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Editorial

2020 – it was a year of transformations. At its beginning, before the Corona Pandemic hit hard in March, the editors of *elni Review* decided to further develop the journal into an electronic resource. Since then, individual articles have been shared with elni members and subscribers to the *Review* on a rolling basis. These are now compiled in the Review issue at hand.

In parallel, the online archive of elni articles released since 2005 received a comprehensive update which is expected to be completed in 2021.

Another 2020 transformation regards the 'elni FORUM' conference series which, as is considered good form by now, took place online on a whole cycle of events under the umbrella topic 'Green Deal – A way forward for EU environmental legislation?'. 2021 will see a new cycle of elni events. Details will be shared soon.

The Recent Developments section features a report of the 2020 elni event on 'Product policies for a Circular Economy'. Further details on this and the other two fora (including recordings, slides) can be found online.

The articles section of the *Review* comprises four highly topical pieces. *Ludwig Krämer* examines the legality of gene drive releases – that are an emerging issue since the discovery of the CRISPR/Cas9 method in 2012 – within the EU and describes the efforts to find some international consensus on gene drive releases.

Nicolas de Sadeleer addresses the Dutch Hoge Raad judgment of 20 December 2019 in the Urgenda case, which triggered broad international response. He finds 'An over-cautions policy for reducing GHG emissions breaches Articles 2 and 8 of the European Convention on Human Rights'.

At the interface of science and policy, *Marlene Ågerstrand* in her contribution 'Better reporting of science to improve regulatory decision-making' explains recommendations by The Society of Environmental Toxicology and Chemistry (SETAC) for reporting ecotoxicity studies to facilitate the use of these studies in research as well as regulatory assessments.

Finally, as trees and forests in Europe are entering centre stage in public opinion and the European Green Deal creates political impetus, *Marco Onida* is taking stock as regards 'Forest and forestry policy between the EU and its Member States'.

We hope you enjoy reading.

Julian Schenten / Gerhard Roller
December 2020

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Gene drives and the EU

Ludwig Krämer

1 Introduction

Gene drive is a technique by which genetically modified animals or plants are deliberately released into the wild, in order to cross with wild organisms and thus contribute to the proliferation of the modified or the introduction of new gene(s). While regular inheritance rules (Mendel's rules) provide that an offspring has a 50 per cent chance to inherit a gene which one of its parents has, that chance is increased by gene drive techniques to up to 100 per cent, so that in theory all the offspring may inherit the modified or introduced gene. The development of gene drives became possible in 2012, when the so-called CRISPR/Cas9[1] method was discovered. This method allows a cheap, precise and easy to handle modification of the genes of an organism. Since then, research on gene drives developed spectacularly, in particular in the USA and the United Kingdom.

Gene drives are only effective in populations of sexually reproducing organisms and do thus not work in bacteria or viruses[2]. For this reason it is, for example, not possible to fight the malaria illness by applying the gene drive technique to the microorganism[3] that is responsible for malaria, while the mosquito is only the carrier ('vector') for transmitting the virus to humans. However, gene drives could be used to modify the gene of mosquitoes such that, for example, only male offspring are born; this would in time lead to the extinction of mosquitoes in a certain area or even globally. Or to take another example: modifying the genes of mice on an island in a way that only male offspring are born could eliminate the whole mouse population on that island within some generations.

Until early 2020, gene drive experiments on the basis of CRISPR/Cas9 methods took place exclusively under laboratory conditions; no field trials or releases into the wild environment took place or became known[4]. The reason for this is that the mechanisms which take place within a cell that is modified with the CRISPR/Cas9 method and the joint effect of several genes to bring about the desired changes in the next generation are not yet completely understood[5]. Furthermore, it is unclear whether the release of a genetically modified animal in the wild will cause unforeseen environmental or human health effects that lead to new problems. In the example of mice released on an island, genetically modified mice might escape to the mainland and affect the mice population there. In the case of malaria, the parasite which causes the illness might use another insect animal as a vector when the mosquito, which until now served as a carrier, disappears[6]. The plasmodium parasite could also mutate and overcome the resistance of the mosquito against the new gene.

2 EU legislation

Within the EU, Directive 2001/18 applies to the deliberate release of genetically modified organisms (GMOs)[7]. The Directive does not apply in particular to GMOs obtained by mutagenesis techniques or methods[8], and there was some controversy in the scientific literature over whether GMOs which were obtained by using the CRISPR/Cas9 method fell under the provisions of the Directive. This controversy was decided in 2018 by the Court of Justice of the EU (CJEU)[9], which recurred in particular to Recital 17 of the Directive[10], from which it deduced that only those mutagenetic methods were excluded from the field of application that had conventionally been used in a number of applications and had a long safety record. This formula referred to mutagenesis obtained through the use of chemicals or radiation. However, since CRISPR/Cas9 and similar techniques were only developed from 2012 onwards, they neither had a long safety record nor were they, at the time of adoption of

1 CRISPR is the acronym for Clustered Regulatory Interspaced Short Palindromic Repeats. These are segments of bacterial DNA which, when paired with a specific guide protein such as Cas9, can be used to make targeted cuts in an organism's genome. Cas9 is the acronym of the CRISPR associated protein 9.

2 Gene drives can therefore not be used to fight the corona virus.

3 The microorganism in question belongs to the plasmodium group. It is a parasite and different from a virus.

4 However, on 1 May 2020, the US Environmental Protection Agency authorised a field trial of the genetically modified mosquito Aedes aegypti in Florida by the private company Oxitec; that mosquito transmits zika, dengue and other diseases. The specimens approved for release only produce male offspring, so that the mosquito population will decrease.

5 For example, Megan Scudellari: *Self-destructing mosquitoes and sterilized rodents.* Nature 2019, no. 571 of 9 July 2019, p. 160, reports an attempt to genetically modify the gene of a mouse, in order to generate white fur, undertaken at the University of San Diego (California). For unknown reasons, the white fur was generated only with 72 per cent of the mice and only with female mice.

6 There are about 3,500 different mosquito species. Malaria is transmitted by the Anopheles mosquito, of which some 400 different species exist. About 50 transfer the malaria parasite, among them Anopheles gambiae, Anophels stephensi, Anopheles culifacies, Anopheles falciparum and Anopheles vivax. Malaria is only transmitted by female mosquitoes.

7 Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, OJ 2001, L 106, p. 1, as last amended by Commission Directive 2018/350, OJ 2018, L 67, p. 30.

8 *Ibidem*, Article 3 and Annex I B.

9 CJEU, case C-528/16, *Confédération paysanne and others*, ECLI:EU:C:2018:583.

10 Directive 2001/18, recital 17: "*This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have along safety record*".

Directive 2001/18 – 2001 – used in a number of applications. Therefore, they fell into the field of application of the directive[11].

Directive 2001/18 required Member States to apply, with regard to the release of GMOs, the precautionary principle and make sure that *all* measures were taken to "*avoid adverse effects on human health or the environment*" from the deliberate release of GMOs. Any release had to be authorised and an authorisation could only be granted when the provisions of the Directive were respected (Article 4) and, in particular, an environmental risk assessment had been performed. These provisions were further explained in the recitals of the Directive: living organisms, explained recital 4 "*may reproduce in the environment*"; the "*effects of such releases on the environment may be irreversible*". It was therefore necessary to apply the prevention principle (recital 6).

In light of these statements, the requirement that "*all appropriate measures are taken to avoid adverse effects on human health and the environment*" (Article 4) showed its full meaning. The objective of the Directive was to prevent genetically modified organisms which could provoke an adverse effect in the environment from being released[12]. Member States were not allowed to take compensatory measures once such an adverse effect had been caused, but had rather to intervene beforehand to "*avoid*" adverse effects. The Directive was thus quite demanding in its requirement not to cause adverse effects to humans or the environment.

Annex II to the Directive further elaborated on what should be understood as "*adverse effects*"[13]: any spread of GMOs into the environment was, according to that provision, an adverse effect which had to be avoided. This is consistent with the general objective of the Directive which intended to allow, under strictly supervised conditions, the release of genetically modified plants – and at a later stage perhaps of animals – Into the environment, in order to increase or improve agricultural production; however, it intended to avoid the possibility of genetically modified plants from crossing with wild relatives in the environment and thus producing genetically modified wild organisms. For this reason, the environmental risk assessment required by the Directive before any authorisation for a release could be given, had explicitly required comparing the effects of the GMO with those of a non-modified organism[14].

In particular, scientists oppose this understanding of the Directive. They do not consider the spread of a GMO in the environment to be an adverse effect *per se*. According to their understanding, any possible effects of a gene drive have to be addressed by the management measures preventing negative effects of the spread of GMOs (the gene drive activity) on humans and the environment.

In this author's opinion, the spread of GMO(s) in the environment via gene drive activities is an adverse effect *per se:* Directive 2001/18 was established in order to regulate genetically modified crop plants and animals which typically do not spread on their own in the environment. It carefully differentiates between "*deliberate releasing*" and "*spreading*". The deliberate release constitutes a controlled dissemination of the GMO plant or animal; its risk assessment has to carefully examine whether there are wild relatives of the plant or animal in Europe with which a crossing could occur, and asks Member States and the EU to avoid "*any*" such risk or crossing, using preventive and precautionary measures to reach this result. In contrast, the "*spreading*" could lead to such a crossing with wild relatives and produce potentially irreversible effects. Calling gene drives anything else than "*adverse effects*" which have to be "*avoided*", is not in conformity with Annex II C.3.1.d. Therefore, the wording and the general objective of Directive 2001/18 does not support the opinion of scientists according to which gene drive activities are neutral and only subject to management measures under Directive 2001/18.

The conclusion is thus that Directive 2001/18 considers the spread of GMOs in the environment to be an adverse effect which it intended to avoid. It follows from this that any gene drive which was generated using CRISPR/Cas9 or similar techniques is incompatible with the Directive. Gene drive field trials and releases into the EU environment are prohibited.

3 Gene drives – a global problem

The genetic modified animals and plants do not stop at national frontiers. Therefore, the gene drive problem is a global problem. And the problem is not limited to mosquitoes: A recent publication enumerated more than 30 different species for which gene drives applications were at present under different stages of development[15].

[11] CJEU (*supra* note 9): "*Article 3 of Directive 2001/18 read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are exempted from the scope of application of that directive*".

[12] This requirement that any spread in the environment is an adverse effect and must be assessed also follows from the requirements that "*potential adverse effects must not be discounted on the basis that they are unlikely to occur*" (Annex II, C.3.1.(b) and that the "*magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur*" (Annex II C.3.2).

[13] Directive 2001/18 (*supra* note 7) in the version of Commission Directive 2018/350, OJ 2018, L 67, p. 30, Annex II, C.3.1.d: "*Adverse effects may occur directly or indirectly through exposure pathways or other mechanisms which may include: - the spread of the GMOs in the environment, ...*"

[14] *Ibidem*: "*A comparison of the characteristics of the GMO(s) with those of the non-modified organism… will assist in identifying the potential adverse effects arising from the genetic modification*".

[15] R. Steinbrecher a.o.: *Potential applications and risks*, pp. 72ss. in: Critical Scientists of Switzerland (CSS) - Ecological Network for Social and Environmental Responsibility (ENSSER) - Vereinigung Deutscher

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The question is thus what approach the EU should take at international level with regard to the allowing of gene drives. Pleading for a total ban of gene drives, as in the EU, does not appear to be a solution. This follows from considerations concerning the reason why gene drives are researched and studied. There are in particular three main objectives for using gene drives discussed in the scientific literature.

(1) Gene drives could help in diminishing vector-transmitted diseases.

Such diseases include, next to malaria, the dengue fever, zika, chikungunya and numerous other diseases for which medical treatment, including vaccination, is not available, too expensive or not effective for other reasons. The World Health Organisation (WHO) estimated the number of vector-borne mortalities at 700,000 per year[16]; the overall economic losses have not yet been estimated, but are immense; illness, treatment and premature deaths alone are estimated to generate costs of about 12 billion dollars per year. The main vectors are mosquitoes, followed by sandflies, blackflies, bugs, ticks and snails.

(2) Gene drives could diminish or extinguish invasive species, such as mice or rats on islands which constitute a risk to the local fauna or flora.

For example, in New Zealand there is a discussion regarding the use of gene drives for pest control for some forms of wasps, rats, or weasels in order to rid New Zealand of such invasive species by 2050[17]. For smaller islands within a country, such as Nantucket and Martha's Vineyard (USA), private initiatives are also reported to exist.

(3) Gene drives could support agricultural production by reducing the presence of pest organisms, such as fruit flies, moths or weeds, which damage the production.

Damage to agricultural production is considerable. In the USA, the annual loss in agriculture due to invasive species alone was estimated at 120 billion dollars per year[18]. The European Commission estimated that invasive species cause economic damage in the EU of 12 billion euro per year[19]. In New Zealand the annual economic loss caused by two invasive wasp species, is estimated at 133 million dollars[20].

A fourth reason to develop gene drives is not too loudly discussed, but needs to be mentioned. This is the use of gene drives for military purposes (bioweapons), including (state-sponsored or other) terrorist purposes. The United States Department of Defense[21] is very actively engaged in the research of gene drives. This is, however, only the most transparent information which is publicly available. There is no doubt that other powers such as China or Russia are also conducting research in this area. Even smaller countries are very likely to be active in this research, as it is relatively cheap.

As this rough overview already shows, considerations to use gene drive are not limited to Europe, but are discussed globally, in particular in the United States, Australia, New Zealand and Africa. Therefore, the following questions raised by the laboratory research and release into the wild of gene drives need to be answered at global level. These questions include, but are not limited to:

– Is it ethically responsible to release genetically modified animals or plants into the environment, thereby practically creating 'new' or definitely extinguishing species? The 'egg-laying woolly milk-sow' is just one extreme, populist example, but the global extinction of species – the malaria-transmitting mosquito for example – or the elimination of certain weeds or the fruit fly are more likely possibilities.
– Who decides such questions? Who has to be consulted and to agree? As gene drives may affect the entire global population of a plant or an animal and as the effects may be irreversible, would there have to be a global consensus? What happens if such a consensus is not reached? Who would oversee whether the consensus is respected? With the risk of a gene drive having effects worldwide, should European countries co-decide whether gene drives to eliminate malaria in Africa should be allowed, or is this a decision for African countries only? Would the slow increase of malaria cases in Southern Europe[22], also due to rising temperatures, at least entitle Southern European countries to

Wissenschaftler (VDW) (eds): *Gene drives. A report on their science, applications, social aspects, ethics and regulations*. Bern - Berlin 2019. The species mentioned were: Anopheles gambiae, Anopheles stephensi, Aedes aegypti, Cules quinquefasciatus (all these are mosquito species), common fruit fly, spotted wing fruit fly, Mediterranean fruit fly, Asian citrus psyllid, Kissing bug, Australian sheep blowfly, flour beetle, common wasp, German wasp, Argentine stem weavil, house mouse, white footed mouse, brown rat, wild cat & feral cat, brushtail possum, common rat, stoats, lionfish, common starling, snail, two species of flatworms and five species of nematodes, brewers' yeast and candida albican.

16 WHO, *Global burden of major vector-borne diseases* 2017, cf. who.int/vector-control/burden_vector_borne_diseases.pdf?2ua=1 (accessed 8 May 2020).

17 New Zealand Government: *Accelerating predator free New Zealand. A Cabinet Paper*. Wellington 2016; Sustainability Council of New Zealand: *A constitutional moment. Gene drive and international governance*. 2018, pp.61ss; Royal Society Te Apárangi: *The use of gene editing to create gene drives for pest controls in* New *Zealand*. Wellington 2017. A private movement, "Predator-free 20502 is active in New Zealand, promoting, among others the use of gene drives.

18 US Department of Agriculture: *Economic and social impacts of invasive species*, 2005. invasivespeciesinfo.gov/subjects/economic-and-social-impacts.

19 Commission COM (2008) 789, p. 2

20 Royal Society Te Apárangi: *Gene editing: scenarios in pest control*. Wellington 2019, p. 11.

21 US Defense Advanced Research Projects Agency (Darpa); Advanced Research Projects Activities (IARPA). See also National Academy of Science, Engineering US Intelligence and Medicine (NASEM): *Gene drives on the horizon: advancing science, navigating uncertainties and aligning research with public values*. Washington 2016, pp. 159ss.

22 See E.T. Piperaki - G.L. Daikos: *Malaria in Europe: emerging threat or minor nuisance*? Clinical Microbiology and Infection 2016, p. 487.

participate in the decision-making process in Africa?

- Who decides whether the laboratory research is sufficiently advanced to proceed to a release of gene drives? Who decides whether the precautionary approach or principle is sufficiently safeguarded[23]? Who decides whether the management measures in place are sufficient to prevent the escape of a genetically modified organism, a chain reaction in the natural environment or impacts on other organisms or humans?

A very comprehensive study by the US National Academy of Science, Engineering and Medicine (NASEM) of 2016 concluded: "*There is insufficient evidence available at this time to support the release of gene drive modified organisms into the environment. However, the potential benefits of gene drives for basic and applied research are significant and justify proceeding with laboratory research and highly controlled field trials*". Who will decide whether the NASEM struck the right balance between the benefits and disadvantages of gene drives, whether the benefits of a release in the USA were well weighed up against the disadvantages in other countries or regions, whether there is enough evidence available to allow releases, whether the controls are strict enough?

4 The negotiations within the Convention on Biodiversity

Internationally, the discussions are, to a good part, concentrated within the Convention on Biological Diversity (CBD) and its two protocols, the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing[24]. The EU has ratified the CBD and the Protocols.

Within the CBD, the discussion on gene drives is organised under the heading of "*synthetic biology*", which was the subject of discussions at the 14th meeting of the Parties in 2018. In preparation for this meeting, the EU Council adopted conclusions, where it stated[25]: *"(The Council) (R)eaffirms that in dealing with organisms, compounds and products of synthetic biology, and in particular organisms containing engineered gene drives, the precautionary approach as described in the preamble of the Convention should be applied; in this context reconfirms that there could be potential adverse impacts on biodiversity arising from such organisms".*

The 14th Meeting of the Parties of the CBD was confronted with a suggestion, supported in particular by environmental organisations, to provide for a moratorium on gene drive releases. During the meeting, several countries pleaded in favour of such a moratorium, others against it. The Organisation of African Union (OAU) which had discussed the issue, in particular in view of the fight against malaria, had not formally adopted a position, but had left it to its Member States to decide on their position. According to media reports, 50 out of the 55 Member States of the OAU were opposed to a moratorium[26].

The Conference of the Parties of the CBD adopted a Decision which did not include the suggestion for a moratorium[27]: *"(The Conference of the Parties) calls upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention, and also calls upon Parties and other Governments to only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when (a) scientifically sound case-by-case risk assessments have been carried out; (b) risk management measures are in place to avoid or minimise potential adverse effects, as appropriate; (c) where appropriate, the "prior informed consent", the "free, prior and informed consent" or "approval and involvement" of potentially affected indigenous peoples and local communities is sought and obtained, where applicable in accordance with national circumstances and legislation*". The Conference declared that it might adopt a recommendation at its next meeting and asked one of its committees to prepare a draft text.

The 15th Conference of the Parties, originally scheduled for October 2020 in Kunming (China), was postponed, though, as well as the preparatory meetings for that Conference, due to the Corona Crisis. Preparatory texts have not yet been made available, though the European Parliament called on the Commission and the Member States to push for a global moratorium[28].

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23 The content of the precautionary approach is itself not uncontested. While it is understood in the EU to allow public authorities to, in the absence of full scientific or technical certainty as to the existence or dimension of a risk for human health or the environment, take measures to prevent the realisation of the risk, the precautionary approach is in the USA often perceived as a means to restrict scientific and technical innovation, see e.g. NASEM (*supra* note 21), p. 172.

24 See generally F. Keiper- A. Atanassova: *Regulation of synthetic biology: developments under the Convention on Biological Diversity and its Protocols*. Frontiers in Bioengineering and Biotechnology, 9 April 2020, 8:310.

25 Council conclusions of 9 October 2018, document 12948/18, paragraph 30.

26 There is no official document on the position of the different members of the CBD. According to unofficial sources, Egypt, Morocco, Gabon and Madagascar favoured a moratorium, South Africa, Nigeria and Ghana pleaded in favour of further research and activity. Furthermore, Bolivia and Venezuela were in favour, while New Zealand, Malaysia, India, Indonesia, Argentina, Peru and Switzerland were against a moratorium.

27 Convention on Biological Diversity, Decision 14/19 of 30 November 2018, CBD/COP/14/19.

28 European Parliament, Resolution of 16 January 2020, P9_TA(2020/0015 (2019/2824(RSP)), paragraph 13: *"(The European Parliament) calls on the Commission and the Member States to call for a global moratorium at the COP 15 on releases of gene drive organisms into nature, including field trials, in order to prevent these new technologies from being released prematurely and to uphold the precautionary principle, which is enshrined in the Treaty on the Functioning of the European Union as well as the CBD*".

The wording of Decision 14/19 clearly indicates that the Conference of the Parties made an appeal to apply the precautionary approach[29] and to be transparent, but did not intend to impose this. Anyway, decisions and recommendations by the CBD are not binding on the parties[30] and even less on Non-Parties[31] and private organisations[32].

A Swiss-German study on gene drives of 2019 stated that there was "*an urgent need for effective international and legally binding regulation of gene drive organisms*"[33]. However, such a legally binding international agreement on gene drives is not realistic. Indeed, neither the CBD Secretariat nor, as far as can be seen, the EU or any country[34] has until now suggested developing an international agreement on gene drives. The interests of countries and of private companies and organisations rather go in the direction of allowing gene drive releases into the wild. In particular, the USA, the country where most of the gene drive research takes place, is opposed to international commitments, in particular in the environmental sector. The USA did not only refuse to adhere to the Biodiversity Convention and its protocols; it also did not ratify a considerable number of other environmental agreements[35]. And it is doubtful whether an international agreement on gene drives without the USA participating would be very effective, all the more as China, Russia, India, African countries, Indonesia, United Kingdom, Australia and New Zealand might also hesitate to commit to a binding agreement.

5 Final remark: The likely development within the next decade

The numerous unanswered questions mentioned above clearly demonstrate that it is premature to allow, anywhere, gene drive releases into the natural environment. The risk that the natural environment would be irreversibly impaired, is simply too high. An international moratorium for several years would thus be reasonable, though it is not clear how it could be enforced. And the international development which already rejected a moratorium in 2018 appears to go into another direction[36]. The prohibition of releasing gene drives into the wild, which exists within the EU, is therefore very likely to be bypassed by those international developments. The discussions on gene drives within the Convention on Biodiversity will probably lead to recommendations to apply a precautionary approach for the release of gene drives, to ensure that risk assessment and risk management measures are taken and that affected communities agree to such releases. Releases are likely to address mosquitoes first, in order to combat malaria or other tropical diseases transmitted by mosquitoes. The economic pressure will then lead, in a next step, to allowing gene drives in order to support agricultural production and, progressively, improving the fight against invasive alien species.

Decisions on releases of gene drives will be taken by States. Their agreement and that of the affected population will be asked for, often encouraged by financial promises. Though there is a general agreement that the effects of a gene drive release might be global, there will most probably not be a body under the CBD or created ad hoc to decide on gene drive releases. Also the consent of the affected population will not be a serious condition: for example, the agreement of the EU population is unlikely to be sought when a gene drive release in Africa is planned, even though individual genetically modified specimens might reach Europe and affect the species living there. As there is no monitoring body in function or planned, the information on plans to release gene drive, the agreements, compliance with the provisions on responsible scientific and technical measures will be difficult to obtain and verify. Of course, no ex-post monitoring is foreseen.

As regards the EU, the pressure from the agricultural sector to permit gene drives in order to fight pest animals or plants and to repair competitive disadvantages with regard to imports from countries where gene drives are permitted are likely to lead to an amendment of EU law and to the authorisation of gene drives within the next decade.

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29 The different terminology ('precautionary principle' and 'precautionary approach') has its origin in the 1992 UN Conference on Environment and Development in Rio, where the USA refused to accept the use of the term 'precautionary principle', arguing that such a principle did not exist in public international (environmental) law.

30 See generally on this problem T. Staal, *Authority and legitimacy of environmental post-Treaty rules*. Oxford etc, 2019.

31 The CBD has at present 196 Parties, among them the EU and its 27 Member States. The USA and the Holy See are not Party. The USA does however participate in the meetings of the CBD.

32 A number of private organisations, such as the Bill-Gates-Foundation or an organisation called "Target Malaria" have the objective to eradicate malaria, including with the help of gene drives.

33 CSS - ENSSER - VDW (*supra* note 15), p. 14. The 338-page report summarised well the different problems raised by gene drives and their application. It concluded (p. 12): "*we can still say very little about what will happen with gene drives in actual real-life settings, with completely different surrounding conditions, high genetic variation in wild populations and myriad interactions with other species and complexities. The behaviour of gene drives and gene drive organisms in the real world may be very different from any laboratory experiment and modelled projection*", and pleaded for the use of alternative methods, such as the development of vaccines.

34 See the Council Resolution, *supra* note 25. The Commission could, of course, develop a draft international agreement on gene drives, try to obtain a Council mandate according to Article 218(3) TFEU to submit the draft to the CBD and thus initiate international negotiations. However, the Commission itself pursues, in general, a pro-biotech policy and does not appear to think of such an initiative.

35 These conventions include the Stockholm Convention on persistent organic pollutants, the Basel Convention on the transfer of waste, and the Aarhus Convention on access to information and to justice as well as the participation in decision-making in environmental matters, to name just a few agreements.

36 See also the USA decision mentioned *supra* in note in 4.

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The institute's activities are organized in Divisions - Chemistry, Energy & Climate Protection, Genetic Engineering, Sustainable Products & Material Flows, Nuclear Engineering & Plant Safety, and Environmental Law.

The Environmental Law Division of the Öko-Institut:
The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

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I·E·S·A·R
Institute for Environmental Studies and Applied Research
FH Bingen

The University of Applied Sciences in Bingen was founded in 1897. It is a practiceorientated academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

The *Institute for Environmental Studies and Applied Research* (I.E.S.A.R.) was founded in 2003 as an integrated institution of the University of Applied Sciences of Bingen. I.E.S.A.R carries out applied research projects and advisory services mainly in the areas of environmental law and economy, environmental management and international cooperation for development at the University of Applied Sciences and presents itself as an interdisciplinary institution.

The Institute fulfils its assignments particularly by:
- Undertaking projects in develop-ing countries
- Realization of seminars in the areas of environment and development
- Research for European Institutions
- Advisory service for companies and know-how-transfer

Main areas of research

- **European environmental policy**
  - Research on implementation of European law
  - Effectiveness of legal and economic instruments
  - European governance
- **Environmental advice in developing countries**
  - Advice for legislation and institution development
  - Know-how-transfer
- **Companies and environment**
  - Environmental management
  - Risk management

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sofia

The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.
The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.
The sofia team is multidisciplinary: Lawyers and economists are collaborating with engineers as well as social and natural scientists. The theoretical basis is the interdisciplinary behaviour model of homo oeconomicus institutionalis, considering the formal (e.g. laws and contracts) and informal (e.g. rules of fairness) institutional context of individual behaviour.

The areas of research cover
- Product policy/REACh
- Land use strategies
- Role of standardization bodies
- Biodiversity and nature conversation
- Water and energy management
- Electronic public participation
- Economic opportunities deriving from environmental legislation
- Self responsibility

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- VolkswagenStiftung
- German Federal Ministry of Education and Research
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- German Federal Environmental Agency (UBA)
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- Federal Ministry of Consumer Protection, Food and Agriculture

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