WHY A NEW REGULATORY FRAMEWORK FOR BIO-PRODUCTION ?

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OECD
BETTER POLICIES FOR BETTER LIVES

OECD (1992)

"The OECD report, *Recombinant DNA Safety Considerations*, published in 1986, set out a concept called "Good Industrial Large-Scale Practice (GILSP)" applicable to intrinsically low-risk r-DNA organisms used in industrial production. The concept encompassed certain criteria which an r-DNA organism must meet in order to be given GILSP status.

It stated that r-DNA GILSP organisms can be handled, on a large scale, under the same conditions of minimal controls and containment procedures as would be used for the host strains. The key principle for GILSP is that the r-DNA organism should be as safe as the low-risk organism from which it is derived".

OECD (1992). Safety considerations for biotechnology 1992

European Commission (2010)

"This new publication presents the results of 50 projects, involving more than 400 research groups and representing European research grants of some EUR 200 million. This figure brings the total Commission funding of research on GMO safety to more than EUR 300 million since its inception in 1982 in the Biomolecular Engineering programme"...

"The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies".

European Commission (2010). A decade of EU-funded GMO research (2001 - 2010)

Bergeson (2015)

"Given the mind-numbing complexity of the jurisdictional maze, it is completely unclear how a new product developer would begin the regulatory approval process, as none of these issues is intuitively self-evident. Little guidance exists to direct innovators to the appropriate agency and office within that agency to begin the review process, let alone outline what that process is, how long it might take, and how much it might cost before the product can be commercialized. Yet these are the very questions for which financial backers demand answers often as a predicate for funding".

Bergeson (2015). *Industrial Biotechnology* 11, 237-245.

Keasling (2015)

"Regulation is another challenge for the field, and it is also rather complex...Experiments are classified into six categories based upon the number of regulatory hurdles they are required to clear to receive approval. Additionally, the EPA, USDA and the FDA regulate the use and commercial production of genetically modified microbes, plants, and food and drugs".

"In both locations (*US and EU*) the task of getting engineered organisms approved for use ranges from challenging to very challenging. Companies spend a significant amount of money and time on meeting regulatory requirements, delaying progress by years, and sometimes decades".

Keasling (2015). *International Innovation* 185, 24-25.

National Academy of Sciences (2015)

"Beyond standards, an updated regulatory regime is needed to speed the safe commercialization of new host organisms, new metabolic pathways, and new chemical products. Such regimes must be harmonized across national boundaries, enabling rapid, safe, and global access to new technologies and products".

NAS (2015). Industrialization of biology: a roadmap to accelerate the advanced manufacturing of chemicals. ISBN 978-0-309-31652-1

Mandell et al. (2015)

"Our results demonstrate that mutational escape frequency under laboratory growth conditions is a necessary but insufficient metric to evaluate biocontainment strategies".

"Therefore, the expanded genetic code of GROs can be exploited both to prevent their undesired survival in natural ecosystems and to block incoming and outgoing HGT with natural organisms".

Mandell et al. (2015). *Nature* 518, 55–60.

Key issue for future OECD work

- Is it possible to design laboratory standard tests that can be "*harmonized across national boundaries*" that:
  - Guarantee an acceptable level of biocontainment ?
  - Can be readily performed by standards laboratories?
  - Can be legalised?
  - Will shorten and streamline the regulatory process to enable business ?