Genetically engineering wild species

Protection or destruction of nature?

EVENT REPORT

This event aimed to provide space to discuss if the European Parliament should or shouldn't rely on genetically engineered gene drives as part of the EU Biodiversity Strategy to address the current biodiversity crisis.

The event took place on 8.12.2020 and was hosted by:

The rapporteur *César Luena Lopez* (S&D) **& shadow rapporteurs** *Ville Niinistö* (Greens/EFA); *Soraya Rodriguez Ramos* (Renew Europe); *Alexander Bernhuber* (EPP); *Nikolaj Villumsen* (GUE/NGL) **of the European Parliament's own initiative report on the EU biodiversity strategy**

Background

An emerging scientific field called **'synthetic biology'** is exploring the genetic engineering of wild species as a means to protect biodiversity. Some scientists and conservationists see the need for 'new innovative tools' for nature conservation and suggest the use of genetic engineering of wild species as a *'nature based solution'* to halt biodiversity loss. They are for example promoting the use of a technology, called Gene Drive to remove invasive alien species from islands. Others warn however that this technology could instead harm ecosystems and further accelerate biodiversity loss.

While the European Parliament[1] - from a precautionary perspective - in January 2020 called for the adoption of a global moratorium on first environmental field trials with gene drive technology, a principled political & societal debate around synthetic biology for nature conservation and its governance on EU level is still outstanding. Similar position-finding and regulatory processes currently take place in international fora such as the IUCN and the UN Convention on Biological Diversity.

What are gene drive organisms?

Gene drive organisms (GDOs) are genetically modified organisms (GMOs) carrying specially constructed genetic material that is capable of overriding the normal rules of inheritance. When these organisms reproduce, selected traits are passed on to the offspring at a much higher rate than would normally occur.

The term 'gene drive' can have different meanings, including:

1. a method used to increase the inheritance of specific genes or traits;
2. the modified genetic material within a GDO that causes such altered inheritance, and is itself passed on at an artificially high rate.

Gene drive organisms could be used to rapidly alter the genetic make-up of wild populations, with the aim of either changing certain characteristics, collapsing these populations, or even eradicating an entire species. All of these possibilities would have the potential to irreversibly alter ecosystems and adversely impact biodiversity.[2]

How does a gene drive work?

Gene drives distort normal patterns of inheritance. Normally, we receive 1 of 2 copies of a given gene from either parent, with a 50:50 chance of each copy being passed on.

Gene drive systems distort that rule, promoting the inheritance of a particular copy of a gene from the parent to offspring. (a) CRISPR[3]-based gene drive systems cut the equivalent allele on the wild-type chromosome, causing the cell to copy them via homology-directed repair. (b) Converting heterozygotes to homozygotes in the germline guarantees inheritance, enabling rapid spread through populations.

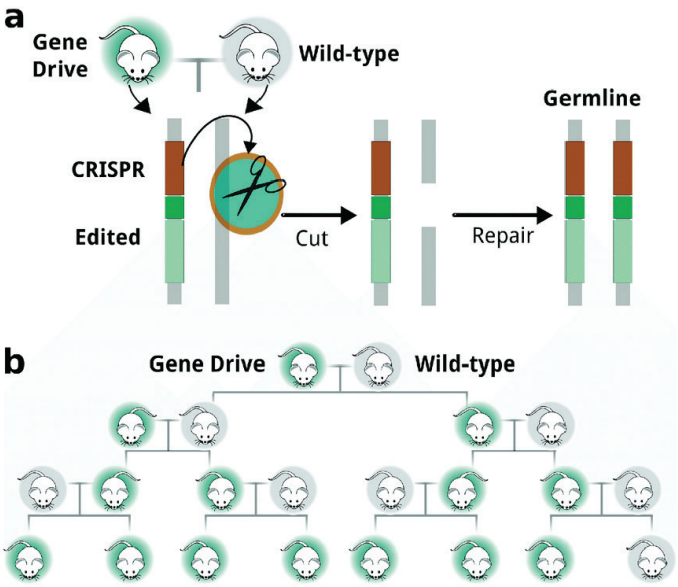
This distortion in and of itself is relatively harmless, but when coupled to a genetic trait that affects an individual's survival or ability to reproduce, it becomes a powerful tool that can be used for population control or even local elimination.[4]

[1] European Parliament resolution of 16 January 2020 on the 15th meeting of the Conference of Parties (COP15) to the Convention on Biological Diversity. P9_TA(2020)0015

[2] ENSSER/CSS/VDW (2021). **Genetically engineered gene drives: IUCN report on Synthetic Biology lacks balance.** A critique of the IUCN report 'Genetic Frontiers of Conservation: An assessment of synthetic biology and biodiversity conservation' – with regards to its assessment of gene drives. - 2-page summary - https://genedrives.ch/new-publications/

[3] CRISPR: Clustered Regularly Interspaced Short Palindromic Repeats.

Figure: [4] Conservation demands safe gene drive - Scientific Figure on ResearchGate.



Speakers

Dr. Kevin Esvelt

Dr. Kevin M. Esvelt is an assistant professor of the MIT Media Lab, in Cambridge, USA, where he leads the Sculpting Evolution Group in exploring evolutionary and ecological engineering. He helped pioneer the development of CRISPR, a powerful new method of genome engineering. In 2013, Esvelt was the first to identify the potential for CRISPR "gene drive" systems to alter wild populations of organisms and is a patent holder on this technology.

On the topic of gene drives for conservation he co-authored this article: ***"Conservation demands safe gene drive"***

View Biography

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Birgit Winkel

Birgit Winkel is a biologist specialized in microbiology, biochemistry and ecology. In 2017 she started working at the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety with the focus on GMO regulation and research concerning the environmental risk assessment for the deliberate release of GMO.

She is also responsible for the coordination of the German position on Synthetic Biology in international negotiations, namely the CBD and the IUCN. During the German EU Presidency in 2020 she served as the co-lead-author for the orientation lines on Synthetic Biology for SBSTTA 24 for the EU and its member states.

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Dr. Kent Redford

Dr. Kent H. Redfort is Principal at Archipelago Consulting established in 2012 and based in Portland, Maine, USA. Before that he spent 14 years in the conservation NGO world and 10 years as a professor at the University of Florida.

He also worked at the intersection of conservation and synthetic biology for 7 years and currently serves as Chair of IUCN's Task Force on Synthetic Biology and Biodiversity Conservation which published in May 2019 ***"Genetic frontiers for conservation: an assessment of synthetic biology and biodiversity conservation."***

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[4] Esvelt KM, Gemmell NJ (2017) **Conservation demands safe gene drive**. PLoS Biol 15(11).; Figure: Conservation demands safe gene drive - Scientific Figure on ResearchGate. *Available here* [accessed 10 May, 2021]

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Dr. Ricarda Steinbrecher

Dr. Ricarda Steinbrecher is a biologist and molecular geneticist based in Oxford, UK. Her work currently focuses on synthetic biology, new genetic engineering techniques such as CRISPR/Cas9, and gene drive organisms. Dr. Steinbrecher is a member of the Federation of German Scientists (FGS/VDW) whom she represents at international UN negotiations such as the Convention on Biological Diversity (CBD) and its protocols, in which she is involved since 1996.

She [served on the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management of Genetically Modified Organisms (2009-2013) of the CPB and] presently serves on the Technical Expert Group on Synthetic Biology of the CBD. She is both a founding and board member of the European Network of Scientists for Social and Environmental Responsibility (ENSSER) for which she lead authored this publication: ***"Gene Drives: a report on their science, applications, social aspects, ethics and regulation (CSS/ENSSER/VDW 2019)"***

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Dr. Margret Engelhard

Dr. Margret Engelhard is head of Division for GMO-Regulation and Biosafety at the German Federal Agency for Nature Conservation. She is micro- and molecular biologist and has a long scientific vita in synthetic biology and technology assessment research.

She is member of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology of the Convention on Biological Diversity (CBD). She is also a co-author of the report ***"Gene Drive Organisms: Implications for the Environment and Nature Conservation"*** that is endorsed by seven European environmental agencies.

View Biography

Dr. Christopher J. Preston

Dr. Christopher J. Preston is a Professor of Philosophy at the University of Montana in Missoula (USA). He works on the ethics of emerging technologies and issues related to wildlife recovery. He is author of the book: ***"The Synthetic Age: Outdesigning Evolution, Resurrecting Species, and Reengineering Our World"*** (MIT Press 2018). His current writing is on rewilding.

View Biography

Moderation by: Natasha Foote

Journalist for agriculture and health issues

Is the genetic engineering of wild species necessary to address urgent problems such as the global spread of invasive alien species?

Answer by
Dr. Margret Engelhard

"It is not the question, if we only have the possibility to use synthetic biology on exactly this species to save it.
The question really is: Is it an appropriate tool and is it really working and is it really taking us to the more general goals of nature protection?"

Is the genetic engineering of wild species an adequate tool for nature conservation? What are the alternatives?

Answer by
Dr. Kent Redford

"No it is not adequate in the sense that it in and of itself is sufficient."

"By no means do I think that there are technical solutions to the problems that we are in. The solutions will rely on value-based changes, they will rely on the consequent political based changes and economic based changes. And all of that will be required to be able to then use the tools properly for attempts to achieve our biodiversity outcomes."

"If much of our effort were devoted to try and fix agriculture, *both, to provide food but also to stop destroying nature,* **I think we would be doing the best thing we could for the natural world."**

"We heard [...] some comments about **the need to change politics, the need to change values and where there are existing strategies that can be effective. I think those should come before the applications of biotechnology. An area where I think we need to do better is obviously habitat protection.** *It is not working well enough, we haven't done enough of it."*

Answer by
Dr. Christopher Preston

Answer by
Dr. Kevin Esvelt

"I have learned that we really need to be humble when it comes to engineering complex systems. That we can't possibly understand them in their entirety."

"As technologists, we should identify possible options for the smallest possible change that we think may solve the problem [...]" "We should ask the communities [...] and then proceed developing that option."

"I see [those] applications on the level of symptom healing instead of really working on the reasons why we have the [...] degradation of species." "It is not really tackling the problems."

"I am wondering if it really is an alternative."

Answer by
Dr. Margret Engelhard

Answer by
Dr. Ricarda Steinbrecher

"I do not believe that any technology, including this one, is going to help us out *to halt the rapid biodiversity loss and ecosystem decline.* **They cannot save us at all."**

"If we really want to find solutions, we need to understand, what and where the problems are. Just treating symptoms will not bring us any further. Agriculture for example is really at the root of a lot of the problems."

"I feel agriculture needs to change into something that actually is in service of biodiversity, that does not destroy it, but that somehow picks up a functionality to support nature and then nature and the environment will support agriculture as well. Like agri-ecological systems are a big example for that."

"Ecosystem-based approach is a common terminology. It is valuable as guidance for selecting the right approach to solve problems."

"A discussion on the engineering of wild species and it's implications for nature protection has only just begun, thanks to the IUCN."

"The opinions among EU Member states on gene drive organism differ: One part calls for a case-by-case regulation. Another part is of the opinion, that according to the precautionary principle, gene drive organisms should not be released before certain concerns are addressed."

Answer by
Birgit Winkel

Q *Which impacts and risks do we have to consider?*

Answer by
Dr. Kent Redford

"There has been little consideration of the impacts of synthetic biology on biodiversity. As a result [...] in 2016 at the IUCN World Conservation Congress, IUCN members passed resolution 086 asking the IUCN to undertake an assessment [...]."

"One of the things that the assessment emphasizes is that **it is important to look at the applications intended for conservation benefits,** *such as the removal of invasive species.* **But it is as important to look at applications not intended for conservation benefits but with potential implications for achieving conservation outcomes."**

"We really agree with EFSA that there's a number of open questions, concerned with environmental risk assessment and management and that we will have further elaboration to work on it."

"We have the problem that we don't know how to compare it because we haven't had something like this before."

"We have a full bundle of societal questions that we have to newly think about"

"We also have legal challenges for example, when we change a protected species - is it still something that we want to protect?" "Do we cross the line when we genetically engineer protected species?" "Is that still going along with our concept of nature?"

"We think that a technology assessment approach would be the right approach to also tackle the question that goes beyond the mere risk assessment."

Answer by
Dr. Margret Engelhard

Answer by
Dr. Kevin Esvelt

"The challenge is that we don't know what the ecological effects are going to be until we actually try in some region of the wild."

"You cannot test the version that you believe will spread indefinitely. So, I do not support calls to say: find an isolated island and try the full power gene drive there, I think that is a terrible idea. I think history shows that people will move it and it might hitchhike on its own, in the case of rats, obviously they stole away on ships on their own, so **I don't advocate using that form of technology in field trials and if you cannot use it in field trials you can't even test it."**

"Since we are talking about technologies that could shape species or at least local populations of species, we should only consider those versions of gene drive that might be appropriate for the application in question. And that in term determines who will be impacted and therefore who must have a seat at the table."

"I want us to focus on the aspect of unpredictabilities and novel risks with regards to gene drive organisms."

"We find that with CRISPR-based gene drives, there is resistance building up that will stop the drive from working. *A lot of research is focused on this at the moment to overcome that problem. The one possible solution found is to use sequences of highly conserved essential genes as target sequences for the gene drive. Unfortunately these highly conserved sequences often will be shared with other close relatives and then* **gene drives can actually move to other species. We need to consider that as well."**

Answer by
Dr. Ricarda Steinbrecher

Would it be morally acceptable and ethically justifiable to genetically engineer wild species?

Answer by
Dr. Christopher Preston

"When we think of the ethics of an emerging technology we tend to think immediately of the benefits and harms it might bring. But benefits and harms are not everything an ethicist considers when determining right and wrong for a new technologies."

"The question someone concerned about a synthetic age must ask is whether the technology might destroy the very thing it had set out to save."

"There are questions about the consent of those who might live in a gene driven world, especially indigenous people and future generations. Or questions of power: who gets to develop and deploy the technology? There are questions about the social relations a particular technology might create or destroy. There are even epistemic questions about what vision to take towards the biological world. Is it life or machine? A complex hole or a set of changeable parts?"

"These difficult debates cannot be settled by visiting experts only but by stakeholders and affected publics through transparent, open and informed deliberation."

Where does the EU currently stand when it comes to regulating gene drives?

"Genetically engineered gene drives are seen as GMO, so they are regulated under the current directive 2001/18/EC."

"EFSA was asked by the Commission to identify or to assess if existent guidance from EFSA is enough for risk assessment and they found that it could be a good basis but there are some things that need to be considered more..., so they need an adaptation"

"There are no gene drives at the moment in the pipeline to be released in Europe and I don't think that will be happening in the next years at all."

Answer by
Birgit Winkel

Introductory remarks by:

MEP Cesar Luena Lopez, S&D

'While proponents of synthetic biology advocate for its use in wildlife to remove invasive alien species from threatened ecosystems, others warn that it is an uncontrollable and irreversible **"genetic chain reaction"** that, once tested or deployed in the wild, could not only permanently damage ecosystems and further accelerate biodiversity loss, but also have important implications for humanity's relationship with the natural world. The truth is that gene drives present a genetic, ethical, environmental, and in some cases, medical dilemma."

"There is also a regulatory gap. The United Nations Convention on Biological Diversity, with its Cartagena Protocol on Biosafety, is the appropriate forum to develop and agree on globally binding rules. However, to date, this new technology lacks specific and binding regulation at the national, EU and international levels, as existing regulations on genetically modified organisms (GMOs) are insufficient to address gene drive technologies." "There is no assessment of this technology to determine its suitability. No methods have been developed to assess the risks, nor is there a specific, legally enforceable agreement on liability and redress."

"In light of this situation, and despite the promising potential applications, the European Parliament in January (2020) called for the adoption of a global moratorium on the first environmental field trials of gene drives as a precautionary measure."

"However, a fundamental political and societal debate on synthetic biology for conservation and its governance at the EU level has yet to take place. Therefore, with this interactive online roundtable, we want to learn about and discuss the promises and dangers, ethical issues, state of the science, assessment and regulation of gene drive in the context of proposals for the use of synthetic biology for nature conservation." "Only in this way can we lay the groundwork for a broad political and societal debate that will enable us to make responsible and precautionary decisions about this new and controversial technology in the EU."

Input by

Dr. Christopher Preston - on ethical considerations regarding gene drive technology & synthetic biology

"When we think of the ethics of an emerging technology we tend to think immediately of the benefits and harms it might bring."

"In conservation, the promise of eradicating invasive rodents, neutralizing disease vectors, enhancing genetic diversity in rare species, improving crop harvest, creating heat resistant corals are all enticing benefits associated with different genetic technologies. On the other hand impacting non-target species creating unexpected resistance in organisms, disrupting an ecosystem's balance or using up slender research funds are all potential harms."

"Looking impartially at the balance between the likely benefits and the risk of harms, is a key task for an ethicist."

"But benefits and harms are not everything an ethicist considers when determining right and wrong for new technologies. Think about why we don't clone people, or why we encouraged democracy and consent or why we seek to preserve biodiversity in the first place. There's something more at stake in these cases than simply a benefit or a harm. If you want to be suitably broad about the ethics of genes drives you have to take the discussion beyond risks and benefits."

"I used the term of the synthetic age to characterize the future synthetic biology and gene drives might create. In a synthetic age some of the world's deepest biological processes are set aside to create a world shaped more and more by human design."

"A world that is found is replaced by a world that is made. Genetic engineering takes up the task of shaping the future of nature."

"Using a gene drive to reshape parts of the world that previously lived wild and free cuts the very root of what nature, the world outside of human design, is supposed to be."

"The question someone concerned about a synthetic age must ask is whether technology might destroy the very thing it had set out to save."

"There are questions about the consent of those who might live in a gene driven world, especially indigenous people and future generations. Or questions of power: who gets to develop and deploy the technology? There are questions about the social relations a particular technology might create or destroy. There are even epistemic questions about what vision to take towards the biological world. Is it life or machine? A complex hole or a set of changeable parts?"

"These difficult debates cannot be settled by visiting experts only but by stakeholders and affected publics through transparent, open and informed deliberation."

Q

Question by
MEP Rodriguez Ramos, Renew Europe

"How do we create a dialogue between conservationists and initiators of this new genetic engineering/synthetic biology to bring the ethical and moral issues to the forefront of evaluating this new technology?"

"I think the conversation should be broad in terms of what ethical concerns are brought to the table. It should also be broad in terms of who is allowed to sit at the table."

Answer by
Dr. Christopher Preston

[5] The quotes presented in this report represent a shortened and condensed version of the recorded utterings at the event. This has been done with the aim of extracting key messages and to improve legibility. In certain instances, sentences have been remodelled in their structure by the editor to improve understanding for the reader. The content was left unchanged.

Input by

Dr. Kent Redford - on the state of assessment of synthetic biology (including gene drive technology) for biodiversity conservation within the IUCN

View Presentation

"There has been little consideration of the impacts of synthetic biology on biodiversity. As a result of this lack of consideration in 2016 at the IUCN World Conservation Congress, IUCN members passed resolution 086 asking the IUCN to undertake an assessment and to propose a policy on the intersection between synthetic biology and conservation. Gene drives are considered as one of the synthetic biology applications."

"IUCN assembled a task force." "This task force [...] prepared and published the technical assessment which was released in May 2019."

"One of the things that the assessment emphasizes is that it is important to look at the applications intended for conservation benefits, such as the removal of invasive species. But it is as important to look at applications not intended for conservation benefits but with potential implications for achieving conservation outcomes."

"This document then, the technical assessment, was used as the basis for preparing a draft IUCN board motion which was published and made available for comment."

"This motion [...] was to have been voted on in June of 2020 at the IUCN World Conservation Congress in Marseille. The congress was not held and this motion was one of nineteen [...] which was not placed to be available for online voting. And so [...] our resolution is going to have to wait until IUCN holds a meeting or develops an alternate way of being able to assess this. The reason that it and the other nineteen were held was that there were so much comment and concern, supportive and negative, from the membership that it could not easily be resolved. And that leaves us where we are now, in a holding position."

Q

Question by
MEP Nikolaj Villumsen (GUE/NGL)

"What would justify the use of synthetic biology and especially gene drives for nature conservation?"

"IUCN has not taken a position on this [...] I can answer the question for myself, but not speaking for the IUCN." "We are not achieving biodiversity objectives, so the current set of tools in the way they are being applied and the funding that is made available is not allowing us to achieve our goals. And not achieving them results in an increasing loss of biodiversity. So there is a need to consider all potential tools to see whether or not we can put ourselves in a situation of being able to preserve nature."

Answer by
Dr. Kent Redford

Q

Question by **moderator Natasha Foote to Dr. Kent Redford**

"There has been criticism around the choice of allegedly biased authors, with conflicts of interest regarding the IUCN report, I just wanted to hear how you would respond to those criticisms."

"I think more pointedly that the criticism was an attempt to get the audience for the assessment not to read it but rather to attack the process and thereby say that the product was illegitimate which is the word that was used. IUCN officially through its president and acting director general, wrote a letter endorsing the effort. I will stand by it [...]"

Answer by **Dr. Kent Redford**

Q

Question by **moderator Natasha Foote to Dr. Ricarda Steinbrecher**

"There has been a lot of criticism both by civil society organizations and IUCN members alike regarding the IUCN assessment report. I just wondered how you responded to that criticism and whether you share that criticism."

"The IUCN assessment report really does not explore the risks at all. The authors for example have not mentioned gene drives in agricultural settings despite the fact that a lot of gene drive research is meant for agricultural pests, and the risk that such releases entail."

"But mostly what I found problematic is that there was the notion that we supposedly can deal with the risks simply by risk management, the notion that risks can actually be predicted and that it is going to be safe."

Answer by **Dr. Ricarda Steinbrecher**

Q

Question by **moderator Natasha Foote to Dr. Kent Redford**

"You said that we are not archiving our biodiversity objectives [...]. Why not? Are the reasons not more political than technological and shouldn't we explore political avenues?"

"By no means do I think that there are technical solutions to the problems that we are in. The solutions will rely on a value-based changes, they will rely on the consequent political based changes and economic based changes. And all of that will be required to be able to then use the tools properly for attempts to achieve our biodiversity outcomes."

Answer by **Dr. Kent Redford**

Input by

Dr. Kevin Esvelt - on gene drives for conservation purposes

View Presentation

"If some people say, I'm the inventor of gene drive technology, that is definitely false. Evolution made gene drive, it's ubiquitous throughout species. It operates through many many different forms."

"What is different now is that we have tools such as CRISPR."

"In 2014, my colleagues and I decided that we needed to tell the world that we believed that this technology was possible in order to initiate these kinds of discussions about the possibility of future applications." "We were very concerned with ensuring that there is adequate regulation, that there is discussion with a wide variety of communities who might be interested in the technology for various reasons, that it cannot be misused and that it can be appropriately localized, because again, there is many different forms of gene drive."

"Since we are talking about technologies that could shape species or at least local populations of species, we should only consider those versions of gene drive that might be appropriate for the application in question. And that in term determines who will be impacted and therefore who must have a seat at the table."

"It is worth pointing out that as of now gene drive technology is completely non-profit and as the author of many patents held by universities I worked hard to ensure that intellectual property is a barrier that prevents the commercialization of this technology for the time being. We want to allow enough time in particular for the public health applications to go first, before it gets swept up into controversies over the commercialization of biotechnology."

"My group primarily does not work on conservation applications. That is not our primary focus but we have to some extent been swept into this because there is interest in using these kinds of technologies that we are developing to replace inhumane chemical poisons, particularly rodenticides. We are all aware that other people in the world would like to use it for conservation and in particular New Zealand has this predator free 2050 initiative. They want to get rid of all invasive rats. And one of my concerns with that is what the indigenous people of Aotearoa, the Maori, think of this. So, the last five years, my team has gone to the Aotearoa every year at least once and discussed this with diverse Maori."

"And they have been guiding us in our technical development of different versions of the technology to determine whether it might be consistent with their values and their obligation to protect the land. So, this is the kind of process that we would like to see more broadly."

"I would love to see a registry that requires transparency at the beginning and community sponsorship to register and perceive. The World Health Organization is considering creating this kind of registry. I highly recommend some kind of endorsement from the European Parliament, or create your own. It would be a tremendous advance for open science and community voices."

Q

Question by
MEP Soraya Rodriguez Ramos (Renew Europe)

"Under which conditions would gene drives in your perspective be safe to use, what would safe use mean to you?"

Answer by
Dr. Kevin Esvelt

"The challenge is that we don't know what the ecological effects are going to be until we actually try it in some region of the wild." "You cannot test the version that you believe will spread indefinitely. So I do not support calls to say: find an isolated island and try the full power gene drive there. I think that is a terrible idea. I think history shows that people will move it and it might hitchhike on its own, in the case of rats, obviously they stole away on ships on their own, so I don't advocate using that form of technology in field trials and if you cannot use it in field trials you can't even test it."

"A gene drive can always have an advantage in which case it will spread indefinitely to which I have spoken out very strongly against in the conservation world. We don't want to hit rats with a technology that will suppress their populations but will also spread to all rats in the world because of course rats are everywhere. And we can't possibly get the consent of all communities everywhere to do this and we don't know whether rats are doing something important in Eurasia. Instead, we would want to use a technology that either does not cause the suppression effect to spread at all and be definitely confined to the territory of the Aotearoa. Or we might want to use one that amplifies for a limited number of generations and then stops and goes away."

"In 2015, I got together with many other developers and we hammered out agreements as to what safeguards we should use in the laboratory. And we concluded you should always use at least two, ideally the splitting technique for molecular chains to limit the effects, but also something like laboratory walls or using an isolated population so that you're never relying on just one containment technique. And we have a new paper coming out with similar recommendations to be considered before field trials, that similarly take a very cautious approach before we move forwards."

"I'm not actually aware of any case in which there is a gene drive anywhere near ready to go for conservation."

Input by

Dr. Margret Engelhard - on the risk assessment on gene drive organisms

View Presentation

"What is now new and challenging for us for risk assessment?"

"We really agree with EFSA that there's a number of open questions concerned with environmental risk assessment and management and that we will need further elaborations to work on it."

"There are general new challenges and there are also specific new challenges. The challenges are connected to a lack of data, to the methods and how to really model it."

"So the first question would be, is this GDO working as a tool [...], does it have the concrete and the wider function?"

"So the concrete question would be, is it really working to eradicate a species on an island? Can we develop a good risk assessment / risk management system? Will we ever be able to have a sound risk assessment and to evaluate?"

"We have the problem that we don't know what to compare gene drives with because we haven't had something like this before. Do we cross a line when we genetically engineer protected species? Is that still going along with our concept of nature? How do we adapt the risk assessment, management measures and the monitoring concepts?"

"We have to define protection goals and limit of concerns. We have some - well basic questions - is the approach we should put our money on?"

"We also have legal challenges for example, when we genetically change a protected species - is it still something that we want to protect?"

"We have a full bundle of societal questions that we have to newly think about"

"We think that a technology assessment approach would be the right approach to really also tackle the question that goes beyond the mere risk assessment."

Q

Question by
MEP Alexander Bernhuber (EPP)

"What do you think: If a species will die out because of climate change and the only chance to protect them is to use GMO? Do you think, let the species die out or use GMO to protect them?"

"Well I think this question should probably be taken a bit broader. So it is not the question, if we have only the possibility to use synthetic biology on exactly this species to save it."

*"**The real question is:** Which track are we going to take in the view of how many species are dying out? And is it an appropriate tool, is it really working and is it really taking us to the more general goals of nature protection?"*

Answer by
Dr. Margret Engelhard

Q

Question by
MEP Ville Niinistö (Greens/EFA)

"What is the difference between natural selection, natural evolution and this? And what are the consequences, when it comes to safety?"

Answer by
Dr. Margret Engelhard

"I think it's an important question, because we always hear the comparison to natural phenomena and it is important to know that of course there is a continuity."

"Yes in nature we have a lot of phenomena, we see similarity with all sorts of things."

"The question of concern for me is, when it comes to risk assessment: Is it something that happens in nature we cannot prevent or is it something we deliberately do and have to take the responsibility for. And when we take the responsibility for it, we should only do it, if it's safe."

Input by

Dr. Ricarda Steinbrecher - on risks and novelty of gene drive organisms

View Presentation

"I want us to focus on the aspect of unpredictabilities and novel risks with regards to gene drive organisms."

"Engineered gene drives are very new. I think it was Kevin saying something like they [gene drives] exist everywhere. Well, retrospectively some elements, some phenomena found in nature are now being referred to as "gene drives" by some, while they were not called that in the past. They were called then selfish genetic elements, like transposons [...] which are part of speciation - but they do not have the implications and risks of engineered gene drives. So the term natural and nature-based does not mean safe or predictable, that is quite important. And furthermore, the concepts and components that we are taking from nature here are redesigned, recombined and moved into new context and into new species."

"Some form of a natural phenomenon of supposed "gene drives" occurs in mice, also in some insects. And you will find that the individual, who has these genetic elements, is actually often avoided by other individuals for mating purposes. There is a co-evolved safeguard, so that the species can continue. So you see: naturally occurring phenomena are embedded in co-evolutionary mechanisms - in synthetic gene drives it is not."

"We find that with CRISPR-based gene drives, there is resistance building up that will stop the drive from working. A lot of research is focused on this at the moment to overcome that problem. The one possible solution found is to use sequences of highly conserved essential genes as target sequences for the gene drive. Unfortunately these highly conserved sequences often will be shared with other close relatives and then gene drives can actually move to other species. We need to consider that as well."

"And so called "local" gene drives are [...] theoretical and are not a reflection of what is possible and of what will happen in reality."

"Employing secondary gene drives to send after a first release [of a separate gene drive] to stop them, like so called "immunizers" are again largely theoretical and also incapable of restoring the genome."

"I just want to quickly say something about other ways on how you could approach problems. Ecosystem-based approach is a common terminology. It´s valuable as guidance for selecting the right approach to solve problems. It´s used and defined under the Convention on Biological Diversity and I think it is good guidance. Sometimes we hear the term „nature-based solutions". Well what does nature-based mean? If you think of it, nuclear power – well yes - it´s nature-based, carbon and biodiversity offsets, nanotechnology, geoengineering, well all of these, in a way are nature-based. Genetic modification. It´s nature-based There is a problem with the term. So how do you actually really define something to know what it is and make sure it´s safe?"

Q

Question by
MEP Ville Niinistö (Greens/EFA)

"Do you see a possibility to develop risk assessment for gene drives from this broader perspective?"

"What can be learned from experiences with similar technologies in the past?

Answer by
Dr. Ricarda Steinbrecher

"At present, I feel it is not possible, there are so many open questions, we need extra guidance."

"I think it will take a while to really understand what it is we need to ask and how to go about it."

"And can we learn from the past?" "Yes, we can learn from the past definitely, making things safe [...] and don't use it until we know it's safe."

Q

Question from the audience

"Who is is funding gene drive research?"

Answer by
Dr. Ricarda Steinbrecher

"There is quite a lot of funding from the US Defense Advanced Research Projects Agency, DARPA."

"The Gates Foundation is a big funder, Tata Foundation is a funder. There are certain interests behind the big projects. The US National Academy of Sciences in their early (2016) report on gene drives highlighted the problem of its use in a malicious and in a so called "dual use" aspect, which is the military aspect."

Input by

Birgit Winkel - on the current state of EU discussions on synthetic biology towards COP 15 of the Convention on Biological Diversity

View Presentation

"My task today is to introduce you to the international negotiations on synthetic biology under the CBD (the Convention on Biological Diversity)."

"The negotiation starts with a draft recommendation which is provided from the CBD secretariat on the basis of decisions made before on work done in the intersectional period. For synthetic biology this work is done by the AHTEG beyond the mere risk assessment."

"Based on this recommendation, there are discussions in the EU Council's Working Party on International Environmental Issues, on which changes need to be done to the recommendation."

"And this is the preparation for the meeting of the Subsidiary Body on Scientifical, Technical and Technological advice which is also called SBSTTA24."

"At the end of this coordination in the EU there stands the development of orientation lines by its member states." "At SBSTTA, the member states do negotiate for themselves, so the orientation lines only give a frame for the negotiation by the member states."

"The result of the negotiation at SBSTTA will be a recommendation to the COP15. This recommendation will be published again and there will be a development of position papers by the EU and its member states."

"The position paper will be the start of negotiation at COP15 which is supposed to take place in October 2021 in Kunming, depending on the pandemic." "At COP15 there will be a decision on synthetic biology. And this decision is binding for all the parties, so it is a very important part. It will be translated into [...] European law."

"The orientation lines now contain that the EU and its member states support an efficient horizon scanning process that is suitable to assess and identify the potential positive and potential negative impacts of synthetic biology. We propose to recall paragraph 9 to 11 of decision 14/19 [on synthetic biology from COP 14] which is the part that reaffirms the precautionary principle; and we emphasize a precautionary approach with respect to engineered gene drives including when used for biodiversity goals."

"We took the European Parliament's goal of a global moratorium into account but the call for the moratorium was not supported for a range of reasons. Instead the precautionary approach was again emphasized."

Q

Question by **moderator Natasha Foote to Birgit Winkel**

"Where does the EU currently stand when it comes to regulating gene drives?"

"Genetically engineered gene drives are seen as GMO, so they are regulated under directive 2001/18."

"EFSA was asked by the Commission to identify or to assess if existant guidance from EFSA is sufficient for risk assessment. They found that it could be a good basis but there are some things that need to be considered more..., so they need an adaptation."

"There are no gene drives at the moment in the pipeline to be released in Europe and I don't think that this will change in the next years."

Answer by
Birgit Winkel

Q

Closing question by
moderator Natasha Foote to all speakers

"In your opinion, is the genetic engineering of wild species an adequate tool for nature conservation? If so, why? And if not, what should be done instead to halt biodiversity loss?"

"We heard from Dr. Redfort earlier some comments about the need to change politics, the need to change values and where there are existing strategies that can be effective. I think those should come before the applications of biotechnology. An area where I think we need to do better is obviously habitat protection. It is not working well enough. We haven't done enough of it. [...] I think that is something that needs to be explored more and is a place that I would go to, before some of these technological applications."

Answer by
Dr. Christopher Preston

"I will try to be brief, because the first half of what I wanted to say was already presented by Dr. Preston."

"So, when we ask the question about should we use genetic engineering of wild species, is it an adequate tool, I agree with Christopher that the answer is no, it is not adequate in the sense that it in and of itself is sufficient. It is adequate in the sense that it should be considered as one of the tools and I would suggest as only further down the list of things to consider, before we have found that existing tools are not adequate for this."

"And if much of our effort were devoted to try and fix agriculture, both, to provide food but also to stop destroying nature, I think we would be doing the best thing we could for the natural world."

Answer by
Dr. Kent Redford

"I think there are two levels to it: Is it adequate? And: Is it appropriate?"

"So when we discuss if gene drives are an adequate tool for nature protection [...] I see applications on the level of symptom healing instead of working on the reasons why we have the [...] degradation of species. [...] It is not really tackling the problems."

"The second level is that I am wondering if it really is an alternative."

"If you are really going to change organisms through gene editing, I think we should only do it in a discourse with society. And I think it is not decided yet by society and society needs to be integrated. And it is very important to integrate indigenous people and local communities but it is also very important to integrate the whole society that might be affected."

"And therefore we think a possible way [...] would be to develop technology assessment tools to really make visible these other levels. [...] Well, in a way it is a risk that we are going to change our concept of life. What would this mean in general for nature protection? And we really have to answer these questions."

Answer by
Dr. Margret Engelhard

"I so much agree that if we really want to have solutions, we really need to understand where the problems are, just treating symptoms will not bring us any further and current agriculture is really at the root of a lot of the problems."

"I feel agriculture needs to change into something that actually is in service of biodiversity, that does not destroy it, but that somehow picks up a functionality to support nature. And then nature and the environment will support agriculture as well. Like agro-ecological systems are a big example for that."

"I do not believe that any technology, including this one, is going to help us out to halt the rapid biodiversity loss and ecosystem decline. They cannot save us at all."

Answer by
Dr. Ricarda Steinbrecher

"A discussion on the engineering of wild species and it's implications for nature protection has only just begun, thanks to the IUCN. Because before that, the European dialogue in the working parties and also at CBD level did not differentiate between different kinds of applications and their aim. This is still just a beginning and it is good that it starts. But we cannot see yet, which opinion the different member states have. The opinions on gene drive organism go into two different directions. One part thinks that it should be regulated case-by-case. So therefore, Directive 2001/18 is enough. Other member states are of the opinion, that according to the precautionary principle, gene drive organisms should not be released before certain concerns are addressed."

Answer by
Birgit Winkel

MEP Ville Niinistö (Greens/EFA)

"We need to have a dialogue on creating rules, for how gene drives will be handled in the future. And I think one big key takeaway for us, in the European Parliament and for Europe is that, it's obvious that we need to find international rules for this. There cannot be a different set of rules, as the effects may go beyond the national jurisdiction."

"Obviously this discussion also is very useful for the European Parliament, in relation to our work on the European Union's biodiversity strategy."

"And it's part of our discussion about our vision for the EU to be a global pioneer in biodiversity protection. And then there will obviously be the EU's position on the COP meeting of the Convention on Biodiversity and the IUCN."

"I think the key takeaway from the discussion is that [...] the best way to protect humanity's future, is to protect our biological diversity, to change the way we use resources and make it sustainable."

"Obviously the risks and uncertainties are high, especially if we don't have a rigid robust regulation on how you control, how you monitor, what can be put into a field test, if it can be put to a field test. And that's why the parliament called for a global moratorium on first field trials with gene drive organisms in January 2020"

"We thought that there need to be definite rules before this can be even applied in the field test. Because if we don't control that, we don´t know the consequences of what happens."

"We need to set up a democratic participatory and inclusive process for technology assessment as suggested by Mrs. Engelhard. It could be a next good step to go forward with this. And this should be a global process to assess if this technology could ever become a tool for nature conservation or other purposes."

"But to finalize, I think also takeaways are that when we go into these discussions, we have to change a lot in politics, we have to change a lot in our common economies and to create ecosystem-based solutions which strive to restore ecosystems and improve their resilience, instead of modifying."

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