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Published in:
Journal of Responsible Innovation

DOI:
10.1080/23299460.2020.1738023

Publication date:
2020

Routledge
Taylor & Francis Group

Journal of Responsible Innovation

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/tjri20

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To cite this article: Jason A. Delborne , Adam E. Kokotovich & Jeantine E. Lunshof (2020) Social license and synthetic biology: the trouble with mining terms, Journal of Responsible Innovation, 7:3, 280-297, DOI: 10.1080/23299460.2020.1738023

To link to this article: https://doi.org/10.1080/23299460.2020.1738023

JOURNAL OF RESPONSIBLE INNOVATION
2020, VOL. 7, NO. 3, 280–297
https://doi.org/10.1080/23299460.2020.1738023

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RESEARCH ARTICLE

Social license and synthetic biology: the trouble with mining terms

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ABSTRACT

In the wake of controversies over first-generation biotechnologies, the growing field of synthetic biology appears cognizant of the need to attend to the social, political, cultural, and ethical dimensions of innovation. Public engagement has emerged as an important means for attending to these dimensions. Here, we call attention to the problematic nature of one paradigm being drawn upon to conceptualize this public engagement for synthetic biology: social license to operate (SLO). After reviewing SLO's emergence in the resource extraction context and the existing critiques of SLO, we examine its current use in the synthetic biology literature. We argue that an SLO-derived model of engagement is especially inadequate for synthetic biology due to unique challenges posed by synthetic biology and the limited conception of engagement provided by SLO. We conclude by discussing alternative public engagement paradigms and examples better suited to inform synthetic biology governance.

ARTICLE HISTORY
Received 31 May 2019
Accepted 28 February 2020

KEYWORDS
Community and stakeholder engagement; public engagement; responsible research and innovation; social license to operate; synthetic biology

Introduction

In the wake of controversies over first-generation biotechnologies and genetically modified organisms (Delborne 2008; Kinchy 2012; Kuzma 2018; Schurman and Kelso 2003), the growing field of synthetic biology appears cognizant of the need to attend to the social, political, cultural, and ethical dimensions of innovation (Jasanoff and Hurlbut 2018; Macnaghten, Owen, and Jackson 2016; Montoliu et al. 2018). For the purposes of this paper, we define synthetic biology as an umbrella term that refers to a variety of fields using science and engineering to modify living systems, including, for example, genetic engineering, gene editing, synthetic species, and engineered gene drives (see, for example, Convention on Biological Diversity 2019; Lai et al. 2019, 1146; Redford et al. 2019, 5). As social scientists and an ethicist active in these realms of research, we have witnessed first-hand how the culture of science has begun to internalize such priorities. For example, *Gene Drives on the Horizon* (National Academies of Sciences, Engineering, and Medicine 2016) includes explicit attention to issues of responsible conduct, human values, and

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public engagement (Delborne served on this committee). More recently, the Defense Advanced Research Projects Agency's (DARPA) Safe Genes funding program announced the formation of a Legal, Ethical, Environmental, Dual-use, and Responsible innovation (LEEDR) team of experts aiming to achieve 'transparency and engagement in its Safe Genes research' (DARPA 2017) (Delborne and Lunsof served as members of research teams that received Safe Genes funding).

While these official pronouncements and related engagement activities (Buchthal et al. 2019; Hartley et al. 2019; Bartumeus et al. 2019) surrounding the development of synthetic biology offer cause for optimism, we are concerned about the emergence of a specific metaphor for justifying engagement, 'social license to operate' (hereafter, SLO). As participants in debates in this field, we have noticed a rise in the use of the term SLO to refer to the end-goal of public acceptance of synthetic biology. Delborne and Lunsof confronted this terminology in a workshop organized by the U.S. Army Corps of Engineers, Engineer Research and Development Center in May 2017, where 'Social License' was an organizing component of the agenda. According to the published technical report,

> The initial agenda for the workshop (Appendix B) refers to 'Social License,' but discussions at the workshop led to the conclusion that the term 'Social License' is problematic because it implies one-sided, commercial interest in pursuing technologies. The term 'Community Engagement' better captures the two-way learning process that is discussed here. (Warner et al. 2019, 3, footnote 1)

Motivated by this observation, we here present a more rigorous exploration of SLO's conceptual origins, measure and analyze its current use in the field of synthetic biology, and discuss SLO's potential consequences for shaping thought and action.

Public engagement is a very broad and high-level term – activities may be directed towards communities, stakeholders, and broader publics (National Academies of Sciences, Engineering, and Medicine 2016, 131; Thizy et al. 2019). Our focus here is on community engagement, where research studies and public health or environmental interventions implicate, for geographic reasons, members of a community. In this context, we address the emerging practice of intertwining the concepts of *community engagement* and *social license to operate* (e.g. Dare, Schirmer, and Vanclay 2014), in particular in the context of environmental applications of synthetic biology. Here, the ethics of informed consent arguably fall short of ensuring responsible research, as informed consent refers to decision-making by individuals, but cannot stand for community consensus (Kolopack and Lavery 2017).

To quantify the overall rise in use of SLO (often abbreviated as 'social license'), Gehman, Lefsrud, and Fast (2017) found that while news media mentioned 'social license' under ten times a year from 1997 until 2002, the frequency rose to over two-thousand times in 2016. One might interpret this trend as evidence of increasing acknowledgement of the power of the social – that decisions about research and development do not rest only in the hands of companies, scientists, and formal regulators, but also with communities. Indeed, the 'social' in SLO resonates with Social Impact Assessment, defined as 'the process of identifying and managing the social issues of project development, and includes the effective engagement of affected communities in participatory processes of identification, assessment and management of social impacts' (Vanclay et al. 2015, iv). Vanclay et al. (2015) point out that Social Impact Assessment is tightly connected with

Environmental Impact Assessment, both of which emerged in the 1970s with rising concerns about social and environmental impacts of industrial and technological development.

But SLO did not, in fact, emerge through a progressive evolution that built upon social or environmental impact assessments. Our probe of the origins of SLO, its context of use, and its rhetorical implications, suggests that the synthetic biology community would do well to abandon the language of obtaining 'social license' and instead emphasize reciprocity and mutual interaction as key pillars of community engagement (see also George, Kuiken, and Delborne 2019). As detailed below, the operations for which a social license traditionally has been sought are industrial, extractive interventions in the environment, such as mining and forestry. While we acknowledge that the meaning of a term is never completely fixed, the trouble with mining the term SLO for use in the context of synthetic biology is that the conceptual and political baggage of SLO makes it a liability in envisioning the responsible deployment of technology. In the remainder of this paper, we explore the recent use of SLO in the synthetic biology literature, describe why it is especially unproductive in the context of environmental applications, and conclude with an exploration of paradigms of engagement that offer more promise.

Origins of 'social license to operate' and existing critiques

The term 'social license to operate' (SLO) emerged in the context of extractive industries – specifically mining and forestry – in recognition that community opposition could undermine corporate operations, even if formal regulatory approval had been granted by the state (Boutilier and Thomson 2011; Dare, Schirmer, and Vanclay 2014). Thus, the notion of 'social license' implies a kind of permission at the community scale that is not embedded in a formal governmental process. At this general level, pursuing SLO fits with progressive visions of corporate social responsibility, sustainable development, and inclusive politics. But SLO does not necessarily signal altruistic motives; for corporations, the 'license' of ongoing access to resources and the reduced frequency and intensity of regulatory disputes (e.g. lawsuits or protests by locals) provide them with a significant competitive advantage.

It is beyond our scope to judge the impact SLO has had on the mining sector, where it has taken its strongest hold, but we note that substantial criticism has emerged (Kendal and Ford 2018; Owen and Kemp 2013). For example, Owen and Kemp (2013) criticize the term as fitting too neatly into corporate notions of risk management and failing to promote sustainable development: 'Even through an appreciative read, social license remains a pragmatic calculation of what is required to minimize business risk and win the degree of community support required to avoid delay or disruption to company operations' (31). Three specific critiques of SLO in the context of extractive industries strike us as most salient for considering the importation of the term to environmental applications of synthetic biology.

First, social license implies a discrete and binary outcome of seeking permission. 'License' suggests that one either has permission or does not; a license is given or revoked. In addition, licenses given through regulatory processes, which are highly bureaucratized, imply that achieving 'social license' would simply be a matter of following a series of predictable steps, including a final test that bestows ongoing permission. But no

such model exists for obtaining a 'social license.' And as vague as this process is, the revocation of social license, once obtained, is even more opaque. 'Without explicitly agreed parameters qualifying who is party to upholding the license and what the conditions are, it is impossible to determine when companies have or have not satisfied the requirements of the so called 'social license' (Owen and Kemp 2013, 32).

Second, social license fails to adequately address the complexity of social landscapes with diverse stakeholders and competing interests (Kendal and Ford 2018). There is rarely consensus concerning whether and how to pursue a community-transforming action, and issues of power and competing interests are unavoidable in these realms (Overduin and Moore 2017). For example, instead of assuming that communities are homogenous groups that share norms and understandings, it is important to pay attention to the many interests, institutional structures, and processes that constitute communities (Agrawal and Gibson 1999). Social license, by itself, offers no hint of how a process might navigate power inequalities, divergent interests, and diverse cultures of communication and governance (for an example of this void, see http://socialicense.com/index.html).

Third, social license is inspired by the need to avoid conflict and community opposition, in order to allow for smooth operations. The widely embraced 'Pyramid Model' of social license (Boutilier and Thomson 2011) places 'trust' at the highest level, indicating the optimum form a social license to operate can take: namely, when there is 'psychological identification' of the communities with the corporate project, political support, co-management, and a united front against critics. A declared goal of operating with a social license is maximizing return on investment while at the same time 'promoting the reputation benefits at the corporate level' (Boutilier 2014). Such an instrumental envisioning of community engagement undermines the potential for substantive reflection on what form projects should take and how they should adjust to ongoing environmental and social factors.

While we admit that terms can morph and new communities can appropriate terminology for their own purposes, the history of SLO in extractive contexts has the potential to bring unwanted conceptual and political baggage to the field of synthetic biology. The next section explores this notion as an empirical question.

The use of 'social license to operate' in synthetic biology

We conducted a literature search to explore the use of the term SLO in the synthetic biology context and what meanings or definitions were provided or implied. The search was completed in May 2019, and our search terms included both 'social license' and 'social licence', individually, with each of the following: 'synthetic biology', 'synbio', 'CRISPR', 'gene editing', 'gene drive', 'Esvelt', 'Target Malaria', 'Eliminate Dengue', 'Safe Genes', and 'DARPA'. The last five search terms were included because they represent major projects involving synthetic biology or people involved with them. We searched these terms in Google Scholar, PubMed, Web of Science, and Science Direct in order to approximate an exhaustive search of the peer-reviewed literature. We also conducted a standard Google search to find examples in the gray literature and popular media, but a similarly exhaustive search was beyond the scope of this article. However, a broad scan of the non-peer-reviewed literature revealed use across a variety of sectors, providing reassurance that occurrences in the peer-reviewed literature were not simply indicative of an

isolated conversation among academics (note that this exploratory search does not allow us to make quantitative inferences about the frequency of use of the term over time). In both categories, we manually reviewed the search results to exclude instances of SLO discussion not specific to environmental applications of synthetic biology.

The search described above rendered 17 articles mentioning SLO in the peer-reviewed literature on synthetic biology, all of them occurring since 2017 (see Table 1). Most of these articles discussed applications to address pests and invasive species. The exploration of the non-peer-reviewed literature found more than 50 examples of SLO use, all since 2015, from a variety of sectors: government (e.g. Althouse, Prosnitz, and Velsko 2016; CSIRO 2017; Invasive Species Advisory Committee 2017; Kannemeyer 2017; Martinez et al. 2018), popular media (e.g. Field 2017; Regalado 2016; Terazono and Cookson 2019; Manning 2019), non-governmental organizations (e.g. Revive & Restore 2015, 2017), and industry (e.g. Davies and Gutterson 2018; Diehl 2017; Jones 2016).

Across both our peer-reviewed and non-peer-reviewed literature sets, we identified three modes of assigning meaning to SLO. First, there was material that neither defined nor contextualized its use of SLO – therefore seemingly drawing upon the existing definition developed in extractive industry contexts (labeled in tables as 'None' – no definition or contextualization provided). Second, some sources explicitly defined or contextualized SLO in line with understandings from the extractive industry – emphasizing community approval and trust (labeled in Tables as 'STD' – standard definition). Third, some documents, found only in the non-peer-reviewed literature, provided a meaning to SLO that exceeded the standard definition of SLO (labeled in tables as 'ESD' – exceeding standard definition). They called for engagement that went above and beyond achieving trust and approval – emphasizing continual engagement across a variety of scales. Table 1 shows that no peer-reviewed source provided a meaning to SLO that exceeded the standard definition, but we present an example of each category in the non-peer-reviewed literature in Table 2.

Together, our exhaustive search of the peer-reviewed literature and broad scan of other media demonstrate that SLO is indeed used in the synthetic biology context, with meanings that mainly emphasize trust and acceptance, similar to the resource extraction context. In other words, SLO is used in synthetic biology discourse as shorthand for achieving the necessary societal buy-in to advance the development and deployment of a particular technology. The apparently rare exceptions to these general findings include voices that exceed the SLO standard definition by articulating a broad, early, and continuous idea of engagement (Kannemeyer 2017; Lacey and Taylor 2018).

The inadequacy of 'social license to operate' in synthetic biology

While the previous section provides preliminary empirical evidence that some of the problematic aspects of SLO have entered the discourse in synthetic biology, the use of SLO in the field of synthetic biology also raises a host of new challenges not anticipated by its emergence from the forestry and mining sectors. This section reviews four such challenges.

First, novel biological interventions are inherently plagued by uncertainty about outcomes. Communities confronting new mining or forestry operations can extrapolate from other existing operations to begin to consider potential impacts on health and disruptive alterations of the environment. The novelty of synthetic biology products – where

Table 1. Peer-reviewed articles that use the idea of social license to operate in the context of synthetic biology.

Author (Year). Title	Journal	Def. Type	Example Quotation
Baldock (2017). Towards an Affordable and Sustainable Food Supply – Recent Advances and Future Prospects.	*Cereal Foods World*	None	'Constraints on land, water, and other inputs, as well as evolving threats, including biosecurity, climate change, and social license, all create production challenges'. (304)
Baltzegar et al. (2018). Anticipating complexity in the deployment of gene drive insects in agriculture.	*Journal of Responsible Innovation*	STD	'Supra-legal social obligations are captured in the notion of the 'social license to operate' (SLO), which is an informal, tacit agreement between a business or industry and the community in which it operates'. (9)
Dearden et al. (2018). The potential for the use of gene drives for pest control in New Zealand: a perspective.	*Journal of the Royal Society of New Zealand*	STD	'We believe that a 'social licence to operate' is essential prior to the release of any gene drive for pest control in New Zealand. This will require open, honest, two-way communication that builds trust. This may take some time'. (15)
Fritsche et al. (2018). Strategies for Engineering Reproductive Sterility in Plantation Forests.	*Frontiers in Plant Science*	None	'The ability to prevent or limit pollen production from planted forests would provide relief to allergy suffers and mitigate potential social license to operate challenges'. (2)
Goold, Wright, and Hailstones (2018). Emerging Opportunities for Synthetic Biology in Agriculture.	*Genes*	None	'The agricultural sector is often cited as potentially one of the major beneficiaries of synthetic biology … the sector has a long history of early adoption of transformative innovation, including genetic technologies to decrease the use of pesticides and enhance social license' (10)
Hudson et al. (2019). Indigenous Perspectives and Gene Editing in Aotearoa New Zealand.	*Frontiers in Bioengineering and Biotechnology*	None	'Despite inclusion in existing regulatory processes and more positive interactions over the past decade and the responses of participants in this project, a widespread social license for the use of gene-based technologies amongst the Māori community is unlikely in the short term'. (5)
Latham et al. (2017). The ecology and management of mammal invasions in forests.	*Biological Invasions*	STD	'#4. Social License to Operate … if new genomic technologies are to be developed, there is an urgent need to determine if such technologies will be acceptable and what social demands might constrain their specifications and use'. (3134)
Lester and Beggs (2019). Invasion Success and Management Strategies for Social Vespula Wasps.	*Annual Review of Entomology*	None	'A so-called social license to operate is essential prior to the release of any gene drive'. (64)
Ma, Mau, and Sharbel (2018). Genome Editing for Global Food Security.	*Trends in Biotechnology*	STD	'However, public acceptance of new agrotechnologies in agriculture, especially in Western nations (e.g. Social License), arguably impedes their exploitation to support developing regions'. (2)
Mercier (2017). Bringing the 'Trickster Wasp' into the discourse on biotechnological controls of 'Pest Wasps'.	*MAI Journal*	STD	'The SLO is an important principle for the discussion of using scientific tools in a way that the public accepts. Furthermore, the scientific community needs to engage with openness and in good faith to retain an SLO'. (77)

(*Continued*)

Table 1. Continued.

Author (Year). Title	Journal	Def. Type	Example Quotation
Moro et al. (2018). Identifying knowledge gaps for gene drive research to control invasive animal species: The next CRISPR step.	*Global Ecology and Conservation*	None	'While there is a pervasive need to engage the community with the social licence to undertake gene drive research, calls to investigate new approaches for sustainable and economic landscape-wide alternatives to current invasive species population control or eradication need to also progress while being cognizant of the ecological risks'. (12–13)
Murphy et al. (2019). Conserving New Zealand's native fauna: a review of tools being developed for the Predator Free 2050 programme.	*Journal of Ornithology*	STD	'There will be an ongoing requirement to maintain and renew this social licence as new tools and technologies are developed. If this is not done, a technology that has passed proof of concept may nevertheless not be deployable'. (6)
Peck (2017). Re-Framing Biotechnology Regulation.	*Food & Drug Law Journal*	None	'To achieve public buy-in and social license to operate, it is critical that these regulations be promulgated through notice-and-comment rulemaking, rather than through the policy statements, interpretive rules, and guidance documents often used under the Coordinated Framework'. (335)
Pouvreau, Vanhercke, and Singh (2018). From plant metabolic engineering to plant synthetic biology: The evolution of the design/build/test/learn cycle.	*Plant Science*	None	'One of the major potential limitations to the development of plant synthetic biology applications might be the significant hurdles in releasing the final products to the market … Consumer acceptance and social licence are also major issues for the development of transgenic crops'. (9)
Serr, Heard, and Godwin (2019). Towards a genetic approach to invasive rodent eradications: assessing reproductive competitiveness between wild and laboratory mice.	*Island Invasives: Scaling Up to Meet the Challenge*	None	'Finally, beyond the technical issues discussed above, social license for any environmental releases would be crucial'. (68)
Thresher, Jones, and Drake (2019). Stakeholder attitudes towards the use of recombinant technology to manage the impact of an invasive species: Sea Lamprey in the North American Great Lakes.	*Biological Invasions*	STD	'Despite considerable research momentum, the degree to which there is 'social license' (Kendall and Ford 2017) to develop and apply genetic biocontrol against invasive species has not been widely canvassed, but is critical for informed decision making around the issue'. (576)
Tingley et al. (2017). New Weapons in the Toad Toolkit: A Review of Methods to Control and Mitigate the Biodiversity Impacts of Invasive Cane Toads.	*The Quarterly Review of Biology*	STD	'The production and potential release of genetically modified (GM) animals would involve community engagement – to ensure that there is social licence to undertake deployment – and regulation and policy approvals from relevant state and federal governments'. (140)

Notes: 'Def. Type' column abbreviations stand for the two categories that capture the different SLO uses: None = No definition or contextualization was provided; STD = Standard SLO definition. There are no examples in the peer-reviewed articles of uses that exceed the standard SLO definition. Full citations available in References.

Table 2. Examples of the non-peer-reviewed work that use the idea of social license to operate in the context of synthetic biology.

Def. Type	Abbreviated Citation & Source Affiliation	Example Quotation
None	Manning (2019). "Benson Hill Biosystems Acquires eMerge Genetics to Improve Nutritional Value of Crops with Gene Editing." *AgFunder News*. – Media	'Already, gene editing startups are eager to prevent their technology from meeting the same fate as GMOs and to obtain social license from the public at large.'
None	Martinez et al. (2018). "Advancing Federal Capacities for the Early Detection of and Rapid Response to Invasive Species through Technology Innovation." Washington, DC: National Invasive Species Council Secretariat. – Government	'Without public understanding of the scale and impact of invasive species, we will be unable to mobilize public support and gain social license as well as harness new solvers and new solutions to turn the grand challenges of invasive species into grand opportunities'. (19)
STD	Terazono and Cookson (2019). "Gene editing: how agritech is fighting to shape the food we eat." *Financial Times*. – Media	'Venture capital backers stress the need for gene editing companies and scientists to get what they call "social licence" to operate from the public. "They have to generate trust and explain what it is that they're doing," says Sanjeev Krishnan, chief investment officer at S2G Ventures, a US venture fund focused on food and agricultural start-ups.'
STD	Revive & Restore (2015). Meeting Report: New Genomic Solutions For Conservation Problems Workshop. April 6–9, 2015 – Sausalito, CA. – Non-Governmental Organization	'There was strong support for the potential to develop and apply novel genomic approaches to addressing the identified conservation issues. At the same time there was a marked concurrence in the need to consult broadly with publics and regulators to seek the "social license to operate" that is required before actually carrying out any of the work that was outlined'. (12)
ESD	Kannemeyer (2017). "A systematic literature review of attitudes to pest control methods in New Zealand." Landcare Research. – Government	'To secure social license for further scientific advances in novel methods of invasive pest control, social research must be integrated spatially at the local, regional and national scales and within a broader context of social acceptability and change. Social complexities exist for the ethics and philosophy of new or novel technologies, and the public attitude research is yet to be elevated to this level. For new biotechnologies to be socially acceptable, "social licence to operate" needs early and continuous engagement of the science community with society at all levels and in all areas'. (vi)
ESD	Lacey and Taylor (2018). "Asking for Permission? The Role of Social Licence in Coral Restoration." Conference Abstract. Great Barrier Reef Restoration Symposium. – Government	'Drawing on the lessons from documented cases of public values failures in climate science and frameworks for responsible innovation for novel technologies, this presentation argues for a shift away from seeking for a social licence to deploy technologies toward a more transparent and interactive process through which a range of societal actors mutually respond to the shared challenges of determining the ethical acceptability, environmental sustainability and social desirability of embedding these technologies in the world.'

Notes: 'Def. Type' column abbreviations stand for the 3 categories that capture the different SLO uses: None = No definition or contextualization was provided; STD = Standard SLO definition; ESD = Exceeds standard SLO definition. Full citations available in References.

precedents do not always exist – makes it difficult to generate reliable predictions. More specifically, the intrinsic difficulty of an accurate prediction of the effects over time and space of an engineered organism in the environment undermines the legitimacy of requesting – in advance – a 'license' for deployment with no explicit mechanism for ongoing community review and decision-making.

Second, while a mining operation can eventually be discontinued, it may be impossible to stop the spread and activity of many synthetic biology products, such as self-

propagating engineered organisms or a gene drive aimed at eliminating a pest or invasive species. Even if the SLO is somehow revoked, the biological processes that have been set off in ecosystems cannot be easily halted, and reversal – if possible at all – may require further engineering interventions (Esvelt et al. 2014). While mining and forestry operations also include elements of practical irreversibility, and landscapes and ecosystems may be left with permanent damage, the effects of such operations may be easier to contain or reverse if stopped early. In comparison, synthetic biology interventions in ecosystems have the propensity to spread across political and geographic boundaries and persist indefinitely without active countermeasures, making SLO qualitatively more problematic in the context of synthetic biology.

Third, in focusing on providing authority, SLO ignores the potential for community partnerships to shape what form the technology takes. While mining and forestry can certainly be carried out in different ways (e.g. more or less sustainable or polluting technologies and practices), the field of synthetic biology, as an engineering activity, contains great flexibility in design, form, and function. Involving a community at the stage of core design choices is very different from presenting a community with a finished product for approval. Engagement in such decision-making in an upstream manner may actually result in changes to a proposed technology that align with the community's needs and thereby lead to community acceptance (Fisher, Mahajan, and Mitcham 2006; Owen, Macnaghten, and Stilgoe 2012). The vast number of potential applications of synthetic biology, and the different forms each of those applications could take (IUCN 2019), make clear the potential for substantive community participation. The metaphor of obtaining or providing 'license' negates this potential.

Finally, SLO is fundamentally focused on the acceptance of an action – an 'operation,' which shields the phase of problem formulation from community consideration. Failing to question how problems themselves are framed not only avoids the complexity of values at play within a given community, but also minimizes the potential for creative solutions that only emerge in processes of problem re-definition (e.g. ecotourism becomes an alternative to clearcutting a forest only when the problem is re-defined as local economic development rather than maximizing timber harvests). With synthetic biology, there is an especially strong need for preliminary conversations about what problems are being solved, whose problems they are, and what other non-synthetic biology alternatives may exist (Nelson, Andow, and Banker 2009). Problem framing can make certain solutions seem appropriate or inevitable, so it is necessary to interrogate how we arrive at them (Bardwell 1991). If problem framings go unquestioned, easier and safer non-synthetic biology solutions may go unconsidered. In addition, problem formulation is especially important to interrogate because of how synthetic biology applications are often promoted as serving the public good (e.g. see Figure 7 in Esvelt et al. 2014). Any 'public good' framing deserves critical analysis, given its potential to overpower other possible problem framings and solution alternatives.

Positive visions of engagement

Our analysis makes clear that the concept of 'social license to operate' has entered the synthetic biology realm with problematic implications for how we envision community engagement. In light of the arguments we have provided, why not instead build upon a

model that is guided by community interests, features mutual interaction, and challenges power differentials that tend to cause injustice?

Indeed, there have been calls for new forms of engagement to address synthetic biology (Burall 2018; Jasanoff and Hurlbut 2018), and different paradigms already exist that offer alternatives to SLO for navigating the social dimensions of synthetic biology. One such paradigm, *Responsible Research and Innovation*, provides an overarching theoretical framework to responsibly conduct research and deploy technology by building upon the four pillars of anticipation, reflexivity, inclusion and responsiveness (Owen, Macnaghten, and Stilgoe 2012; Stilgoe, Owen, and Macnaghten 2013). A host of funding agencies and institutions working on synthetic biology in Europe have already begun to support this framework (Clarke and Kitney 2016; Delgado and Åm 2018).

We identify three important advantages of the Responsible Research and Innovation framework over SLO. First, the engagement proposed is not seeking instrumental approval of a predetermined product, but a broader discussion on the ends and potential attributes of a technology. For example, Owen, Macnaghten, and Stilgoe (2012) suggest that engagement should reflect 'not only on the uncertain products of science and innovation – their intended and unintended impacts, consequences and implications – but on their very purposes and motivations. Why do it, who might benefit and who might not?' (754). Second, this literature provides insights on how to navigate the complexities and tensions that emerge when designing engagement that accounts for power differentials and local contexts (Di Giulio et al. 2016; Macnaghten et al. 2014). For example, Di Giulio et al. (2016) explore the culturally specific nature of identifying and pursuing responsible innovation and argue that 'without such a vision of inclusion and responsiveness, not only may singularised needs and vulnerabilities be ignored … but the complexity of entanglements between identities, risks, vulnerabilities, practices and technologies may be missed' (15). Third, the focus on responsiveness, as a key element of Responsible Research and Innovation, brings to the fore questions about how to foster an institutional capacity and willingness to change the path of a technology in response to stakeholder and public values – a vital question if engagement surrounding synthetic biology is to be meaningful and consequential rather than window dressing. Because of these advantages, we call for further scholarship and experimentation in learning how to operationalize the Responsible Research and Innovation framework in the context of synthetic biology engagement.

Moving from theory to practice, we now describe two ongoing efforts in synthetic biology research and development that aim to engage communities without falling into the discursive or conceptual traps of SLO. First, *Responsive Science*, which emerged in Kevin Esvelt's 'Sculpting Evolution' group in the MIT Media Lab, has developed an approach that 'fosters open discussion, and encourages research studies and new technologies to be redesigned in response to societal feedback' (ResponsiveScience.org 2019b). The model encourages research based on proactive, open interaction between researchers and communities, beginning in the earliest stages of project ideas and continuing through deployment. It puts into practice a model of 'adaptive science' through the ongoing improvement of technologies – addressing drawbacks and weaknesses – driven by new scientific insights and methods and leveraging community input (Buchthal et al. 2019; Najjar et al. 2017). These priorities contrast sharply with the goal of achieving social license to operate, which seeks community acceptance rather than input.

One concrete example of such community engagement by the Sculpting Evolution group is a project, 'Mice Against Ticks,' which aims to employ (non-gene drive) genetic engineering methods to reduce the incidence of Lyme disease and other tick-borne disorders (ResponsiveScience.org 2019a) (Note: Lunshof has been involved in an accompanying bioethics project [Esvelt, Buchthal, and Lunshof 2017; Lunshof 2019]). In considering a problem of clear community concern (Lyme disease), project researchers reached out to community members at the earliest stage of research design (i.e. before work began on engineering a mouse). After organizing a 'direction-finding workshop' at MIT, which included ecologists, molecular biologists, medical doctors, science policy academics, ethicists, science educators, state and federal regulators, and representatives from island communities and environmental NGOs, the Mice Against Ticks team

> presented a variety of technical options to approximately 30 community members at a Nantucket Board of Health meeting … [followed by] the same presentation at a meeting of the Health Agents from the six towns of Martha's Vineyard and separately to a gathering of a [*sic*] 100 residents and island visitors at the Edgartown library. (Buchthal et al. 2019, 4)

At these meetings, community members heard about technical options that *could be pursued* by the scientific team: the type of mouse immunity, the source and arrangement of engineered DNA, and the method of mouse introduction. For each of these options, informal shows of hands and follow-up discussions served to communicate community preferences, which included a 'strong preference for immunizing mice against both Lyme disease and ticks,' and a preference for 'using only native DNA from white-footed mice if possible, ruling out a CRISPR-based local [gene] drive' (4–5).

> 'Subsequent meetings have refined these choices in light of community suggestions and concerns while remaining broadly consistent with the apparent initial preferences. Experiments for the Mice Against Ticks project did not begin until after these initial community meetings' (6).

In order to give room to concerns or critical questions voiced about the project, the Mice Against Ticks team endeavored to include such persons on the local steering committees that would guide the project. And in sharp contrast to the pursuit of SLO, the scientists publicly stated a willingness to walk away from the research if community support were to end (Esvelt and Buchthal 2017; Esvelt et al. 2017; Lunshof 2019).

Our second example comes from the Genetic Biocontrol of Invasive Rodents (GBIRd) program, a partnership of seven academic, government, and non-profit organizations that are exploring the potential of developing a gene drive mouse to eradicate invasive mice from islands where they threaten biodiversity (see https://www.geneticbiocontrol.org/; Delborne is involved in this project). GBIRd's guiding principles include (GBIRd 2018):

(1) Early and sustained consistent engagement with stakeholders and communities
(2) Proceed cautiously, with deliberate step-wise methods and measurable outcomes;
(3) Engage early and often with the research community, regulators, communities and other stakeholders;
(4) Maintain an uncompromising commitment to biosafety, existing regulations, and protocols as minimum standards (e.g. NASEM [National Academies of Sciences, Engineering, and Medicine] 2016; AAS [Australian Academy of Science] 2017);
(5) Use, and participate in developing best practices;

(6) Only operate in countries with appropriate regulatory capacity; and
(7) Be transparent with research, assessments, findings, and conclusions.

Unlike Mice Against Ticks, GBIRd has focused its engagement practices on interested and expert stakeholders, as a prelude to the future community engagement that would need to occur in selecting potential islands for field trial releases. Delborne, in his role as Co-PI of the project, 'Restoring Ecosystems and Biodiversity through Development of Safe and Effective Gene Drive Technologies' (funded by the DARPA Safe Genes program), conducted a landscape analysis based on stakeholder interviews to inform the project team of the diverse perspectives, values, and interests that surround this issue (Delborne et al. 2019). The engagement team then organized a workshop for diverse stakeholders to interact with the GBIRd project team (Farooque et al. 2019). Participants hailed from academic, government, and non-profit organizations: The Nature Conservancy, US National Invasive Species Council, US Fish and Wildlife Service, Environmental Defense Fund, Humane Society, Hastings Center, US Department of Agriculture National Wildlife Research Center, American Bird Conservancy, Foundation for the National Institutes of Health, Island Conservation, New Zealand's National Science Challenge, Australia's Commonwealth Scientific and Industrial Research Organization, and four U.S. universities (28–29). The workshop agenda addressed technological design choices for the gene drive mechanism as well as the mechanism to control the spread of a gene drive mouse; the design of 'simulated natural environments' as precursors to field trials and associated biosafety challenges; criteria for selecting an island for a future, hypothetical field trial; and strategies for future community engagement (8–9). While votes were not taken on most issues, discussions provided new insights and perspectives to the GBIRd scientific team. For example, one participant raised the question of whether driving an island population of mice to be all-male might create behavioral responses that would undermine the claim that genetic biocontrol is more humane than the use of traditional rodenticides (10-11). Regarding the simulated natural environments, participants were generally impressed with the biosafety measures but recommended greater attention to training protocols to reduce the probability of human error (16). Finally, an innovative exercise involving fictional scenarios to explore criteria for selecting a future island as the site of the first field trial yielded important insights about potential tradeoffs. Participants seemed unwilling to compromise on (1) the island being situated under the oversight of a mature regulatory regime for genetically modified organisms, and (2) a high level of biosecurity regarding public access and unassisted migration (21). Yet, some raised the possibility of relaxing the criteria that the island must not have any other species of rodent other than the house mouse, the targeted invasive species (21). Together, these activities laid the groundwork, not for achieving SLO, but for a multi-directional, ongoing, responsive, and transparent exploration of the possibilities and challenges of developing, testing, and releasing a gene drive mouse in an island ecosystem.

As social scientists and an ethicist explicitly involved in the discourse and experimental practices of engagement about synthetic biology, we call on our community to abandon the term 'social license to operate' as a way of envisioning engagement. Its historical roots bring the baggage of corporate interests seeking to avoid the 'problematic' interference of community opposition, and it metaphorically suggests a one-time approval as a kind of box to check. Unfortunately, our analysis of the recent peer-reviewed literature and scan of broader media suggest that SLO could be taking hold. While we cannot

know whether SLO's deficits explain its traction or simply have come along for the ride, the unique challenges of synthetic biology require new metaphors and models for pursuing community engagement. Our description of Responsible Research and Innovation, Responsive Science, and the GBIRd program are meant to expand the conversation and imagination of how to meaningfully acknowledge, respect, and include public values in the shaping and governance of synthetic biology.

Acknowledgements

We are grateful to Jessica Smith who provided very helpful comments on an early draft of this manuscript, as well as anonymous peer reviewers and editors for their suggestions. Jeantine Lunshof was a member of a team funded in the Fall 2016 cycle of the Greenwall Foundation's Making a Difference program for "A Mutually Responsive Approach to Developing Technologies That Alter Shared Ecosystems" (Kevin Esvelt, PI). Jason Delborne and Adam Kokotovich received funding through a cooperative agreement with the Piedmont South Atlantic Coast Cooperative Ecosystems Study Unit of the U.S. Army Engineer Research and Development Center, "Synthesizing Engagement for Synthetic Biology: Ethical and Social Considerations Surrounding the Environmental Impact of Synthetic Biology" (W912HZ-17-2-0018), 2017–2018.

Disclosure statement

Jason Delborne has been affiliated with the Genetic Biocontrol of Invasive Rodents (GBIRd) international partnership since 2016.

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