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Comments in response to the call on
The Impact of Select Agent Regulations (80 FR 13639)[1]

Establishing national and international environments conducive to the safe and secure use of biology as a manufacturing technology is a core purpose of Biosecure Ltd. We recognise the importance of having effective oversight measures to help focus, in an implementable manner, on the sub-set of activities that may pose particular biosafety, biosecurity and environmental risks. We note the important role that the Select Agent Rules (SAR) have played to date but urge that the purpose and approaches employed be re-examined in light of the current and emerging scientific and policy environments.

First, biology is rapidly becoming an information science. There is an increasing digitisation of biology. For example, published work undertaken by Novartis and Synthetic Genomics illustrates the ability to translate biological data into digital information and back again.[2] In such a world, regulatory oversight measures reliant on the physical presence of a pathogen are obsolete.

Second, biological function is no longer solely connected to taxonomy. An increasing understanding of host pathogen interactions highlights that agents not traditionally considered pathogenic can have that biological function and visa versa.[3] As synthetic biology demonstrates, it is possible to engineer function into, and out of, organisms regardless of the origin of the chassis or the parts.

Third, making things with biology is an international enterprise - from research, through development, to industrial manufacture. Efforts to produce semi-synthetic artemisinin,[4] spun off to produce fuel[5] and high value chemicals,[6] illustrate the reality of international collaboration and cooperation. A demand in one country can be met through an international research team based in a second, scaled up through a commercial relationship with a company in a third, and then produced in a fourth country. This necessitates a harmonised, level international playing field. Self-imposing stringent rules limiting access to, and raising barriers for, making things with biology has the potential to negatively affect the ability of the United States to take advantage of biology as a manufacturing technology. It could help jumpstart international competitors in developing and deploying the next major industrial platform.

Moving forwards, regulations must focus on biological function, not taxonomy and should be harmonized to provide a level international playing field. In particular:

- Research should be supported in developing, modelling, and testing function-based screening approaches. The National Academies report “Sequence-Based Classification of Select Agents: A Brighter Line”[7] should be revisited and expanded to: (i) explore

biological function more broadly, (ii) draw more heavily on the expertise of the synthetic biology community, and (iii) involve a greater range of international expertise.

- Key international partners should be brought into efforts to re-envisage the SAR as soon as possible. This is not a discussion that the US should be having alone. Existing forums for the discussion of oversight of biological risks may be unsuitable for action-focused, practical measures. Building a tailored coalition of interested partners should be considered.

- The U.S. should increase its engagement with key international processes, such as the Biological Weapons Convention, the Chemical Weapons Convention, and the Ngoya Protocol of the Convention on Biological Diversity. This should include a commitment to build coalitions of the willing around the margins of these international processes (regardless of US membership) through the injection of additional resources to help identify and take effective action to harmonize approaches around function-based screening.

References

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[4] Wolfgang Laux, "The Semi-Synthetic Artemisinin Project: Industrialization of a Synthetic Biology derived product", see: http://www.unog.ch/80256EDD006B8954/(httpAssets)/710AA8FEFF29EEBFC1257BDE003407FD/$file/BWC_MX_2013-Presentation-130814-AM-Sanofi.pdf

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[6] Derek McPhee *et al*, "Deriving Renewable Squalane from Sugarcane", Cosmetics & Toiletries, Vol. 129, No. 6 | July/August 2014, see: http://www.centerchem.com/Customer-Content/www/News/PDFs/CT1407_RenewableEmollientfromSugarcane-Amyris.pdf

[7] National Research Council, "Sequence-Based Classification of Select Agents: A Brighter Line", National Academies Press, 2010, see: http://www.nap.edu/catalog/12970/sequence-based-classification-of-select-agents-a-brighter-line