Food and Agriculture Organization of the United Nations

MINISTRY OF AGRICULTURE OF THE CZECH REPUBLIC

FAO expert consultation

"Review of biosafety regulatory systems: focus on genome editing and compatibility with relevant international agreements"

28-30 August 2018, Prague, Czechia

Project GCP/INT/790/CEH

Introduction

Since the first publications of the recombinant DNA techniques, Governments have applied a two-track policy towards modern biotechnology that can be summarized as 'maximising benefits and minimizing risks'. Maximising benefits, such as for improved food and nutritional security, climate change adaptation and mitigation, decreased pressure on natural resources through circularity while increasing the biomass, is typically done through research strategies and investments, while actions for minimizing risks are usually taken through designing and implementing national biosafety systems and regulations.

The Cartagena Protocol on Biosafety (CPB) to the Convention of Biological Diversity (CBD) entered into force in 2003 and contains procedures for transboundary movement of living modified organisms (LMOs) in the period while Parties develop and adopt their national legislations on biosafety. Parties to the CBD and CPB have the obligation to take the necessary and appropriate legal, administrative and other measures to ensure an adequate level of protection in the field of the safe transfer, handling and use of 'living modified organisms resulting from modern biotechnology' that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. An important element of that task is to implement its obligations under the CBD and CPB in a way that is consistent with its other international obligations, such as in the frame of the World Trade Organisation (WTO), the UNECE Convention on access to information, public participation in decision-making and access to justice in environmental matters (Aarhus Convention), the International Plant Protection Convention (IPPC) and others.

A key element of these international agreements as well as of any national legislation is to periodically review and assess regulatory frameworks and their implementation. This includes a review of the text in terms of clarity, applicability, consistency, proportionality, workability, and enforceability. Review of the text for clarity and applicability is particularly important in the light of new scientific developments, such as genome editing. Review for consistency refers to consistency with both the national regulations and international agreements. Assessment refers to an evaluation of the implementation of the regulatory frameworks in terms of effectiveness, efficiency, socio-economic impacts and impacts on the regulated sectors.

The countries with economies in transition in Europe and Central Asia with exception of Uzbekistan and Turkmenistan are parties to the CBD and most of those (except the Russian Federation) have also ratified the CPB. However, being at very different stages of preparation, adoption and enforcement of their domestic legislations on biosafety and may experience challenges in the implementation of the regulations. The recent accession to the WTO by a great number of these countries, and the trigger of regional trade integration processes (accession to European and Eurasian Unions) is placing additional challenge in making the national biosafety regulations compatible with the relevant international agreements.

The expert consultation follows a series of similar biosafety events with focus on Eastern Europe and Central Asia, organized in Prague in the years 2006, 2008, 2013, 2015 and 2016 in collaboration with FAO and the Czech government in the frame of the project GCP/INT/790/CEH.

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Objectives

The objectives of the FAO expert consultation on 28 – 30 August are to:

(i) Raise awareness about the review of the national biosafety regulations
(ii) Contribute to the current discussions on genome editing taking into account the maximizing of benefits and minimizing risks approach
(iii) Discuss compatibility with international agreements and discuss the draft FAO Compatibility guide
(iv) Share experiences and the practices in different countries in the region.

The *modus operandi* will be introductions of technical papers to the specific topics by various experts and discussion, updating and validation of the technical papers, which can serve as practical checklists for review and assessment of regulatory frameworks, including on compatibility with relevant international agreements.

Topics

- WTO-SPS compatibility with domestic biosafety regulations, while other international agreements such as the Aarhus Convention, the Nagoya-Kuala Lumpur Protocol on Liability (CBD) and IPPC will be also discussed
- GENOME EDITING:
  - Benefits for improved food and nutritional security climate change adaptation and mitigation, decreased pressure on natural resources through circularity while increasing the biomass in agriculture, livestock and food systems
  - Regulation and risk assessment

Expected outputs:

- Technical papers on (i) the applications of NBTs for improved nutrition, climate change adaptation and mitigation etc.; (ii) regulatory aspects of NBTs; (iii) national biosafety systems' compatibility with international agreements
- Collection of additional examples of biosafety provisions that are likely to be consistent with the CBD and the CPB, and examples of provisions that have been found inconsistent with other international obligations. (The World Trade Organisation (WTO/SPS), The Aarhus Convention, IPPC) and examples of regulatory decisions that have been found inconsistent with other international obligations (e.g. drawing for example from WTO panel conclusions).
- Validated guide

Participants are experts from Armenia, Azerbaijan, Serbia, Turkey, Moldova, Belarus, Kyrgyzstan, Kazakhstan, Tajikistan, Czechia, Ukraine; BSBA, BSEC, Pannonia Biotechnology Association, CSOs and private sector.