Moldova's National Biosafety Frameworks: progress and needs in risk assessment

Central and Eastern Europe Training course on Risk Assessment of Living Modified Organisms

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Moldova geo-political background

Ex-soviet country in transition facing challenges and changes, balancing between west and east

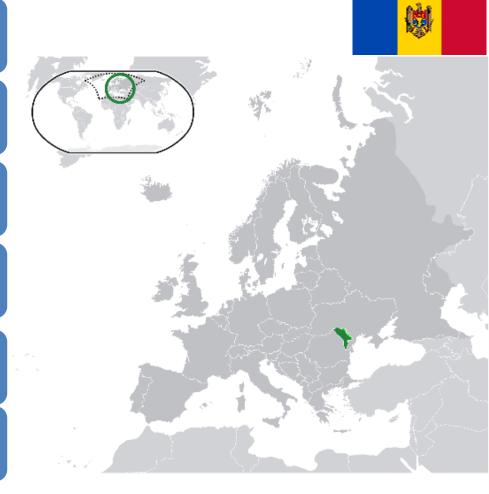
EU-Moldova Association Agreement signed July 27, 2014 (Benefits from Deep and Comprehensive Free Trade Areas (DCFTAs)

Multinational country with integrity issues – Transnistrian separatist republic & Gagauzian autonomous unit

Dependence on energy imports, but rather high expectations from alternative sources in the future (including projects of EU financial assistance)

At least 1/3 of population working abroad (remittances to budget), labour is a problem

EU is Moldova's biggest trade partner (66% of exports, mainly Romania), then Russia (10%) and Belarus (6%)



Moldova eco-geographic background

Landlocked small hilly-steppe country neighboring with Romania and Ukraine

74% of the land meant for agriculture (over ¹/₄ of GDP is from agro-farming)

14% is forest vegetation (half of natural origin, half plantations)

PA index is 5,61% (mainly paper PAs, including 3 Ramsar sites, 1 National Park)

Chernozem soil, the most fertile in the world, covers 75% of country's land



Country profile in agriculture

- Agriculture is an important branch of the national economy of the Republic of Moldova due to the fact that the productive sector of the economy has, in general, an agroalimentar character.
- The most part of population is involved in the agroalimentar sector of the economy and are the rural habitants (58,5% of population).
- To be mentioned that agriculture lands occupy 75% of the country's territory and the income value of the GDP from the agriculture sector is 14,2% (2016).

Country profile in agriculture

- The total surface area of agriculture land constitute approximately 1500 thousand ha (except Transnistria). The cereals and leguminous plants occupy about the 65% of the territory, inclusive 43% - spring cultures.
- Important crops are winter and spring grains, including wheat, barley and maize, as well as potatoes and other vegetables and horticultural crops and fruit.
- About 60% of the country's agricultural output is produced by individual farmers and household plots of 10 hectares or less.

Resources of agricultural plants

- A wide range of species is used in the agriculture, forestry, horticulture and floriculture of the Republic of Moldova.
- For example, 95 species represented by 560 sorts and hybrids of crops (cereal, technical, fodder, fruit-growing, vegetable etc.) are used in agriculture.
- Most of them (80%) have been introduced from other floristic regions.
- Local agricultural plant varieties (grape-vine, apple tree, pear tree, cherry tree, plum tree, kidney bean, chickpea, horse bean) are cultivated in individual farms.
- For example, about 350 genotypes of bean were gathered from individual farms.

Biotechnologies and genetically modified organisms

- Research in the field of biotechnology and genetic engineering has been recently started in the Republic of Moldova. The usage of some biotechnological methods in agriculture and medicine are considered priority activities. In the field of biological methods in agriculture, there is a tendency of gradual switching to using biological preparations instead of chemicals and to cryoconservation of gametes of breeding animals. Biotechnological methods are used in pharmaceutics to create some biologically active substances.
 - The permanent activities of ensuring the safe handling and use of biotechnologies and genetic engineering have a great importance.



National Regulations on Biosafety

- Law on Biosafety (No. 755 –XV of 21.12.2001).
- Law ratifying the Cartagena Protocol on Biosafety to the Convention of Biological Diversity (No. 1381-XV of 11.10. 2002).
- Government Resolution concerning the National Commission on biological safety (No. 603 of 20.05. 2003).
- Government Resolution on Regulations concerning the issuance of permissions for various types of activities related to the testing, manufacture, utilization and creation of genetically modified organisms (No. 1153, of 25.09. 2003).
- Governmental Resolution on labeling of food products and the standards on labeling of housekeeping chemical products (No. 996 of 20.08.2003).
- Law on ecological agro-food production (No. 115-XVI of 09.06.2005).



National Regulations on Biosafety

- Biosafety Action Plan for 2009-2015 , approved in May 2009
- UNEP-GEF Implementation of the National Biosafety Framework for Moldova project, 2006-2010
- FAO Regional TCP project on biotechnology and biosafety for Armenia, Georgia and Moldova, 2009-2011
- Environment Action Plan for 2014-2023 (Government Resolution No. 301 of 24.04.2014)
- Strategy in food security for 2017-2022
- Law on GMOs (...has been in Parliament for two years for approval ?!)



Strengthen the national regulatory regime:

- Biosafety law revised, amended and harmonized in line with the requirements of the European Union
- Sectorial laws amended and completed in environment, agriculture, health care, standardization: Law on Environmental Protection, on Seeds, Protection of Plant Varieties, Horticulture, Phytosanitary Quarantine, Animal Breeding, Public Sanitary Epidemiological Security. Health Care, Protection of Consumer Rights, Standardization, Metrology
- New secondary regulation to support the LMO Law is developed to ensure monitoring, inspection, control, custom control procedures, risk assessment, LMO register, packaging, labelling and transportation, public information and participation and now is under consultation and approval process

Strengthen the national administrative system for handling requests:

- Roster of experts for Risk Assessment appointed and approved
- Criteria for experts were elaborated
- Guidelines elaborated on how to perform Risk Assessment on environment and biodiversity conservation
- Technical Committees within Ministries and Departments appointed to be involved in Risk Assessment procedures
- Check-list for Risk Assessment practitioners developed
- Guidelines and manual for Risk Assessment of main agricultural crop varieties (soy bean, maize, sugar beet) written and under publication
- Electronic Template for LMO Register placed on BCH web-site

Main challenges:

- No notification submitted for approval and therefore no practical case of Risk Assessment procedure application
- Experts are good scientists but have no experience in Risk Assessment
- Therefore there is a need in training and education.



Main Barriers and Challenges

- Lack of experienced or authorized experts on Risk Assessment
- Inappropriate data and/or lack of databases
- Insufficient national methodologies for assessment and evaluation
- Insufficient scientific data and arguments regarding adverse risks of LMOs
- Experts on Risk Assessment have no sufficient experience and knowledge to provide RA procedures
- Insufficient level of awareness of public and decision-makers



We also render thanks to:

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This is Moldova!



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