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For the European Federation of Biotechnology (EFB) "Synthetic Biology" is not a new and emerging issue, rather it reflects a continuum of advances in biotechnology. The EFB strongly supports the EU aim to promote a knowledge-based bio-economy. We therefore urge European decision makers to provide a framework in which scientific developments, including applications of so-called Synthetic Biology, can flourish while addressing safety concerns for those cases where caution is justified.

EFB supports the commonly-held view that there is no need to develop a new regulatory framework for Synthetic Biology. In those cases where a product incorporating Synthetic Biology falls under the scope of the GMO legislation and/or the Cartagena Protocol on Biosafety, existing regulatory oversight is adequate for current and foreseeable Synthetic Biology applications.

"Synthetic biology" covers a wide range of potential applications, making it impossible to define it in a way that is meaningful and future-proof for the range of potential applications, products and sectors. EFB signals that operational definitions presented so far -e.g. as developed by the Ad Hoc Technical Expert Group on Synthetic Biology in the framework of the Convention on Biological Diversity- are too broad, too vague and will impact life science applications beyond the intended scope.

EFB supports the position that current applications of Synthetic Biology are adequately regulated by existing regulatory frameworks. Therefore the development of a new regulatory framework specific to Synthetic Biology is unnecessary, duplicative and potentially damaging to the EU objective of promoting a knowledge-based bio-economy.

Furthermore, technologies are rarely totally safe or unsafe. Using technologies as a basis for regulatory oversight creates unfound discrimination between similar products developed by different techniques. By stigmatizing a broad group of techniques, an inconsistent picture emerges that confuses, inspires fear and leaves a sense of lack of control. EFB stresses that the safety assessment of products, including those from Synthetic Biology, should be based on their characteristics that determine safety, and not on the use of specific techniques to produce them.

In this respect, EFB believes that it is premature to ask the AHTEG on Risk Assessment and Risk Management under the Cartagena Protocol to establish a process for the development of guidance on risk assessment of LMOs developed through Synthetic Biology. Instead, effort should be focused on the identification of any gaps where existing guidance is inadequate.

The EFB and its members will continue to be a partner in this dialogue which is essential for successful life science research and development in the European Union.

The European Federation of Biotechnology (EFB) is Europe's non-profit federation of National Biotechnology Associations, Learned Societies, Universities, Scientific Institutes, Biotech Companies and individual biotechnologists working to promote biotechnology throughout Europe and beyond. The mission of EFB is to promote the safe, sustainable and beneficial use of the life sciences, to promote research and innovation at the cutting edge of biotechnology, to provide a forum for interdisciplinary and international cooperation, to improve scientific education and to facilitate an informed dialogue between scientists and the public. With more than 100 Institutional members from across Europe and more than 30,000 personal members, the EFB has 14 Regional Branch Offices in Europe to support its activities in the various areas of biotechnology covered by the Federation.