Trends in Biotechnology

CellPress

Focus Issue: 50 years after Asilomar

Editorial

Innovation and biotechnology: 50 years after Asilomar

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It was 50 years ago that the pioneers of modern biotechnology gathered in Asilomar, California to collectively discuss and share knowledge about the emerging technology that has become known as genetic modification. Bringing together the brightest and best minds that had been undertaking recombinant DNA experiments over the previous 2 to 3 years allowed the resulting guidelines that were developed for future experiments to be based on the most accurate and up-to-date science as was possible. The codification of recombinant DNA experiment guidelines paved the way for a massive explosion in biotechnology research, products and benefits.

The first 25 years of biotechnology innovation proceeded relatively unhindered by externally motivated regulations. The guidelines developed by experts at Asilomar served as the basis of regulatory systems in countries, predominantly industrially developed ones, that engaged in recombinant DNA research. The 1980 United States Supreme Court ruling in *Diamond v. Chakrabarty*, determining that genetic innovations were patentable, further contributed to increased investments into the emerging technologies [1]. One of the first was the development of genetically modified (GM) insulin during the early 1980s, which is still a successful product today[i]. Genetic modification technology was used to develop new yeast and other microbial technologies that brought benefits to food-processing industries. Further successes followed during the mid-1990s with the commercialization of GM crops[ii]. As the third millennium arrived, the future of biotechnology seemed bright, with multiple innovations on the cusp of commercialization.

The predominantly risk-appropriate regulations that accompanied the first 25 years of biotechnology were rapidly derailed at the start of the 21st century. Pressure from activist and environmental organizations, perhaps politically rather than scientifically motivated, resulted in needless regulations and regulatory burdens. The once-bright future of biotechnology dimmed considerably, as governments in greatest need of increased food production and human health innovations enacted stifling regulatory barriers, with many actually banning the use of biotechnology. One result of these bans and barriers is that hundreds of millions of individuals continue to face food insecurity, as higher yielding and more nutritious varieties have been prevented from production in their countries. This is especially the case in Africa, where one in five lack a sufficient food supply on a daily basis[iii]. Even industrial countries have enacted stricter-than-necessary regulations, as witnessed by the EU having to deregulate its pharmaceutical biotechnology regulations in 2020 to allow for clinical trials of the new mRNA coronavirus disease (COVID) vaccines.

The past 25 years of opposition to biotechnology have contributed to the politicization of science. Innovative microbes, drugs, vaccines, crops, fish, livestock, and insects have all encountered significant regulatory delay before commercialization in many countries, if the technology has even been commercialized at all. This issue of *Trends in Biotechnology* explores the relationship between regulation and innovation in biotechnology, with special attention to agriculture and human health. First, an opinion article by Ludlow and colleagues discusses what it means for a regulation to be risk appropriate and science based [2]. Three additional articles then consider how regulation can support, or stifle, innovation. Lubieniechi and colleagues give their opinion about

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risk assessment in genetically engineered crop plants and livestock [3]. Dederer shares an opinion about the regulatory approach to pharmaceuticals either derived from or containing GM organisms and provides an outlook toward emerging technologies such as gene therapy [4]. Finally, Thakor and Charles review the regulatory uncertainty surrounding GM microbes, particularly their application to plant growth [5].

If the food security and health of humanity have any hope of dramatic improvement over the next 25 years, then governments will need to reject politically motivated opposition to biotechnology and respect the 50 years of safety as well as the economic and environmental benefits that have accrued following adoption. Progress toward many of the United Nation Sustainable Development Goals, such as No Poverty, Zero Hunger, and Good Health and Well-Being, may stagnate due to risk-inappropriate regulation. For significantly reduced food insecurity and dramatically improved human health by 2050, there needs to be a global return to the wisdom of the pioneers of biotechnology and the risk-appropriate regulations they envisioned and developed.

Resources

[i]www.fda.gov/about-fda/fda-history-exhibits/100-years-insulin

[ii]www.newscientist.com/article/mg14219301-100-transgenic-tobacco-is-european-first/

[iii]www.fao.org/newsroom/detail/hunger-numbers-stubbornly-high-for-three-consecutive-years-as-global-crises-deepen–un-report/en

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4. Dederer, H.-G. (2025) Human health and genetic technology. *Trends Biotechnol.* 43, 522–532
5. Thakor, A. and Charles, T. (2025) Recombinant DNA: Unlocking untapped microbial potential for innovation in crop agriculture. *Trends Biotechnol.* 43, 533–539