Al-Farabi Kazakh National University (KazNU)

Faculty of Biology and Biotechnology

DISCIPLINE: «Modern Problems of Plant Genetics»

Lecture 6

Risk and safety assessment of genetically modified plants.

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Aim of the lesson: **familiarization with risk and safety assessment of genetically modified organism (GMO).**

Plan of the lesson:

1. **Biosafety and regulation of genetically modified plants.**
2. **Risk and Safety Assessment of RNA Interference – Based Genetically Modified Plants.**
3. **Techniques for Genome Editing.**
4. **Risk and safety assessment of genetically modified foods.**
5. **Modern biotechnology and the threat of bioterrorism.**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

- **A variety of techniques are available to select and introduce desirable traits in plants ranging from conventional breeding techniques and genetic engineering to a growing number of modern biotechniques, including genome editing.**

- **Each of these techniques to modify plant genomes is expected to remain in use to different extents.**

- **Products of genetic engineering are a reality in our daily lives—whether as industrial and medicinal applications or for animal and human consumption.**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

- **In comparing conventional breeding techniques, established techniques of genetic modification, and new breeding techniques, the European Commission (EC)’s Group of Chief Scientific Advisors concluded that (a) assessment of safety can only realistically be made on a case-by-case basis and depends on features of the end product, and (b) genetically and phenotypically similar products deriving from the use of different techniques are not expected to present significantly different risks.**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

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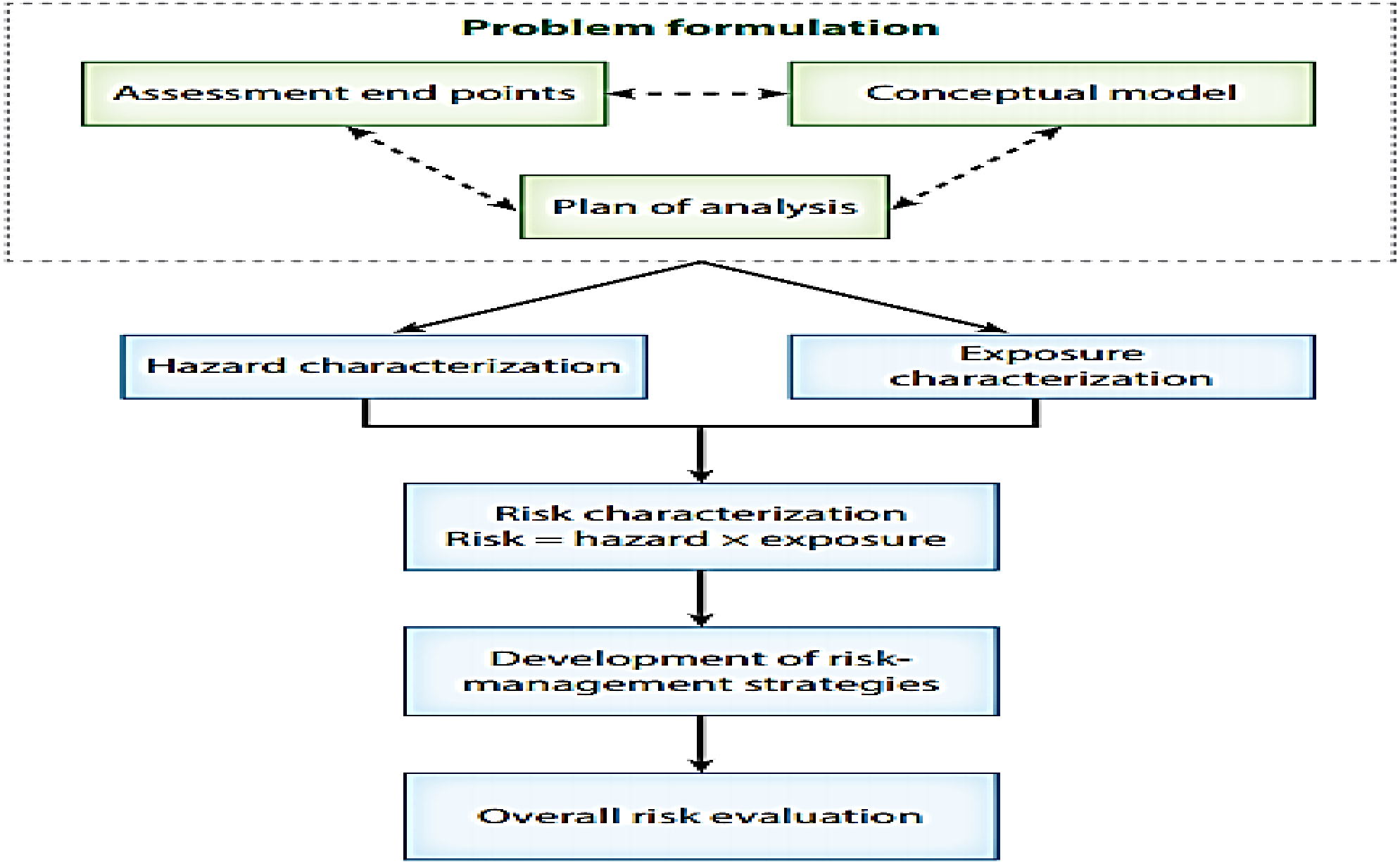
- **In line with these important conclusions, the European Academies Science Advisory Council states in its policy report on genome editing that there should be full transparency in disclosing the process used, but the aim should be to regulate the specific agricultural trait or product rather than the technology by which it is produced.**

- **Consequently, products of modern biotechniques would be excluded from a specific regulation if the genetic changes they produce are similar to, or indistinguishable from, a product of conventional breeding and if no novel, product-based risk can be identified.**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

- **The risk assessment process of GM plants follows an internationally harmonized, multi-step approach to identify and characterize possible hazards and to determine the likelihood of harmful outcomes.**

- **Assessments conclude about the possible risks posed by particular GMOs and the need to implement risk management measures (Figure 1).**



- **Core steps of the risk asessment process of genetically modifid (GM) plants (Figure 1).**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

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- **Problem formulation is the fist step of the risk assessment process, which provides a logical and traceable framing approach to downstream risk assessment steps and which assures that the provided information is relevant for decision making.**
- **Problem formulation starts with the identifiation of potential adverse effects (hazards) by considering the characteristics of the GM plant and its closest non-GM counterpart.**
- **Using this comparative approach, it elucidates possible pathways to harm by which the GM plant may adversely affect human and animal health or the environment.**

* BIOSAFETY AND REGULATION OF GENETICALLY MODIFIED PLANTS.

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- **Despite t he existence of general principles, GM-plant regulation differs between jurisdictions. One major difference relates to the legislative trigger that determines the need for regulatory oversight (novelty of product versus nature of the applied technique).**
- **The diversity of strategies and standards for G M plants might be caused, among other things, by the fact that not all countries (e.g., Argentina, the United States, and Canada) follow the Cartagena Protocol on Biosafety, which was adopted in January 2000 at the Convention on Biological Diversity and entered into force on September 11, 2003.**
- **The Cartagena Protocol on Biosafety facilitated the establishment of national biosafety regulatory systems with the objective of contributing “to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modifid organisms resulting from modern biotechnology”.**

* RISK AND SAFETY ASSESSMENT OF GENETICALLY MODIFIED PLANTS.

- **Environmental Risk Assessment**
- **For the cultivation of GM plants carrying an insecticidal trait e.g., which produce an insecticidal protein, such as a Cry protein from *Bacillus thuringiensis* (Bt)], the risk to biological control organisms can be grouped in three categories:**
- **(a) The plant transformation process may have introduced potentially harmful, unintended changes;**
- **(b) the insecticidal protein may directly affect**
- **nontarget species (toxicity); and**
- **(c) indirect effects on biological control may occur because of changes in crop management or to crop-based arthropod food webs.**

* Risk and Safety Assessment of RNA Interference – Based * Genetically Modifid Plants.

- **Posttranscriptional RNAi is an efficient tool for studying plant gene function and has been used for crop improvement for a long time. For RNAi-mediated gene silencing, dsRNA has to be produced as a trigger.**

- **This can be achieved via genetic modification by the introduction of sense, antisense, or hairpin (hp) constructs homologous to the respective target gene or by infection with a recombinant plant virus carrying part of the target gene in an approach termed virus-induced gene silencing.**

* Risk and Safety Assessment of RNA Interference – Based * Genetically Modifid Plants.

- **An early example of an RNAi-based GM plant is the FLAVR SAVR tomato with reduced polygalacturonase expression and delayed fruit softening. More recently, RNAi has been applied to obtain GM plants with improved nutritional value and enhanced product quality.**

- **Some of these plants have been deregulated and commercialized in several countries. They include soybean with high oleic acid and low linoleic acid, non browning ArcticTM apple, and potato with reduced acrylamide formation and black spot resistance.**

* Techniques for Genome Editing.

- **Subsequently, researchers using artificial zinc-finger nucleases (ZFNs) could achieve endogenous gene targeting but with low efficiency (23). However, over the past few years, the development and application of meganucleases, ZFNs, transcription activator-like effector nucleases (TALENs) designed in a more sophisticated manner, and, most recently, CRISPR/Cas9 systems increased the editing efficiency and resulted in various site-directed gene-editing events in a growing number of plants.**

RISK AND SAFETY ASSESSMENT OF GENETICALLY MODIFIED FOODS.

Everyone is interested in the question: does consuming genetically modified foods pose any additional health risks compared to consuming conventional foods bred using selective breeding methods? It should be noted that GMO products differ from conventional ones by the presence of genetically modified DNA and proteins that are foreign to humans.

It is believed that foreign DNA, purely hypothetically, can be integrated into the cells of the body or into bacteria that form the intestinal microbiota (microflora). However, DNA entering the digestive tract undergoes cleavage and loses its ability to encode proteins.

RISK AND SAFETY ASSESSMENT OF GENETICALLY MODIFIED FOODS

For example, a huge amount of foreign DNA from fish, meat, and plant foods enters the digestive tract. However, there are no consequences in terms of changes in the genetic properties of human cells or intestinal microbiota.

All attempts by researchers to prove that foreign DNA can be integrated into the genome of body cells and lead to the production of foreign protein have proven fruitless. It was also not possible to scientifically prove the fact that such DNA enters the bacteria of the intestinal microbiota and changes their properties.

Eating foods containing GM organisms does not pose any risks, as confirmed by scientific research. There are no proven facts of harm to human or animal health from eating GM organisms or their products.

THE RISKS OF GENETICALLY MODIFIED PRODUCT

The risk of eating foreign proteins may be associated with their toxic effects, effects on various body systems and the occurrence of allergic reactions. Therefore, before using a specific GM organism in the food industry, a comprehensive examination of its safety is carried out.

It should be noted that all assessments carried out by the European Food Safety Authority (EFSA) did not reveal increased allergenicity of approved GM products. Thus, although hypothetically the production of proteins in a GM organism as a result of GM modification may have negative effects when consumed as food, their absence is guaranteed at the stage of biomedical safety assessment.

ADVANTAGES OF APPLICATION OF GMOS IN AGRICULTURE

According to modern scientific ideas, the cultivation of GM crops is economically feasible and safe. Breeding GM plants and breeds of GM animals has advantages in terms of nutritional value, increased yield, food safety, reduced use of pesticides, and minimization of the impact of anthropogenic activities on natural ecosystems.

This is evidenced by the fact that the total area sown with biotechnological crops in the world amounted to 175.2 million hectares in 2013, which is more than the entire area of arable land in Russia. In 2013, GM crops were sown in 27 countries, including 5 EU countries. The top ten in terms of crop area are the United States and all BRICS countries, except Russia. In total, 60% of the world's population lives in countries that sow genetically modified crops. Mainly genetically modified soybeans, corn and cotton, and some types of vegetables are grown.

ADVANTAGES OF USING GMOS IN AGRICULTURE

According to Klumper and Qaim (2014), the use of GM technologies can increase yields by 22%, producers' profits by 68%, while reducing the use of pesticides by 37%. GM plants have unique properties: resistance to pests and herbicides - weed control agents.

The global reduction in the use of herbicides and insecticides as a result of the introduction of GM technologies is 0.2 million tons per year. The herbicide content in the final product is reduced by up to 10 times. As a result of the use of GM crops, the population and diversity of insect pests and weeds in farmland areas is reduced.

Safety of GM products

Existing sanitary requirements are sufficient to ensure the safety of new products. Russia has an effective sanitary control system.

Rosportebnadzor carries out state registration of products with a comprehensive risk assessment and taking into account the GMO content in them. Safety assessment includes molecular genetic studies, medical and biological safety assessment, sanitary and epidemiological examination.

Hygiene and epidemiology centers in all constituent entities of the Russian Federation are equipped with high-tech equipment that allows the use of screening, qualitative and quantitative methods for determining GMOs of plant origin, based on molecular biological technologies.

SAFETY OF GMO PRODUCTS

New equipment makes it possible to detect with the maximum degree of reliability both GMO lines approved for use in the prescribed manner and new 2nd generation GMO lines, as well as genetic inserts characteristic of genetically modified organisms not registered in the Russian Federation.

Some GM varieties of corn, rice, soybeans, sugar beets, and potatoes have undergone a comprehensive safety assessment by Rosportebnadzor. For example, in the first half of 2019, more than 16 thousand samples of food products were examined for the presence of GMOs.

Safety of GMO products

According to the results of a study by Rospotrebnadzor, from July 1, 2019, the import of fresh papaya produced in China into the Russian Federation has been suspended, and all products have been recalled from circulation.

For all identified violations of mandatory requirements, administrative enforcement measures were taken in accordance with the Code of the Russian Federation on Administrative Offenses, orders were issued to confiscate products, and orders to eliminate the identified violations were issued.

SAFETY OF GMO IN FOOD PRODUCTS

Technical Regulations of the Customs Union TR CU 022/2011 “Food products regarding their labeling” establishes that the labeling of food products must contain information about the presence of components obtained using GMOs in food products, if their content is more than 0.9%.

In order to improve the safety system and control the circulation of genetically modified products, Rospotrebnadzor is constantly working to update previously approved and develop new methods and techniques for testing food products for GMO content.

GMOS AND RUSSIAN LEGISLATION

Growing and breeding GMOs is a science-intensive and high-tech area of biotechnology. The results of research in this area are used in agriculture, the production of innovative food products, and medicines.

Today it is one of the trends in biotechnology, bionanotechnology and biomedical sciences. However, in Russia today, regulations for the state registration of GMOs have not been developed, so in fact there is no permission for their production in the country, although the import of the corresponding products is permitted.

The same legislation in Kazakhstan does not allow the production of GMOs, but import if their GMO content is not higher than 0.9% .

GMOs and Russian legislation

Experts in the field of molecular biology and genetics oppose the possible introduction in Russia of a complete ban on the cultivation and breeding of GMOs at the legislative level. First of all, this will negatively affect the development of science in this direction.

In addition, agricultural producers will find themselves even more dependent on imported feed and feed additives; crop production, in the absence of modern varieties, will lose competition to imported products. Innovative sectors of the pharmaceutical industry will suffer. Enterprises that use genetically modified bacteria, fungi, plant and animal tissues in the production of drugs will be at risk. The need for foreign medicines will increase.

GMOS AND RUSSIAN LEGISLATION

As a result of laboratory examinations, Rospotrebnadzor identified GMO lines unregistered in the Russian Federation, including new generations, in 22 food product samples:

1. papaya pineapple pieces 6x6 mm “Premium”, freeze-dried, manufacturer “Nantong BrightRanch Foodstuffs” (4 samples), genetic markers p35S, pNos, tNos, npt II were detected;
2. pieces of papaya in oatmeal porridge “Bystrov” without cooking “Gourmet Assortment” with papaya and pineapple”, manufactured by Nestle Russia LLC (16 samples), genetic markers p35S, pNos, tNos, nptII were detected;
3. fresh papaya, manufacturer Ning An Yuanfeng Economic and Trade CO., LTD, China, genetic markers CaMV 35S, FMV 35 S, NOS terminator, nptII gene were detected.

These batches of goods have been withdrawn from circulation in stores. Rospotrebnadzor continues to monitor GMOs in food products.

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty that regulates the movement of living modified organisms (LMOs) resulting from the use of modern biotechnology from one country to another.

The Protocol was adopted on January 29, 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on September 11, 2003. Kazakhstan ratified the Cartagena Protocol in 2008 and thereby assumed obligations to develop and adopt appropriate measures.

Cartagena Protocol on Biosafety

Competent national authorities

Government of the Republic of Kazakhstan No. 1282 dated December 26, 2008 - “On measures to ensure the fulfillment by the Republic of Kazakhstan of obligations arising from the Cartagena Protocol on Biosafety to the Convention on Biological Diversity” - The Ministry of Education and Science of the Republic of Kazakhstan has been appointed as the competent national authority.

Performs administrative functions relating to Articles 8,9,10,12,21 of the PBC. Authority to make decisions on the import and export of LMOs and GMOs.

Cartagena Protocol on Biosafety

Competent national authorities

National Contact Points for the PBC
Coordination Center for the Cartagena Protocol on Biosafety (CPB-NCC) - Ministry of Agriculture of the Republic of Kazakhstan.

Coordination center for the clearing-house mechanism on biosafety to the PBC (BCH-NCC) - RSE "National Center of Biotechnology" SC MES RK

* Modern biotechnology and the threat of bioterrorism.

- In the recent past, the threat of a global bioterrorist attack has increased dramatically. In addition to the already existing microorganisms and techniques, the recent explosion in biotechnology has considerably added to the arsenal of the bioterrorist.
- Molecular technologies are now available which can be used by committed bioterrorist groups to manipulate and modify microorganisms so as to make them increasingly infectious, virulent or treatment resistant for causing maximum casualties.
- Infectious diseases which are likely to be used as bioweapons are Anthrax, Botulism, Plague, Smallpox and Brucella.

- Molecular techniques like immunoassays and nucleic acid amplification are now available to detect bioattacks.

- **Home tasks:**

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