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Zahra Meghani
University of Rhode Island, meghaniz@uri.edu

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Zahra Meghani

University of Rhode, Kingston, USA

Research Article

Abstract

This article contends that the environmental release of genetically engineered (GE) animals with heritable traits that are patented will present a challenge to the efforts of nations and indigenous peoples to engage in self-determination. The environmental release of such animals has been proposed on the grounds that they could function as public health tools or as solutions to the problem of agricultural insect pests. This article brings into focus two political-economic-legal problems that would arise with the environmental release of such organisms. To address those challenges, it is proposed that nations considering the environmental release of GE animals must take into account the underlying circumstances and policy failures that motivate arguments for the use of the modified animals. Moreover, countries must recognize that the UN International Covenant on Civil and Political Rights and the UN International Covenant on Economic, Social and Cultural Rights place on them an obligation to ensure that GE animals with patented heritable traits are not released without the substantive consent of the nations or indigenous peoples that could be affected.

Policy Implications

- Nations considering the environmental release of genetically engineered (GE) animals with patented heritable traits must take into account the underlying circumstances and policy failures that motivate arguments for the use of the modified organisms.
- Countries must recognize that as parties to the UN International Covenant on Civil and Political Rights (ICCPR), they have an obligation to not permit the environmental release of GE animals with patented heritable traits without the substantive consent of the nations or indigenous peoples that could be affected.
- Countries must acknowledge that the UN International Covenant on Economic, Social and Cultural Rights (ICESCR) places a duty on them to ensure that GE animals with heritable traits that are patented are only released in the wild with the free, informed consent of the nations or indigenous peoples that could be affected.
- Countries must ensure that the non-governmental organizations (NGOs), corporate entities and other organizations over whom they have authority respect the right of indigenous peoples and other nations to make informed, free decisions about the presence of GE animals with patented heritable traits in their territories.

Environmental release of genetically engineered animals with gene drives: international treaties and patents

The ability of nations[1] and indigenous peoples to act autonomously is invariably constrained by various state and non-state actors. This article argues that the environmental release of genetically engineered (GE) animals with patented heritable traits will present an additional challenge to the efforts of nations and indigenous peoples to engage in self-determination.

Proponents of GE animals (specifically, GE insects) with patented heritable traits have proposed releasing them in the environment arguing that they could serve as public health measures or as solutions to the problem of agricultural insect 'pests'[2] (see, for instance, Godfray et al., 2017). Germline cells or early embryos would be altered by means of genetic modification,[3] with the change affecting the progeny of the engineered organism at a percentage higher than the one described by Mendel's law of inheritance; such a modification is referred to as a 'gene drive' (see Burt, 2003; Champer et al., 2016; Harvey-Samuel et al., 2017; Hammond and Galizi, 2017).

The possible threat to biodiversity from the open release of such modified animals has received attention (Courtier-Orgogozo et al., 2017). This article brings into focus two complex political-economic-legal problems that would arise with the environmental release of GE animals (including GE insects) with heritable traits that are patented. First, if those modified organisms encroach on the territories of peoples and countries that have not consented to their presence on their lands or waterways, their political right of self-determination will have been violated by the parties responsible for

the environmental release of the animals. Second, if a patented heritable trait spreads through future generation of the wildtype of the species in those territories, it would constitute a de facto privatization of a commons of those nations and indigenous peoples.[4]

Drawing on multiple disciplines, this article advances the discussion about the significance of the open release of GE animals with gene drives. In particular, the legal scholarship on the unintended genetic drift of GE seed is used to develop an analysis of the political and ethical significance of the encroachment of GE animals with gene drives on the territories of nations and indigenous peoples. The analysis breaks new ground in four respects. First, by invoking the United Nations (UN) International Covenant on Civil and Political Rights (ICCPR) and the UN International Covenant on Economic, Social and Cultural Rights (ICESCR), it is argued that the environmental release of GE animals with gene drives could pose a threat to the political rights of indigenous peoples and nations *unless* their right to make informed, free decisions about the presence of those animals in their lands and waters is respected by the nation responsible for the release. Second and relatedly, the case is made that nations whose regulatory agencies authorize the environmental release of GE animals with gene drives have an ethical and legal obligation to ensure that those animals do not encroach on the territories of indigenous peoples and nations that have not consented to their presence on their lands or waters. The releasing nation's duty is not obviated even if individual researchers, corporations, non-governmental organizations (NGOs) or other proponents of the biotechnology manage to persuade particular indigenous peoples or nations to agree to the release in their territories. Third, using philosopher Onora O'Neill's account of non-state actors as (secondary) agents of justice, it is argued that NGOs, corporations, and other organizations (such as public-private partnerships) can be agents of injustice if they fail to respect the right of indigenous peoples and nations to make free, informed decisions about matters that affect them. And fourth, it is demonstrated that the notion of free, informed consent that O'Neill developed (using Kant's ethical theory and which is used at the level of individuals) can be used meaningfully for social groups and associations, in this case, indigenous peoples and nations, respectively. Thus, this article advances the discussion about the ethico-political salience of the release of such animals.

The following policy guidelines are proposed for the globally relevant risks and collective action problems posed by the environmental release of GE animals with heritable patented traits:

- Nations considering the environmental release of GE animals with patented heritable traits must take into account the underlying circumstances and policy failures that motivate arguments for the use of the modified organisms.
- Countries must recognize that as parties to the UN ICCPR and the UN ICESCR, they have an obligation to ensure that GE animals with patented heritable traits are not released in the environment without the substantive consent of the nations or indigenous peoples that could be affected.
- Nations must ensure that the NGOs, corporations, and other organizations based in their jurisdiction respect the right of indigenous peoples and other nations to make informed, free decisions about the presence of GE animals with patented heritable traits in their territories.

GE animals (including insects) with patented heritable traits: how, why, and ecosystem concerns

Researchers and biotechnology companies have been using techniques of modern biotechnology to modify animals, with the introduced trait or change passed on to some percentage of the animal's progeny (Moura et al. 2018). As a rule, those animals and their progeny are kept in contained facilities. A variety of strains of engineered mice are routinely used in medical research; the animals are kept in laboratories. GE goats, GE chicken and GE rabbits developed for the purposes of manufacturing pharmaceuticals are housed in secure farms (see, for instance, Svoboda,). A GE salmon has been approved for use as food in Canada and the US; the 'manufacturer' intends to raise them in contained facilities to prevent their encroachment on the wild (Gonzales, 2018). GE pigs that are resistant to a viral infection that tends to occur in industrial livestock farms are under development (Burkard et al., 2018), presumably, they would be raised on farms for use as food.

So while the creation of animals with germline modification is not a new phenomenon, what is different now is the push to deliberately release in the environment animals with patented modified traits that are passed on at a rate higher than the one described by Mendel's law. Key advocates of gene drives have proposed affecting the genetic modification by means of recently developed gene editing techniques (see, for instance, Molteni, 2018).[5] Gene editing enables more precise engineering of the genome than other techniques of genetic modification. (Gene editing can be performed on somatic cells or germline cells (including very early embryos).) CRISPR is cheaper and easier to use than other gene editing methods.

For the purposes of public health or as an agricultural pest control measure, two types of gene drives are under consideration for insects, specifically, population replacement gene drive and population suppression gene drive (James, 2005; Marshall and Akbari, 2016).[6] Population replacement gene drives would change (or eliminate) traits of the modified insect and its progeny, say, for instance, their ability to transmit pathogens. If GE insects with a population replacement gene drive are released in the wild, and if they successfully mated with their wildtype, then the introduced trait would occur in the resulting progeny, and over multiple generations spread throughout the wildtype population.

In contrast, a population suppression gene drive, for instance would affect a modification that undermines the survival ability or the fertility of the engineered animal and its progeny. GE mosquitoes with a population suppression gene drive have been proposed as a public health tool for mosquito-borne diseases (see, for instance, Alphey, 2016;

Burt and Crisanti, 2018). If GE mosquitoes with population suppression gene drives are released in 'sufficient numbers',[7] and they successfully mate with their wildtype counterpart, then, presumably, over time the wildtype population of that mosquito strain would be reduced and possibly eliminated. Thereby obviating the need for pesticide use. Rendering chemical pesticide use unnecessary is presented as a key justification for the use of GE insects for the purposes of public health or to address the problem of agricultural insect pests. (This article does not engage with the arguments for the use of GE animals with patented gene drives as the solution to the problem of invasive species, but some of the concerns discussed here are of relevance for that case too).

Ecosystem concerns

The Convention on Biological Diversity, a key multilateral environmental treaty, conceptualizes ecosystems as 'dynamic complex(es) of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit' (CBD (undated)). If GE animals with gene drives that belong to a species that is highly mobile, reproduces sexually, very fertile, and has a relatively short generation time, and if 'sufficient numbers' of such modified animals are released in the environment and they mate successfully with their wildtype counterpart, then their impact could be felt in multiple ecosystems around the globe. A concern with the environmental release of GE animals with gene drives is the possibility of horizontal gene transfer (HGT).[8] The National Academies of Sciences, Engineering, and Medicine (NASEM) (2016) report on gene drives noted that HGT among plants is more likely than between other species (because closely related, but separate, plant species tend to hybridize), but it recommended that 'the possibility of the horizontal exchange of gene drives between species should be evaluated prior to environmental release' (p. 40). There are also worries about off-target effects (i.e. unintended genetic change) and the possibility of the target species evolving resistance to the trait introduced by the gene drive (Ogaugwu et al., 2019).

In any ecosystem, a change in all members of a species (or even a substantial percentage of the species)[9] could have implications for other species because the biotic elements of ecosystems shape in varying degrees multiple aspects of each other's existence. The existence of species is directly or indirectly entwined in different ways (ranging from mutual dependency to competition to predation) and to different degrees (Rose, 2010; van Dooren, 2018) . So, if animals with a *population replacement gene drive* are released in the environment such that a substantial percentage or all of the future generations of the wildtype population inherit the patented engineered trait, then depending on the trait and given the relationship between that species and other species, there could be a ripple effect in the ecosystem. For instance, if a particular species (because of the modification) is no longer available in sufficient numbers as a primary source of food for other species, then those species may adapt or die out, thereby possibly affecting yet other species that are dependent on them. The uncertainty about the possible consequences of the environmental release of GE animals with gene drives would remain after successful field trials and even environmental releases in particular ecosystems because of the variability between ecosystems.

The environmental release of GE animals with *population suppression gene drives* may have profound consequences too given the interconnected existence of species. If the population of the species that is the target of the population suppression gene drive collapses or even significantly reduces, then depending on the nature of that species' relationship with other species in the ecosystem, the impact could be significant.

The introduction of GE animals with germline modification (that occurs at a rate greater than the one described by Mendel's law) could have substantial implications for any country whose ecosystems are affected; the ramifications are likely to be amplified for indigenous peoples and global South nations. The land inhabited by indigenous peoples, while only 20 per cent of the globe and spread across 90 countries, is crucial for preserving biodiversity, adaptation to climate change, and management of ecosystems (Gümplová, 2018). Seventeen countries have the greatest biodiversity on the planet (Mittermeier et al., 1997); those global South nations are in the Andean region, the Amazon basin, and in South Asia (Janni, 2004). Given that the greatest biodiversity of the planet is concentrated in the ecosystems of the global South, including the territories of indigenous peoples, it is likely that they would disproportionately experience the immediate and direct impact of changes caused by the introduction of GE animals with patented heritable traits that exceed the Mendelian rate of inheritance.

There could also be political-economic-legal problems occasioned by the environmental release of GE animals with gene drives. Part 1 argues that if the environmental release of such animals results in them encroaching on the territories of indigenous peoples and nations that have not consented to their presence in their land or waters, then their political right to self-determination will have been violated by the parties responsible for the release. Part 2 contends that the open release of such organisms could, in effect, constitute the de facto privatization of the species to which those animals belong, in violation of the claim that countries and indigenous peoples have with respect to that species (qua commons) in their territories. Part 3 considers the question whether concerns about the threat to the political autonomy and sovereign rights of nations and indigenous peoples from the environmental release of GE animals with gene drives should be privileged over public health and agricultural insect pest problems.

Part 1: violation of the political right to self-determination

GE insects with gene drives are among the most likely candidates for environmental release, so this article uses them as examples to expose the complexities and complications

of the open release of GE animals with gene drives. GE mosquitoes with a (CRISPR-based) population suppression gene drive are under development. Those mosquitoes would be akin to a GE mosquito with a patented heritable trait that has been 'manufactured' by Oxitec Ltd.[10]

The Oxitec OX513A GE mosquito is meant to have a population suppression effect and it has been modified to be dependent on tetracycline for its survival. Virtually all of the progeny of the engineered mosquitoes have the heritable trait (specifically, a synthetic genetic sequence that makes them dependent on tetracycline for their survival) (US FDA 2016). When the OX513A GE mosquito successfully mates with its wildtype counterpart, the majority of the offspring do not survive to adulthood in environments where tetracycline is not available in sufficient quantities (US FDA 2016). The Oxitec OX513A GE mosquito does not have a CRISPR-based gene drive. Since 2009, the Oxitec OX513A GE *Aedes aegypti* mosquito has been field trialed or used in the Brazil, the Cayman Islands, Malaysia and Panama for the purposes of reducing the wildtype *Aedes aegypti* population, with the goal of decreasing the transmission of pathogens from infected female mosquitoes to humans (de Campos et al., 2017). Whether that OX513A GE mosquito has reduced the transmission of infection in humans remains an open question; there is a dearth of peer reviewed, published studies on the matter (see also de Campos et al., 2017 on the subject).

Some proponents of gene drives advocate releasing in the environment GE mosquitoes with (CRISPR-based) population suppression gene drives (Molteni, 2018). If they successfully mate with their wildtype population, the assumption is that over time it will lead to significant reduction in their wildtype counterpart population, presumably, resulting in lower incidence of mosquito-borne diseases in humans.

GE insects with (CRISPR-based) population suppression gene drives have also been proposed as a solution to the problem of agricultural insect pests (Godfray et al., 2017). The aim would be to undermine the survival ability of the engineered insect and its progeny. The plan is to release in the environment GE insects with population suppression gene drives and if they successfully mate with their wildtype counterpart that are considered agricultural insect pests, the progeny would not survive and consequently the wildtype population of that insect, presumably, would decrease over time. (Oxitec has developed GE Diamondback moths, GE fall army worms, GE spotted-wing drosophila, and GE med fly that will have a population suppression effect on their wildtype counterparts that are considered agricultural insect pests (Oxitec 2002–2018); as of January 2019, presumably, the Oxitec GE insects do not have a CRISPR-based gene drive).

Below, it is argued that if GE insects with patented heritable traits enter the territories of nations or indigenous peoples who have not consented to their presence, their autonomy would have been violated by the nation(s) responsible for the release. Specifically, their claim to their natural resources would be undermined.

Violation of the autonomy of nations

To get a grasp on the threat that the environmental release of GE animals (including insects) represents to the political right to self-determination of nations, it is useful to consider the analogous case of genetic drift of genetically modified (GM) seed (i.e., the adventitious presence of GM seed in nations that have not permitted their use within their borders). The inadvertent presence of GE seed on lands where they are not licensed for use is a serious matter that continues to be the subject of legal scholarship (see, for instance, Aoki, 2009; Bernhardt, 2005; Blakeney, 2016; Cole et al., 2014; Delaney, 2007; Glascoe, 2017; Haugo, 2014; Kariyawasam, 2010; Kool, 2010; Lynd, 2013; Ma, 2012; Mgbeoji, 2007; Peck, 2008; Schlessinger and Endres, 2015).

While a number of scholars have focused on the significance of genetic drift of GM seed for US farmers, Peck (2008) has examined at length its international implications. This article extends Peck's analysis to GE animals with germline modification that is inherited at a rate higher than the one described by Mendel's law. Moreover, while Peck considers the problem occasioned when a country uses GE seed without taking measures to ensure that the autonomy of other nations is not violated, this article argues that the nation responsible for the release of GE animals with gene drives has an obligation to make sure that the autonomy of indigenous groups that could be affected is not undermined either.

Analyzing cross-border GM seed contamination, Peck has argued that if a nation (that is pro-GM seed) does not institute regulatory measures that ensure that its use of GM seed with patented heritable traits will not result in the contamination of the ecosystems or food supply of countries that do not welcome the presence of genetically modified organisms (GMOs), it violates their political right of self-determination. That infraction qualifies as a form of political harm, even if the GMO presence is nominal (Peck, 2008). To make her argument, Peck invokes two UN treaties – the ICCPR and the ICESCR.

The UN International Covenant on Economic, Social and Cultural Rights (ICESCR) is a multilateral treaty that was adopted by the UN General Assembly in 1966 and came into force in 1976. States that are party to it have a duty to grant economic, social, and cultural rights to former colonies.[11] The International Covenant on Civil and Political Rights (ICCPR) is another multilateral treaty of the UN General Assembly that was also adopted in 1966 and came into effect in 1976. The treaty obligates states that have ratified it to respect a number of rights of colonized peoples as well as nations.

The language of Article One of the ICESCR and the ICCPR is identical. Article One of the two treaties guarantee the right to self-determination to peoples (in the wake of WWII, the term 'peoples' was re-defined to refer to defined territorial regions that were former colonies and comprised of ethnically diverse populations).[12]

According to Article 1 of the ICESCR and the ICCPR:

1. All peoples have the right of self-determination. By virtue of that right, they freely determine their political status and freely pursue their economic, social and cultural development.
2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case, may a people be deprived of its own means of subsistence.
3. The States Parties to the present Covenant, including those having responsibility for the administration of Non-Self-Governing and Trust Territories, shall promote the realization of the right of self-determination, and shall respect that right, in conformity with the provisions of the Charter of the United Nations.

Invoking the ICESCR and the ICCPR, Peck (2008) has argued that when a nation that uses GM seed does not ensure that the modified seed with heritable traits do not enter the territories of nations that are opposed to them, it violates their political right to self-determination. When non-state actors, such as corporations, use (or allow the use of) GM seed but fail to ascertain that the modified seed do not encroach on the territories of nations that do not want their presence, then *the state that enabled the release is responsible* for the violation of the political right to self-determination of the affected countries. The unstated premise of Peck's argument is that an agent (in this case, a state) is culpable if the harm potential (i.e. risk) could have been reasonably foreseen *and* if the agent had the authority to prevent the harm but chose not to. Peck (2008) contends that the introduction of GM seed in Brazil by Syngenta (in violation of that country's law), for instance, is ultimately traceable to the US' pro GMOs stance:

> The sum total of U.S policies regarding GMOs–including initial regulatory assumptions, reaction to the precautionary principle in international agreements, failure to ratify the CBD (Convention on Biological Diversity), and domestic labeling policy – results in a reality in which the adventitious presence of GMOs is inevitable in the food and seed stocks in the United States, and increasingly in other countries that do not produce GMOs in large quantities, and in some cases do not desire them . . . Because of the fact of adventitious presence, that policy decision is being quietly spread to other countries where the people, through their respective political processes, have determined that GMOs are unwelcome, or in which the issue has yet to be settled (pp. 56–57).

Peck (2008, p. 57) elaborates on her point by noting that '[b]y introducing unwanted GM products into the food supply of nations that have not yet had the opportunity to arrive at political solutions for dealing with those products, U.S. GMO policy creates the same effect as the intrusions by foreign sovereigns that motivated the international recognition of the right to self-determination'.

Peck's argument has relevance for a key concern of this article, that is, the political significance of the environmental release of GE animals with gene drives. Nations have the authority to regulate the activities of research entities, commercial enterprises, NGOs, and other organizations within their borders and determine the conditions under which they provide or sell their products or technical know-how to those beyond their borders. So, when a nation *chooses* to not institute regulatory policies that would ensure that the organizations within its borders do not act in ways such that it results in GE animals with gene drives encroaching on the territories of countries that have not authorized their presence, it violates their political right to self-determination that is guaranteed in the ICESCR and the ICCPR.[13]

It is also worth considering that even if a nation may have technically permitted the presence of the modified animals (say, GE insects) in its territories, it would not constitute substantive consent if it was coerced, manipulated or deceived by the parties advocating the release of the GE animals.[14] The parties in question could be, for instance, NGOs, commercial entities, or other organizations (such as public-private partnerships). The notion that non-state actors, such as NGOs and corporations, can be agents of injustice is based on O'Neill's work (2001, 2004). She argues that those non-state actors can function as (secondary) agents of justice insofar as they have the capacity to ensure that the rights of individuals are respected. Conversely, they can be agents of injustice. The following are some of the ways in which a nation could be deprived of the opportunity to make a free, informed decision and thus exercise its agency by the sellers of GE animals or organizations who are their proponents:

1. The proponents (or sellers) of a modified insect meant for agricultural pest control purposes withhold or misrepresent research data (about, say, the efficacy of the GE insect as an agricultural pest control measure or the uncertainties about it ecological impact) from the target nation's regulatory agencies and publics.
2. The proponents (or sellers) of a modified insect intended to serve as a public health tool present the GE organism to regulatory agencies and the publics as posing no human health risks even though there is uncertainty about the possibility of harm.
3. The proponents (or sellers) of a modified insect act in ways that deter or prevent that country's regulatory agencies or public health authorities from attending to their fiduciary responsibility to the public (for instance, by providing 'incentives' to public officials or using other means to manipulate them).
4. Without disclosing their specific normative commitments or relevant organizational affiliations, the proponents (or sellers) of a modified insect attempt to influence efforts to create regulations that would apply to the GE insect, thereby, possibly undermining the likelihood of the creation of new regulatory schemas that would enable its tailored and rigorous oversight (see, for instance, the

complaint letter from the African Centre for Biodiversity et al., 2015 to Dr. Cristiana Paşca Palmer Executive Secretary Secretariat of the Convention on Biological Diversity).

This is not an exhaustive list. These kinds of violations constitute unethical actions and depending on the laws of the affected nation, there could be legal ramifications for the wrongdoers.

The release of GE animals that could pose a threat to the autonomy of indigenous peoples is considered in the next section. To provide a context for that analysis, the notion of self-government of indigenous peoples is juxta-positioned against the conception of autonomy of nations.

Violation of the autonomy of indigenous peoples

Indigenous peoples

There are approximately 370 million indigenous persons, who belong to 5,000 different groups, in 90 countries worldwide (UN, *Sustainable development* . . .). The UN notes that 'Indigenous Peoples are found in every region of the world, but about 70% of them live in Asia . . . Examples of Indigenous Peoples include the Inuit of the Arctic, Native Americans, hunter-gatherers in the Amazon, traditional pastoralists like the Maasai in East Africa, and tribal peoples in the Philippines. While there is no universally accepted definition for 'Indigenous Peoples,' there tend to be common characteristics among them, including:

- They often have small populations relative to the dominant culture of their country;
- They usually have (or had) their own language;
- They practice distinctive cultural traditions;
- They have (or had) their own land and territory, to which they are connected to at
- various levels;
- They self-identify as Indigenous' (UN (undated)).

The above list is not meant to be a set of necessary and sufficient conditions that categorically determines which groups qualify as indigenous peoples and which ones do not. Attempts to create criteria for the category of 'indigenous peoples' must be understood in context. Bello-Bravo (2019) notes that when the question, 'what is indigeneity?', is asked, then the question '*when* is indigeneity?' must also be asked. She contends that the latter question exposes the former question as an act of hegemonic state power to place constraints on, justify exclusion of, or appropriate the natural resources of particular indigenous peoples.

Autonomy of indigenous peoples

The encroachment of modified animals with heritable patented traits in the territories of indigenous peoples, without them having the opportunity to make free, informed decisions about the presence of those organisms in their lands or waters, qualifies as a violation of their political right to engage in self-determination. The UN recognizes that they have that right.

Erica Irene Daes, the founding Chairperson and Special Rapporteur of the United Nations Working Group on Indigenous Populations, successfully argued that indigenous peoples qualified as a colonized peoples. Given that the political right to self-determination as well as the sovereign right of colonized peoples over their natural resources was recognized by various international treaties, Daes contended that the same rights should be extended to indigenous peoples under those agreements. She argues,

> a. Indigenous peoples are colonized peoples in the economic, political and historical sense;
> b. Indigenous peoples suffer from unfair and unequal economic arrangements typically suffered by other colonized peoples;
> c. The principle of permanent sovereignty over natural resources is necessary to level the economic and political playing field and to provide protection against unfair and oppressive arrangements;
> d. Indigenous peoples have a right to development and actively to participate in the realization of this right; sovereignty over their natural resources is an essential prerequisite for this; and
> e. The natural resources original belonged to the Indigenous peoples concerned and were not, in most situations, freely and fairly given up (Daes, 2004, p.11).

This article construes self-determination of indigenous peoples to mean collective self-determination of particular indigenous peoples grounded in their right as peoples (that precedes and supersedes their recognition by colonial (or neocolonial) states) to make decisions on the basis of 'their own decision-making process undertaken with sufficient time and in accordance with their cultural traditions, customs and practices' (UN Special Rapporteur on the Rights of Indigenous Peoples et al., 2016).[15]

Drawing on Corntassel (2003), Bello-Bravo (2019, p. 2) clarifies that while indigenous groups have argued for their claim to autonomy (self-government), they have not insisted on 'independent statehood, which per se can be disambiguated from self-government'. Alfred and Ahern (1995, p. 14 cited in Coulthard, 2014, p. 64) write that when most indigenous peoples make a claim to nationhood, they are not desirous of creating a new state, rather they seek recognition and autonomy 'through the achievement of a cultural sovereignty and a political relationship based on group autonomy reflected in formal self government arrangements'. Bello-Bravo (2019, p. 2) notes that 'nation-states have remained either skeptical about, or have simply used . . . (the) legal question (of self-government) as a pretext for avoiding the consequences of fully recognizing the rights of indigenous people to land, resources, genetic property, self-determination, and self-rule'.

That notion of self-definition (of indigenous peoples) stands in contrast to autonomy as usually conceptualized by nations. For instance, a nation committed to neoliberalism is likely to understand its right to self-determination over its territories to be virtually categorical. It would be averse to the idea that is central to many indigenous people's notion of self-determination, specifically, collectively ownership and

management of natural resources shaped and constrained by a commitment to non-domination and non-exploitation. A neoliberal state might not regard governance based on those values as governance; it would consider such territories as terra nullis, that is, ungoverned territories that should be appropriated and privatized so that they can be made 'productive'.

Threats to the autonomy of indigenous peoples: state actors and other organizations (including non-state actors and public-private collaboratives)

Nations whose regulatory agencies authorize the release of GE animals with gene drives have an ethical obligation to take into account the relationships of domination, marginalization, and exploitation between nations and the indigenous peoples within those countries' borders. Ensuring that indigenous peoples that could be affected by the release of GE animals with gene drives are not deprived of their right to make free, informed decisions about the presence of GE animals in their territories will mean *at least* two things. Suppose that a research organization based in the UK has developed GE insects with gene drives and is planning to release them in Brazil with that nation's permission. Given that the research organization is located in the UK and given that the UK has authority over entities within its borders, then in light of Peck's analysis of the Syngenta case, the UK is in effect the state responsible for the release (as is Brazil). As the nation responsible for the release, the UK must not assume that it has to acquire the free, (prior) informed consent of *only* the indigenous peoples that could be affected and who are recognized by Brazil.[16] The UK's ethical responsibility would extend to indigenous peoples who could be affected by the release even if those peoples are refused recognition by Brazil. Second, the UK, as the state responsible for the release, should not assume that it has to respect only the particular set of rights that Brazil affords to the indigenous peoples within its borders.[17] Otherwise, the UK will have failed ethically and become complicit in the oppression of indigenous peoples in Brazil who are denied their claim over their territories by Brazil. This obligation is also reflexive. For instance, if Canada were considering the release of GE animals with gene drives within its borders, then it would have a moral obligation to respect the right to self-determination of the indigenous peoples whose territories are within *its* borders and who could be affected by its decision to release those modified animals. Nations that are guilty of colonial dispossession of indigenous peoples' rights and territories may resist acknowledging that two-fold responsibility. It will mean that they will have to make amends for their past and on-going wrong doings to the previously self-determining peoples upon which the colonialist state's 'territorial, economic, and social infrastructure is constituted' (Coulthard, 2014, p. 40).

Nations considering releasing GE animals with gene drives also should not uncritically accept the conception of indigenous peoples' free, informed decision-making proposed by organizations that represent the dominant interests. Some entities have a history of attempting to undermine the autonomy of indigenous groups (see, for instance, Bello-Bravo, 2019 and Corntassel, 2003 on this subject). Consider that in the wake of the 2016 High Level Dialogue on the Proposed Environmental and Social Standard 7 on Indigenous Peoples (that was held in Addis Ababa), the World Bank released (on its website) a summary of the discussion that stated that government representatives, the current and former UN Special Rapporteur on the Rights of Indigenous Peoples, and the representative of the African Commission on Human and People Rights expressed their 'broad acceptance' of the proposal that the Free Prior and Informed Consent (FPIC) of indigenous peoples should be operationally defined as 'broad community support' (BCS) (World Bank 2016, p. 1).

In response to that World Bank's claim, on 20 May 2016, the UN Special Rapporteur on the Rights of Indigenous Peoples (along with the Chairperson of the Expert Mechanism on the Rights of Indigenous Peoples and the Chairperson of the UN Permanent Forum on Indigenous Issues) sent a letter to the President of the World Bank, Jim Young Kim, and the Bank's executive directors. The letter criticized the Bank's attempt to undermine the autonomy of indigenous peoples by falsely asserting that there was an agreement that the notion of free, prior informed consent should be operationalized as 'broad community support'. The letter also noted that

> d community support' (BCS) is an ambiguous concept with no legal basis under international law and without a clear understanding or meaning. The World Bank's own internal review on the implementation of its existing policy on Indigenous peoples points to the fact that 'broad community support' has not been ascertained in a consistent manner and has failed to ensure good faith consultation leading to outcomes and agreements with Indigenous peoples that guarantee respect for their rights. BCS has been applied in projects that ifestly lacked the substantive elements of FPIC has consequently served to weaken the respect for the collective decisions of Indigenous peoples based on their own decision-making institutions and processes ... We would like to reiterate that the right to give or withhold FPIC is a collective self-determination based right of Indigenous peoples as peoples. Consent must therefore be obtained through Indigenous peoples' own decision-making process undertaken with sufficient time and in accordance with their cultural traditions, customs and practices (UN Special Rapporteur on the Rights of Indigenous Peoples et al., 2016).

This paper contends that the nation responsible for the release of GE animals with gene drives must respect the right of indigenous peoples to make a free, informed decision (using their own decision-making process with sufficient time and in accordance with their cultural traditions, customs and practices) about those organisms' presence in

their territories. It is not obvious whether the 2018 Conference of the Parties to the Convention on Biological Diversity recognized that right of indigenous peoples (the Conference of the Parties is the governing body of the Convention, and it advances implementation of the multilateral environmental treaty by means of the decisions made at its meetings (CBD (undated)). Articles 9(c) and 11 of the draft decision (on synthetic biology) submitted by the Chair of Working Group II of the November 2018 Conference of the Parties to the Convention seems to water down the right of indigenous peoples over their territories on the matter of the environmental release of GE animals with gene drives.

Articles 9-11 of the 'Synthetic Biology: Draft decision (on GE animals with gene drives) submitted by the Chair of Working Group II' are as follows:

> [Article] 9. 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:
>
> 9a. Scientifically sound case-by-case risk assessments have been carried out;[18]
> 9b. Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate;
> 9c. *Where appropriate, the "prior and informed consent", the "free, prior and informed consent" or "approval and involvement" of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation;*
>
> [Article] 10. Recognizes that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment;
>
> [Article] 11. Notes the conclusions of the Ad Hoc Technical Expert Group on Synthetic Biology that, given the current uncertainties regarding engineered gene drives, the free, prior and informed consent of indigenous peoples and local communities *might* be warranted when considering the possible release of organisms containing engineered gene drives that may impact their traditional knowledge, innovation, practices, livelihood and use of land and water (my italics).

Insofar as Article 9(c) of the Conference of the Parties to the Convention's draft statement (on synthetic biology) equates 'free, informed consent' of indigenous peoples *with* their 'approval and involvement' in the release of GE animals with gene drives (the latter is a looser, more ambiguous standard), it is at odds with the stance on free, informed consent of indigenous peoples expressed in the UN Declaration on the Rights of Indigenous Peoples, (especially Articles 19 and 32) and the 20 May 20 2016, letter sent by the UN Special Rapporteur on the Rights of Indigenous Peoples to the President of the World Bank and Bank's executive directors (the letter was discussed above). Moreover, Article 11 (echoing the stance of the Ad Hoc Technical Expert Group on Synthetic Biology) seems to not recognize that nations have an obligation to respect the right of indigenous peoples to make free, informed decisions about the presence of GE animals with gene drives in their territories. By asserting that nations 'might' seek the free, informed consent of indigenous peoples rather than stating they 'should', Working Group II (of the 2018 Conference of Parties to the Convention) appears to assume that on the matter of the environmental release of GE animals with gene drives nations may *choose* whether or not to respect the claim of indigenous peoples over their territories.

Part 2: de facto privatization of the commons of indigenous peoples and nations

Scope of patents of GE animals and insects

The environmental release of GE animals with patented population replacement gene drives could constitute the de facto privatization of the wildtype of that species (as well as the hybrids that may inherit the trait). While individual nations have the right to decide (on the basis of their national interests) whether to issue patents for germline traits or modified organisms, their choices are constrained by international trade agreements as well as inequitable power relations between nations. The UN is committed to the sovereign equality of all nations but in reality some nations (i.e. those with political capital and wealth) are more than the equals of others on the international stage (Hoffman, 2012). It would be naive to assume that the more powerful nations would not throw their weight behind particular corporate or industry interests that they believe align with their national interests as companies attempted to secure patent rights in various nations for their 'products' (see, for instance, Drahos, 1995 on the role of US pharmaceutical companies in crafting the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization (WTO)).

Nations permit patent claimants to draw a distinction between the genetic modification and the entity (as well as their progeny) into which it is introduced. But is that distinction substantive or nominal? Aldrich (2015), for instance, has asked whether it is meaningful to draw a distinction between the (introduced) genetic sequence and the animal within which it is introduced given that the former cannot be separated from the animal. Similarly, Humphries (2015,

p.2) has questioned the distinction between the introduced trait and the animal that is modified on the grounds that if'a patent law extends protection to all material in which the product is incorporated, then a broad patent claim over the gene or gene carrier (vector) of a plant or animal may have the same outcome as patenting the whole plant or animal'.

The analysis of Aldrich (2015) and Humphries (2015) has crucial relevance for the issue of the environmental release of animals with patented heritable traits. As mentioned earlier, when a nation permits the patenting of a heritable modification that surpasses the law of inheritance that is described by Mendel's law[19] *and* it does not bar the environmental release of such animals (and as a result the introduced trait spreads through the future generations of the wildtype of that species), then, arguably, in effect, it implicitly authorizes the privatization of that species.[20] After all, the trait is patented and there is no way to separate the patented modification from the animal.

De facto privatization of commons

Arguments for the use of GE animals with gene drives as public health or agricultural 'tools' are persuasive. However, it is also useful to recognize that the development of gene drives is part of the US project that began in the 1980s to ensure the nation's biotechnology domination in the face of international competition (Cooper, 2011; Meghani, 2017). Cooper (2011) has argued that the growth of the biotechnology sector was fundamentally linked to US' neoliberal shift. While her work predates the development of some types of gene drives, her analysis has relevance for it. She contended that biotechnology development within the neoliberal paradigm aims to dominate life itself (in this case, the species that is targeted for gene drive modification) by re-fashioning it so as to exploit its 'work' (i.e. its life activities) to extract profit from it. It seems reasonable to suppose that Cooper might argue that in a certain sense the ambition motivating research, development and use of GE animals with gene drives is to control and re-shape species so as to turn them into revenue streams for the patent-holding entities.[21] The re-fashioning of species is intended[22] to place hard limits on what and how they can 'be' for the purposes of exercising control over them so as to financialize them (for the patent holder). Given that within the neoliberal paradigm, arguably, the aim of gene drives is to dominate and exploit species for the purposes of profiting from them, indigenous peoples that are committed to having relationships with non-human species that are predicated on non-domination and non-exploitation may have significant reservations about their use.

If the environmental release of modified animals with patented heritable traits results in them encroaching on the territories of nations and indigenous peoples that have not consented to their presence *and* if future generations of the wildtype of that species end up having the modification in any substantial percentage, it could, in effect, amount to the conversion of that species into private (bio)property. The privatization of the natural resources of low-income nations and indigenous peoples without their free, informed consent constitutes wrongdoing for two inter-related political-legal-economic reasons. First, it denies them the right to benefit from their natural resources. The natural resources would include the species that is 'converted' into a patented (privately held) bioproperty as well as any other species that is negatively affected by virtue of its relationship with the 'converted' species. Second, the privatization would, in effect, render indigenous peoples and nations financially beholden to the patent-holding entity for the 'use' of its product. The economic consequences are likely to be particularly pernicious for the poor of low-income nations if the cost of the 'use' of the GE animals adds to the international debt burden of those countries. Governments usually pay those debts and the interests on them by cutting public services and goods for the poor and working class (Labonté and Schrecker, 2007). The privatization of the commons in the territories of indigenous peoples would also place a heavy burden on them. Indigenous peoples are disproportionately poor; they constitute 15 per cent of the world's poor and they comprise about a third of the world's rural poor (approximately 300 million) even though they are only an estimated 5 per cent of the Earth's population (Feiring, 2013).

To understand the implications of the privatization, it is (again) useful to consider the analogous case of genetic drift of GM seed (i.e. the migration of GM seed) onto farm fields meant for non-GM seed. In such cases, Canadian and US courts have ruled in favor of the patent holder. In Monsanto Canada Inc. v Schmeiser, for instance, the Supreme Court found Percy Schmeiser (a farmer) guilty of infringing Monsanto's patent right, even though he had not intentionally planted the GE seed on his farm; the seed had been blown on to his fields and had taken root (Wilson, 2014). Wilson writes, 'armed with the court-enforced strength of its patents, Monsanto aggressively seeks out any growers that may either intentionally or unintentionally infringe upon those patents' (2014, p. 176).

In a 2017 article, Glascoe notes that:

> [p]atent owner corporations like Monsanto frequently monitor and sue farmers using their patented crops, including non-GMO farmers who have fallen victim to their neighbor's genetic pollution or pollen drift. Between 1997 and 2010, Monsanto filed over 144 lawsuits for alleged patent infringement or breach of license for its seeds. In addition to these lawsuits, over 700 infringement disputes with Monsanto have been settled outside of court. Monsanto is not the only company that polices farmland in order to find infringers, regardless of intent or fault. The precedent set by these patent owners and their ruthless enforcement of their intellectual property rights exposes the non-GMO farmers to additional unwanted liability.

> Pollen drift does not merely hurt the land and crop value of these farmers; it also creates a cause of action against them' (Glascoe, 2017, pp. 541–542).

If the GM seed case is considered by the courts to be the appropriate legal precedent for cases of genetic drift of GE animals with patented heritable traits, then countries and indigenous peoples on whose lands or waters GE animals with population replacement gene drives encroach would find themselves legally beholden to the patent holder of the modified animals (Meghani and Boëte, 2018). The fact that they had no intention of violating the rights of the patent holder and did not transport the GE animals to their territories might not absolve them of legal responsibility.

Moreover, if the GM seed rulings are considered legal precedent by investor-state dispute settlement systems, then patent-holding corporations could file a complaint with one of those systems against countries with which it does not have a licensing agreement but on whose lands or waters its patented 'products' have encroached. The Council on Foreign Relations (2018) has noted that the investor-state dispute settlement systems 'typically involve foreign businesses claiming that a host government abused them by expropriating their assets, discriminating against them, or otherwise treating them unfairly'. To get a sense of how investor-state dispute settlement systems might rule, it is illuminating to consider the case of a Canadian gold mining company that cited a treaty between Canada and Venezuela to argue that the latter nation owed it damages because of its 2011 decision to nationalize the gold industry. According to the Canadian company, Venezuela violated an investment treaty between the two nations. The Council notes that '[a] tribunal found that while Venezuela had the legal right to nationalize private sector industries, it failed to properly compensate the company for the expropriated assets' (Council on Foreign Relations, 2018).

In the case of GE animals with patented gene drives, the patent-holding organization could ask the country that it is based in to file a dispute on its behalf against the nation that has not purchased a license to use its bioproducts, but in whose territories its patented organisms have encroached. International Corporate Accountability Roundtable (ICAR) notes that while only states can bring disputes before the WTO's Dispute Settlement system:

> powerful corporations and trade associations exert great influence directly over the WTO Secretariat that facilitates the trade dispute settlement process, as well as through a few dominant governments. Corporations are also heavily involved in determining which cases States bring to the WTO and lobby extensively to obtain a favorable outcome (ICAR 2017).

GE animals with heritable traits that are used as public health measures (or as agricultural pest control) have the potential to generate enormous revenue streams for patent holders. Consider, for instance, the case of the Oxitec OX513A GE mosquito. That GE mosquito with a germline modification (that is inherited at a rate higher than the one described by Mendel's law) has been used in Piracicaba, a Brazilian city with a population of 391,449 as a public health tool against the diseases transmitted by the *Aedes aegypti* mosquito. The 2-year cost of the GE mosquito was priced at US$1.1 million at the rate of US$10 per person in the target area (Servick, 2016). The GE mosquito would have to be periodically re-licensed by the city, adding to its price and thus revenue for the patent holder. In 2016, the cost of the use of the GE mosquito was much higher than the price quoted to Piracicaba. It would be approximately US$1.9 million in the first year and US$384,000 every year after that for a city of 50,000 persons (Alfaro-Murillo et al. 2016). A full-scale release of the GE OX513A mosquito in the Cayman Island for the 2018–19 period would cost US$8 million (Whittaker, 2018). As mentioned earlier, there is a dearth of peer reviewed, published studies on the efficacy of the OX513A GE mosquito in reducing the incidence of mosquito-borne diseases in humans (see also de Campos et al, 2007). A reduction in the gross number of mosquitoes (either by means of an insecticide or the GE mosquito) may not necessarily translate into lower rates of infections in humans because 'just a few (infected) *A. aegypti* may be enough to transmit disease through a susceptible population' (Servick, 2016). However, the financial sector seems to consider patented GE animal with heritable traits that exceed the Mendelian rate of inheritance to have significant profit potential. In 2015, Intrexon, a US biotechnology company, purchased Oxitec, a British company, for US$160 million (Nickel and Gillam, 2015).

The use of GE mosquitoes with self-limiting or population replacement gene drives (that are created with one of the new genetic editing techniques) may have a price similar to that of the OX513A GE mosquito. In fact, the price of GE mosquitoes that have gene edited germline modification might be higher as they might be advertised as the final solution. The larger point here is that patented GE animals with heritable traits if used for public health or agricultural purposes could mean significant profits for the entities that hold their patents.

Part 3: much ado about nothing?

Proponents of the environmental release of GE mosquitoes with gene drives might contend that the worries about the violation of the political autonomy and sovereign rights of nations and indigenous peoples over their commons are not compelling. They might argue that public health concerns, such as the enormous toll of malaria or other mosquito-borne diseases among the poor of low-income countries, take precedence over concerns about the violation of the political right of nations and indigenous peoples to engage in self-definition by deciding what enters their borders.

Prima facie, the argument has bite. It requires a response that takes into account the socio-political-economic context under which the poor of low and middle-income countries experience mosquito-borne diseases. The 2015–16 Zika outbreak in Northeastern Brazil was traceable to the interaction

between a complex of factors. Global warming (a phenomenon that is the product of failure of nations to implement policies ensuring sustainable modes of production) in the context of Brazil's humid, tropical climate may have resulted in the Zika virus reproducing faster than usual in infected mosquitoes and the mosquitoes maturing faster than they would otherwise (HRW, 2017). The outbreak's impact was felt disproportionately in the poorer communities of the Northeastern states of Pernambuco and Paraíba that lacked sanitation services, piped water, waste water treatment facilities, and garbage disposal services (HRW, 2017); there were numerous breeding grounds for mosquitoes in those neighborhoods.

The refusal of the state to respect the sexual and reproductive rights of its populace meant that the Zika virus disproportionately affected young girls and women of childbearing age who are members of socio-economically vulnerable, racialized minorities. During the outbreak, approximately 2,600 children were born with microcephaly and other complications from the Zika virus (HRW, 2017). According to a 2017 Human Rights Watch report, 'more than 75% ... (of the women and girls who gave birth to those children) identify as 'black' (preta) or 'brown' (parda) (as compared to 59 percent in the general population)' (HRW, 2017, p. 26). To state the obvious, the outbreak was a function of a complex of socio-political-economic factors in the context of a failure of democracy wherein some groups were subject to profound poverty, limited access to medical and preventative care, and lack of safe housing and other basic human necessities. A multitude of international and national policy failures are implicated.

The World Health Organization (WHO) does not consider it a matter of chance that poorer communities in low-income countries with significant incidence of mosquito-borne diseases experience substantial prevalence of other diseases of poverty. They are traceable to some of the same structural, systemic factors (WHO 2018a, 2018b; see also Garchitorena et al., 2017; Manderson et al., 2009). Lack of piped water, garbage disposal services, and waste water treatment plants as well as insufficient nutrition and medical and preventative care determine the vulnerability of populations to various diseases. Those structural, systemic factors also affect their ability to resist the infections and recover from them (WHO, 2017a). The capacity of populations to avoid or heal from illness is not always wholly determined by therapeutic or preventative medical interventions. In a 2013 *Lancet* article, Burki notes that '[m]alaria leaves a person vulnerable to malnutrition, and malnutrition leaves them vulnerable to malaria. And of course a person's nutritional status affects how they recover from infection; so malnutrition both raises the risk of contracting a disease such as malaria and worsens its outcome, which in turn leaves the patient enervated, deprived of nourishment, and vulnerable to infection' (p. 587). With respect to mosquito-borne diseases, judicious use of larvicide and insecticide, mosquito population surveillance, treated bed nets, and screened buildings play a critical role in determining the incidence of infections. So, improving the lives (including health) of vulnerable populations in poorer parts of the world means that the underlying structural, systemic factors must be addressed.

Thus, for dengue, the WHO (2018a) espouses environmental management, chemical control (i.e. larvicide and insecticide), and biological control (i.e. use of native varieties of fish in potable water tanks and open freshwater wells). As part of environmental management, the global health agency advocates piped water, waste water treatment facilities, screens on windows and doors, and mosquito bed nets (2018b). In other words, as part of the solution to the high incidence of mosquito-borne diseases, the UN agency recommends raising living standards in poorer neighborhoods where multiple diseases of poverty, including mosquito-borne diseases, are endemic. The WHO has unequivocally stated that it is committed to '[a]ddressing the social, economic and environmental determinants of health as a means to promote health outcomes and reduce health inequities within and between countries' (WHO 2017b, p. 27).[23]

So, the following question must be asked: what *kind* of solution is the environmental release of GE mosquitoes with population suppression or population replacement gene drives for the problem of the high incidence of mosquito-borne diseases among the poor in tropical and subtropical regions? Any response to that question must also take into account that the social determinants of mosquito-borne diseases are *also* determinants of various other diseases of poverty endemic in those regions.

Arguably, the use of GE mosquitoes might be taken as license by nations to avoid making policy changes that would address the social determinants of the diseases that disproportionately afflict and compromise the poor. Moreover, GE mosquitoes with patented heritable traits represent a threat to indigenous peoples' and nations' political autonomy and sovereign right over their commons *and* they might be a significant threat to ecosystems.[24]

The same sort of nuanced and contextualized response is also warranted for arguments in support of the environmental release of GE insects with gene drives as a key (or *the*) solution to the problem of agricultural insect 'pests'. The environmental release of GE insects is a solution to a problem created by the practice of industrial agriculture. Agricultural insect pests are not a significant problem for small scale organic farms (see, for instance, Powell, 2017). According to the Union of Concerned Scientists (undated), large fields of the same crop are very attractive to certain insect species that feed on those plants. As farmers attempt to combat those pests by using chemical pesticides, the insects 'respond' by evolving resistance to the chemical agents, which then motivates farmers to use more and different types of chemical pesticides, which leads to further evolutionary resistance from the insects and so on.

Proponents of industrial agricultural practice contend that it is the only way to meet the food need of growing population in low-income countries and ensure food security to the poor of the global South (Montgomery, 2017). But those sorts of claims must be treated with caution. In the 2016 United Nations Report to the General Assembly, Hilal Elver,

the UN Special Rapporteur on Right to Food notes that '[p]overty, social exclusion, gender inequality, low socioeconomic status and lack of control over productive resources, for example land-grabbing and seed patenting, are all major contributors to malnutrition (including undernutrition (i.e. lack of food experienced by the poor))' (United Nations General Assembly, 2016, p. 7). So, the problem is not inadequate amount of food being grown, but *access* to food, which is determined by a complex of socio-political-economic factors (Patel and Moore, 2018).

Whether the use of GE insects with gene drives in farming practice will result in increase in food production is not known *and* it is not obvious that it will reduce hunger among the poor. The environmental release of GE insects with gene drives also poses ecological uncertainties and risks. Moreover, the modified patented organisms present a threat to the political autonomy of nations and indigenous peoples as well as their sovereign right to their commons.

Conclusion

Deliberations about the environmental release of GE animals with gene drives must take into account the background contexts and policy failures that motivate arguments that present those GE organisms as 'solutions' to public health or agricultural insect 'pests' problems. Nations must also recognize that by virtue of the ICESCR and the ICCPR, they have an obligation to ensure that GE animals with patented heritable traits are not released without the substantive consent of all nations and indigenous peoples that could be affected. Moreover, countries must ensure that their citizens and the NGOs, corporate entities, and other organizations over whom they have jurisdiction do not act in ways that deprive other nations and indigenous peoples of the opportunity to make informed, free decisions about the presence of GE animals in their territories.

Notes

1. The term 'nations' and 'countries' are used interchangeably; the former's use does not denote an ethnically homogenous populace.
2. While all insect species are 'located' in the complex web of relationships between species in ecosystems, humans construe particular species as 'pests' if they undermine their efforts to achieve particular ends (Courtier-Orgogozo et al., 2017).
3. The terms 'genetically modified' and 'genetically engineered' are used interchangeably to denote organisms that have been manipulated in the laboratory by modern biotechnology methods such as recombinant DNA technology or gene editing. Meganucleases, zinc finger nuclease, transcription activator-like effector nucleases, and the clustered regulatory interspersed short palindromic repeats (CRISPR) associated system are gene editing techniques (Maeder and Gersbach, 2016).
4. These problems are different than the ones that the Convention on Biological Diversity's Cartagena Protocol on Biosafety and Nagoya-Kuala Lumpur Supplementary Protocol address.
5. Or some other cas protein. See, for instance, Alphey, 2016; Burt and Crisanti, 2018.
6. There are other ways of classifying gene drives, see, for instance, Marshall and Akbari's (2016) categorization of gene drives as threshold-dependent drives, threshold-independent drives, and temporally self-limiting drives. The different types of categorization schemas for gene drives represent different ways of aggregating them to serve particular purposes, be they heuristic or pragmatic (such as making the use of the modified organisms acceptable to the public).
7. What constitutes 'sufficient numbers' would depend on the type of gene drive that is used (see endnote 6).
8. HGT is the 'transfer' of genetic information to an unrelated organism; it stands in contrast to vertical gene transfer, which is transfer of genetic material from parent to child.
9. See Säterberg et al. (2013); Yoshida (2013) on functional extinction.
10. The 2016 NASEM report on gene drives considers the OX513A GE mosquito to be on a continuum with mosquitoes under development that have gene drives that rely on newly developed genetic editing techniques, such as a CRISPR/Cas9, for risk assessment purposes (p. 103).
11. See UN, *The United Nations and Decolonization* . . . for a list of non-self-governing and trust territories.
12. The idea of nationhood based on a shared ethnic identity was rejected in the wake of WWII in part because it was the justification that was used by the Nazis to affect their morally repugnant and vicious agenda of creating an 'ethnically homogenous Germany' (Gümplová, 2018, p. 180). To foster peace and territorial re-configurations by the allies as well as de-colonization, 'the right to self-determination was granted specifically to "colonised peoples", who were mostly multiethnic or multi-religious entities defined essentially by their subjection to territorial domination by a foreign colonising power. Territorial domination rather than substantive collective identity determined both boundaries and political identity. These "peoples" became prominent holders of the right to self-determination which, moreover, was understood to be uniquely fulfilled by independence and sovereign statehood' (Gümplová, 2018, p. 181).
13. It is unclear which international body would have the clout to seek redress on their behalf.
14. The conception of substantive consent is derived from O'Neill's work (see, for instance, O'Neill, 2010).
15. This conception of the autonomy of indigenous peoples also draws on the UN Declaration on the Rights of Indigenous Peoples, (especially Articles 19 and 32) (UN, 2007).
16. Coulthard (2014) argues that a colonial state that has deprived pre-existing self-determining indigenous communities of their collective rights and denied them their identity may only be willing to provide some of those peoples with some recognition as indigenous peoples provided it is able to do so on terms that permit it to continue its domination and exploitation of them and their natural resources
17. For a detailed, incisive critique of the colonial policy and practice of affording 'recognition' to (certain) indigenous groups of some of their rights to self-determination, see Coulthard, 2014.
18. It should be noted that scientific risk assessments have normative assumptions embedded in them and they are shaped by normative concerns; they are not value neutral (Meghani, 2017; Shrader-Frechette, 1991).
19. The rate at which the trait will spread is a function of the generation time of the species and a multitude of other variables, including the impact of the modification on the fitness of individuals as well as evolutionary resistance to the trait.
20. Presumably, no democratic government has the authority to give categorical rights over the natural resources of the country to a private entity. Patents are issued by federal governments and they give the patent holder the right to determine the conditions under which the patented object, process, trait or entity may be used by others for commercial or research purposes; the right is time de-limited. Nations can and do place limits on the patent holder's rights

for the sake of protecting public health or public order/welfare (Malbon et al., 2014).

21. This would be true of gene drives that replace a 'pest' trait as well as those that suppress the population of the wildtype of the species for a limited number of generations and time. The former type of gene drive would ensure a consistent revenue stream for the patent holder as would the latter kind because, presumably, when its 'effect' wears off and the wildtype population bounces back, it would be need to be used again and again.
22. While that is the intent whether it will be realized is not known given the kinds and multitudes of uncertainty, including risks.
23. The call for all communities to be provided with a safe living environment, including clean water and sanitation facilities, and an end to poverty and hunger are also expressed in the Indigenous Peoples Major Group 2015 policy brief on sustainable development.
24. The environmental risk may be present even if GE mosquitoes with population replacement gene drives are used.

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Author Information

Zahra Meghani is a professor in the Philosophy Department at the University of Rhode Island. Her areas of specialization are ethics, social and political philosophy and feminist theory. She has published articles on environmental ethics, health care ethics, and feminist philosophy.