Overview of biosafety regulations of Living Modified Organisms to support the future regulatory status of precision breeding products in neighbouring countries to the European Union

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INTRODUCTION

The use of Living Modified Organisms (LMOs), or Genetically Modified Organisms (GMOs), is regulated under international and national biosafety law. Most countries have adopted the legal definition of LMO according to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity into their domestic biosafety legislation to regulate the use of LMOs. In certain jurisdictions, however, a somewhat different definition has been adopted that may or may not align in every respect with the LMO definition. For example, the European Union (EU) regulates GMOs based on Directive 2001/18/EC. Precision breeding represents a new challenge for national biosafety regulators when applying the legal definition of LMO or GMO. The consequence of this is that some precision breeding techniques result in organisms and products that cannot be genetically distinguished from their conventionally developed counterparts. Currently, there is no international consensus on whether or not precision breeding products will be subject to regulation. As such, most countries require legal clarity to assess whether precision breeding products will be included under the LMO/GMO definition.

METHODOLOGY

The purpose of this study is to provide an overview of biosafety regulations of LMOs/GMOs in 27 countries near the EU. To support engagement of relevant countries in the COST Action global network, these countries are Armenia, Albania, Algeria, Azerbaijan, Belarus, Bosnia and Herzegovina, Egypt, Georgia, Iceland, Israel, Jordan, Lebanon, Libya, Montenegro, Morocco, North Macedonia, Norway, the Republic of Moldova, the Russian Federation, Serbia, the State of Palestine, Switzerland, the Syrian Arab Republic, Tunisia, Turkey, Ukraine and the United Kingdom. This review will serve as a baseline contributing to further discussions about the potential future regulatory status of precision breeding in these targeted countries. This is done by revising national biosafety legal frameworks, including legal and regulatory measures, and results from a recent online survey for key stakeholders, including biosafety regulatory officers and biotechnology researchers, in the targeted countries. Most comparative reviews on biosafety policy and regulatory developments have

been focused in other countries and regions, but this is the first time a comprehensive overview that includes all of these 27 countries is presented.

RESULTS

Our results classify countries in four main groups based on the approach they adopt to define LMOs/GMOs under domestic biosafety legislation. As such, the key criterion for the clustering of countries is whether the national legislation has adopted the legal definition of GMO under EU law, Directive 2001/18/EC on the deliberate release into the environment of GMOs, or the LMO definition under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Our study also shows that few countries have authorised the use of LMOs/GMOs for primarily R&D activities, whereas many other countries have established a ban on the import and cultivation of LMOs/GMOs. In addition, our results indicate that only one country (Israel) has adopted a legal instrument to determine the regulatory status of precision breeding products, and initial discussions are currently under way in 11 of the targeted countries. Lastly, our study identifies 25 research institutes currently working with precision breeding technologies in plants under containment and/or confinement in 10 of the targeted countries.

DISCUSSION

This article highlights that the definition and interpretation of terms such as ‘in a way that does not occur naturally’, ‘manipulation’ and ‘a novel combination of genetic material’ are a crucial first step to assess the regulatory status of products derived from precision breeding technologies. Also, countries require the adoption of administrative procedures and application forms for the determination of the regulatory status of precision breeding products. Lastly, this article suggests that the need to adopt such procedures relevant to precision breeding and, also, to implement biosafety regulations, is strongly connected to the role of agriculture and biotechnology in the countries and to national economic and socio-political perspectives. This study is supported by COST Action CA18111 ‘Genome editing in plants – a technology with a transformative potential’ (PlantEd), through the Short Term Scientific Mission.