which have not ratified the Supplementary Protocol or do not have in place adequate liability rules in their domestic law.

43. Like the Supplementary Protocol, the Compact suffers from limited participation and representativeness. The shortcomings in participation are likely to become more pronounced, seen as the emergence of genome editing techniques has led to a substantial increase in bio-enterprise investment. Many new companies have emerged and have begun to commercialize these techniques. Furthermore, engineered gene drive techniques are mainly pursued not by the biotechnology industry but rather by research institutions and philanthropic organizations. It currently seems unlikely that these actors will feel compelled to sign the Compact.<sup>55</sup>
44. Besides its limited participation, the Compact's most significant shortcoming is its exclusion of damage resulting from risks that were already known when the LMO was authorized for marketing or release; such a one-sided risk allocation is uncommon for liability regimes addressing activities or substances that are deemed hazardous but socially beneficial.<sup>56</sup> Due to the Compact's complex definition of damage, evidentiary requirements, provisions on determining the adequate response, and claims process, it seems unlikely that potential claims would be successful.<sup>57</sup>
45. Although presented as a confidence-building measure, the Compact must rather be seen as a (failed) attempt to avert the adoption of a legally binding international regime on liability for damage caused by LMOs. At the same time, the considerable complexity of the Compact's text demonstrates the challenges involved in implementing the Supplementary Protocol into specific legislation at the domestic level.<sup>58</sup>

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54 Chapter 7, section G.

55 Chapter 7, section H.

56 Chapter 7, section D.

57 Chapter 7, sections C to G.

58 Chapter 7, section H.

*Chapter 8: A Customary Obligation to Ensure Prompt and Adequate Compensation for Transboundary Damage?*

46. When activities under their jurisdiction cause transboundary harm, states are obliged by customary international law to ensure that foreign victims have access to non-discriminatory remedies and can obtain prompt and adequate compensation.<sup>59</sup> States must also take response measures to prevent and mitigate further damage, including by notifying and cooperating with all other states likely to be affected.<sup>60</sup>
47. The state of origin is neither required nor generally allowed to take response measures in the territory of affected states.<sup>61</sup> Affected states, however, do not bear a general obligation to take response measures under general customary international law, although such an obligation arises from Article 8(h) of the CBD in case a self-dispersing LMO spreads beyond its intended target range and becomes an ‘invasive alien species’ threatening biodiversity. If an affected state takes reasonable mitigation and reinstatement measures, the expenses incurred in doing so become part of the damage for which the state of origin must ensure prompt, adequate and effective remedies under its domestic legal system.<sup>62</sup>

*Chapter 9: State Responsibility for Transboundary Harm Caused by Biotechnology*

48. The law of state responsibility provides far-reaching consequences for breaches of international law, including unlimited responsibility for any injury caused. However, state responsibility is also subject to several limitations and caveats.
49. States are not generally responsible for the conduct of individuals within their jurisdiction. The conduct of natural or legal persons is only attributed to the state under certain limited conditions; there is no ‘vicarious responsibility’ of states for the conduct of private actors within their jurisdiction.<sup>63</sup> Therefore, in the context of transboundary

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59 Chapter 8, section B.

60 Chapter 8, section C.

61 Chapter 8, section F.

62 Chapter 8, sections C and F.

63 Chapter 9, section A.II.

environmental interference, the focus is on the obligations of states to adequately regulate hazardous activities and, in the event of damage, to provide for the liability and redress.<sup>64</sup> However, hazardous conduct can become directly attributable when the state itself engages in such conduct or effectively controls such conduct carried out by non-state actors.<sup>65</sup>

50. To implement state responsibility, it must be shown that the state's conduct was not in conformity with its obligations under international law. However, proving the relevant facts, including what the responsible state *could* and *should* have done to prevent damage, will often involve difficult evidentiary questions.<sup>66</sup> Similar difficulties may arise regarding the proof of causation, especially when the damage only manifests in the long term or when there is more than one possible pathway or multiple states that are jointly responsible for the damage. International courts and tribunals are reluctant to lower the standard of proof required to establish the existence of a causal link between the responsible state's failure to adequately regulate a hazardous activity or organism, and the resulting damage.<sup>67</sup>
51. When a breach can be established, the responsible state must cease the wrongful conduct and make reparation for any injury caused by it.<sup>68</sup> In principle, the obligation to make full reparation applies not only to 'traditional' damage such as personal injury, property damage, and economic loss, but also to damage to the environment *per se*.<sup>69</sup> This will become particularly relevant when self-spreading LMOs cause damage to native species, ecosystems or biological diversity at large.
52. A state's international responsibility can only be invoked by other states. In the absence of dedicated treaties, foreign private actors cannot directly make claims against the state of origin but need to be represented by their respective states. However, unlike conventional cases of *diplomatic protection*, there is no requirement that the private actor must exhaust *local remedies* because the victims have not voluntarily subordinated themselves to the jurisdiction of the source state.<sup>70</sup>

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64 Chapter 9, section A.II.6.

65 Chapter 9, section A.II.2.

66 Chapter 9, section A.III.

67 Chapter 9, section B.II.2.

68 Chapter 9, section B.

69 Chapter 9, section B.II.3.

70 Chapter 9, section C.II.2.

53. Since states are not bound to accept the jurisdiction of any international court or tribunal, there will be no adequate legal mechanism to enforce the liability of the state of origin in many cases; this may well prove to be the biggest obstacle to enforcing state responsibility for transboundary damage caused by biotechnology.<sup>71</sup> Compliance mechanisms established by multilateral environmental agreements such as the Cartagena Protocol may be better equipped to promote adherence to international rules.<sup>72</sup> Yet, they fulfil different functions. While compliance mechanisms are ‘forward-looking’ and aim to ensure the future compliance of states with their obligations, state responsibility remains the relevant regime to rectify injury that has already been caused by breaches of international obligations.<sup>73</sup>
54. Despite its difficulties, the relevance of state responsibility in the context of transboundary harm should not be underestimated because the perspective of being held responsible for non-compliance ensures the effectiveness of all primary rules on prevention and operator liability. This is even more true when states proceed with releasing modified organisms capable of self-dispersion unilaterally rather than in internationally coordinated efforts.<sup>74</sup>

#### Chapter 10: Strict State Liability for Transboundary Harm?

55. Although it is widely acknowledged in legal scholarship that, *de lege ferenda*, there should be a form of subsidiary state liability for significant transboundary harm caused by hazardous activities, the pertinent state practice currently does not provide sufficient ground to presume the existence of a customary rule providing for strict state liability for transboundary harm caused by self-spreading biotechnology. While there are only a few cases in which transboundary harm was left entirely unanswered by the state of origin, most payments were made explicitly on an *ex gratia* basis, and states insisted on not accepting a legal responsibility or liability for the damage.<sup>75</sup>

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71 Chapter 9, section C.III.2.

72 Chapter 9, section C.III.3.a).

73 Chapter 9, section C.III.3.b).

74 Chapter 9, section D.

75 Chapter 10, section B.

56. Consequently, a state is not generally liable for transboundary harm caused by self-spreading biotechnology unless in cases of a breach of international law.<sup>76</sup> Thus, if a state has taken all measures deemed ‘appropriate’ to prevent adverse transboundary effects, it is under no obligation to compensate for damage that occurs nevertheless. This demonstrates, again, the need to strengthen the preventive obligations and, since a moratorium seems difficult to achieve, to agree on clear conditions for environmental releases of engineered gene drives and other forms of self-spreading biotechnology.

*Chapter 11: Compensation for Environmental Damage in International Law*

57. It is now generally accepted that damage to the environment constitutes a category of damage for which reparation must be served under international law. This includes at least the costs incurred by the injured state in assessing the damage, preventing further injury and restoring the environment to its *status quo ante*,<sup>77</sup> provided that the measures taken are appropriate and reasonable in light of the circumstances of the case and the state of science.<sup>78</sup> Compensation is generally served by reimbursing the affected state for the expenses incurred in implementing these measures.<sup>79</sup> These principles apply to all types of environmental damage, including potential transboundary damage caused by products of biotechnology.
58. Compensation must also be made for ‘damage to the environment *per se*’, i.e. temporary or permanent impairments of the environment. While international law appears to favour restoration over the mere payment of monetary compensation, payment of financial compensation is an accepted remedy when the damage cannot be restored.<sup>80</sup>
59. The impairment of environmental goods and services used commercially is compensated according to their ‘use value’, which is usually the market value of the affected natural resources.<sup>81</sup>

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76 Chapter 10, section E.

77 Chapter 11, section A.I.

78 Chapter 11, section A.II.

79 Chapter 11, section A.I.2.

80 Chapter 11, section B.I.

81 Chapter 11, section B.II.2.a).

60. While it is generally recognized that reparation must also be served for injury to elements of the environment with no clear economic value, it is controversial how the type and quantum of such reparation shall be determined.<sup>82</sup> One approach is *compensatory restoration*, which denotes replacing lost environmental assets by preserving or improving other elements of the environment capable of providing environmental goods and services similar to those lost.<sup>83</sup> Other approaches seek to establish a monetary value of the impaired environmental goods and services by referring to *non-market valuation techniques*, including ‘stated preference’ and ‘revealed preference’ methods.<sup>84</sup> Besides, ‘benefit transfer methods’<sup>85</sup> and the costs of ‘hypothetical’ response measures can be used to quantify compensation.<sup>86</sup>
61. The international practice has not yet yielded a generally accepted technique for determining the form and quantum of compensation for environmental damage. Thus, cases of transboundary damage caused by biotechnology will not only pose difficult legal and evidentiary questions about causation but also concerning the establishment and valuation of the damage. The ICJ’s first judgment on the issue has provided little clarity on the issue, because its ‘overall valuation’ approach appears to be mainly based on judicial discretion.<sup>87</sup> Thus, there is currently no clear way to quantify compensation for damage caused by the application of biotechnology, especially when damage is caused to common goods and values, such as global biodiversity.

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82 Chapter 11, section B.II.

83 Chapter 11, section B.II.1.

84 Chapter 11, section B.II.2.b).

85 Chapter 11, section B.II.2.c).

86 Chapter 11, section B.II.2.d).

87 Chapter 11, section B.III.