CHAPTER 15

GENETICALLY MODIFIED ORGANISMS IN FOOD IMPACT ON THE ECOSYSTEM

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INTRODUCTION

Genetic engineering allows providing the world's population with a new type of food ("new food"). This is the main argument of supporters of the spread of transgenes in pharmacology, agriculture, the food industry, horticulture, and nature conservation. Among the food products registered as GMOs, agricultural plants predominate: soybeans (54 %), corn (28 %), cotton and rapeseed (9 % each), and potatoes (1 %). Transgenic products do not spoil for a long time and do not change their appearance. Analyzing information sources, we are convinced that genetic modifications of all food products achieve the following goals: 1) Changing the consumer properties of products. The goal is developing very slowly, and is being industrially spread. For example, rice enriched with vitamin A and minerals has been obtained; tomatoes with a high proportion of iron; rapeseed with a changed composition of fatty acids; soybeans with a high content of phytosterols (to reduce cholesterol). 2) Rational, efficient, and cheap production of food products. 3) Increasing yield. The goal is achieved by introducing genes resistant to: pests; climatic conditions; pesticides; viruses. Considerable attention and resources are paid to such genetic modifications, as they form the basis of modern GMOs. The main problems associated with the study of GM food products are the following: firstly, gaps in the domestic legislative and regulatory framework; secondly, the lack of a control system for products labeled "with GMO" and incorrect labeling "WITHOUT GMO" (for example, table salt, mineral water, sanitary napkins, etc.). For comparison, in Canada and the USA, product labeling: "WITHOUT GMO" – is voluntary, in EU countries all products with GMOs over 0.9 % – are necessarily labeled. In Ukraine, food products labeled "WITH GMO" mean: a) the proportion of GMOs exceeds 0.9 % in any ingredient of the food product; b) the product consists of or is produced on the basis of genetically modified organisms

In European countries and some CIS countries, the legislation provides for the following options for labeling food products: "Own GMO", "Products containing GMOs", "Products with GMOs", "Finished food products containing GM raw materials", "Food products containing food additives or flavorings obtained from GM plants or GM microorganisms". However, on packages with products from domestic manufacturers we see only the mark: "Without GMOs".

The third problem is the high cost of equipment and expensive materials (test systems) for the identification and quantitative determination of GMOs in a single product. Therefore, today the number of laboratories accredited for the determination of GMOs is quite limited. Mostly, these are state laboratories that are part of the State Service for Food Safety and Consumer Protection. Products are identified for the presence of GMOs by laboratory tests, using special equipment in laboratories accredited for compliance with the requirements of DSTU ISO/IEC 17025:2006.

In Ukraine, the following laboratories are accredited for the identification of GMOs in food products: the National University of Life Resources and Environmental Management of Ukraine; the testing center of the State Enterprise "Institute of Eco-Hygiene and Toxicology named after L. I. Medved"; the central testing laboratory for the quality control of goods of the State Enterprise "Ukrmetrteststandart"; the center for diagnostics of viruses and transgenes of seeds and plants; SE "Kyivoblstandartmetrologiya" and regional laboratories of SE "Standard Metrology" cities: Ternopil, Vinnytsia, Cherkasy, Zaporizhia, Donetsk, etc.; regional state laboratories of veterinary medicine: Ivano-Frankivsk, Lviv, Khmelnytskyi, etc. In Lviv, GMOs are determined by the Lviv Regional State Laboratory of Veterinary Medicine; State Control Research Institute of Veterinary Drugs and Feed Additives; PE "Biola".

The fourth problem, lobbying interests and the monopoly position of the German company "R-BiopHarm AG" – a manufacturer of test systems for GMO diagnostics. Test systems are developed by the following companies: SE "Ukrmetrteststandart" (Ukraine); "R-BiopHarm AG" (Germany). Well-established logistics for the sale of drugs in Germany and around the world, SureFood test system kits are distributed by R-Biopharm. Test systems are manufactured by the German company Congen Biotechnologie, which is located in Berlin.

The fifth problem is that the EU and Ukraine have not yet developed methods for detecting non-additive, enhancing or attenuating effects when assessing the degree of risk of GMOs to human health. For example, it is scientifically proven that the same trans gene, depending on its location in the genome (chain) of DNA, the stage of GMO development, and the season, exhibits different activity – unpredictable and uncontrolled. This affects metabolic pathways and properties of final products. For example, lignification of cell walls was observed in Bt-soybean (herbicide-resistant) and Bt-corn (pest-resistant). Therefore, the development of new methods for risk analysis based on a synergistic model (which takes into account the interaction of the transgene at all levels) is relevant for geneticists. The sixth problem is the impact of gene technologies on ecology and the environment. The spread of GMOs and the use of modified DNA leads to uncontrolled interactions.

The main ways in which GMOs enter the environment are:

1) Disposal of intact GMOs and DNA on production equipment and in laboratories through sewage.

2) Spread in a free state due to the cultivation of GMO plants on experimental agricultural plots of land. In this case, trans genes are spread through: pollen, which affects the crossing of plants (horizontal gene transfer); assimilation of DNA from the remains of dead Bt plants by soil bacteria (vertical gene transfer); the negative effect of new GM microorganisms with different properties on insects in the ecosystem chain; an unpredicted change in the properties of GMOs as a result of the interaction of the new gene and the organism.

1. Why do we use GMOs?

Increased concern about food security at the national and international levels is primarily due to the expansion of the spectrum of harmful effects that are generated as a result of the deterioration of the environmental situation, the creation of modified types of food raw materials, the use of a wide range of pesticides and toxic chemicals to combat weeds, pests and diseases on crops, the use of hormonal drugs for growing animals, poultry and fish, as well as the use of a wide range of stabilizers, flavors, dyes and other chemicals for the manufacture of food products. This has given rise to a number of problems in various spheres of life of the countries of the world community, the solution of which will be very difficult to solve without proper financial support. First of all, we must understand the simple truth: "The quality and safety of a healthy food product is laid in the agroecosystem", and therefore its creation must be considered in a single scheme: environmentally friendly farming (technological aspect) – harvesting – storage – production of an environmentally friendly product – trade network – consumer. Violation of a single production cycle at any stage can lead to a deterioration in the quality and safety of both food raw materials and finished products of food industries in general. On the other hand, we should not forget that the need for food products due to demographic changes in the countries of the world community will have an increasingly urgent importance. Since ancient historical eras, the world's population has been growing rapidly: in 1830. the human population grew to 1 billion people, already in 1930 its number was 2 billion, in 1960 – 3 billion, in 1975 – 4 billion, in 1999 – 6 billion, and by the middle of the 21st century the population may reach more than 7 billion people. In this regard, it is obvious that the rate of production of genetically modified food products will increase. According to supporters of genetic engineering technologies, the need to grow GM crops is dictated by the following factors: – the growth of the population on planet Earth, which will suffer from hunger, will double in 2050 and will amount to 1.8 billion; increasing demand for biofuels;- reduction of agricultural land by 19.4 million hectares. Genetic engineering is a relatively young science that is designed to create and improve the characteristics of living organisms by transplanting foreign genetic material into them, for example, fish DNA into a tomato (so that it does not freeze) or bacteria into a potato (so that a beetle does not eat the plant). Genetic engineering is fundamentally different from breeding in that its methods allow overcoming barriers between species, which does not happen in nature. The first genetically modified plants appeared in 1983, and large-scale industrial production of GM crops in the world began in 1996 – at that time they occupied 1.7 million hectares. The area under agricultural crops of genetically modified origin in 2016 reached 185.1 million hectares against 179.7 million hectares in 2015 – reports the International Service for the Acquisition of Agribiotech Applications (ISAAA). Currently, GM crops are grown in 26 countries. By the way, the range of genetically modified crops today is quite wide, including: peas, potatoes, corn, rapeseed, rice, sunflower, soybeans, cotton, sugar beets, flax, chicory, tomatoes, eggplants, peppers, carrots, peppers, etc. The largest number of them is in the USA (72.9 million hectares, which is 39 % of the total area) – about 90 % of all GM crops registered in the world are allowed to be grown here; in Brazil (49.1 million hectares, or 27 %) the largest areas are occupied by crops such as soybeans, corn and cotton; in Argentina (24.4 million hectares, or 12 %) – soybeans, corn and cotton; in Canada (11.6 million hectares, or 6 %) – potatoes; in India (10.8 million hectares, or 6 %) – cotton, in Paraguay (3.6 million hectares, or 2 %) – soybeans; in China (2.8 million hectares, or 2 %). – cotton. At the same time, plants with herbicide resistance genes are grown on approximately 53 % of the area (especially to systemic herbicides – ammonium glyphosate group), combined type with several traits – on 33 % of the area and pest resistance – on 18 %. It should be noted that EU countries are more reserved about the rapid introduction of biotechnological crops into their production.

Thus, in 2016, GM corn MON810 (the only one permitted for cultivation in the EU) was grown by only four countries (Spain, Portugal, the Czech Republic and Slovakia). Germany practically abandoned the cultivation of GM potatoes, and the Czech Republic and Slovakia stopped growing GM corn in 2017. Portugal and Spain also sharply reduced the area sown with GM crops. At the same time, GM crops continue to be imported into the EU for further use as animal feed. In particular, Roundup Ready soybeans are imported. There are imported transgenic rice, sunflower and rapeseed oil on the market. Supporters of GMOs cite a number of advantages of GM organisms: high yield and quality of agricultural crops, increased frost and drought resistance of such crops, the ability to resist many types of weeds, diseases and pests. Instead, a wide range of scientists cite research data confirming the negative impact of GMOs on both humans and the environment as a whole. These include: the occurrence of allergic reactions; suppression of the human immune system, possible metabolic disorders; increased toxicity in food products, destruction of natural ecosystems and disruption of the ecological balance during mass open cultivation of transgenic plants. The international service, which annually publishes a global review of the commercialization of biotechnological crops (ISAAA, 2014), identifies the following most characteristic features of GM corn lines: resistance to various herbicides, resistance to lepidopteran and coleopteran insects, resistance to antibiotics, male cytoplasmic sterility in plants, drought resistance, altered alpha amylase and amino acid composition of grain. Of course, the list of possible risks and dangers from the use of GMOs has not yet been fully disclosed. It should be noted that research in this field of knowledge is quite questionable today, as a rule, they are highly specialized. For example, agricultural scientists associate GM plants mainly with technology, food industry technologists with quality, and scientists in the field of genetics with modifications in the organisms themselves. At the same time, in our opinion, such research should be given a comprehensive direction. An approximate scheme for conducting such research is presented in the figure. What does the situation look like with the production of genetically modified products in Ukraine? Officially, no type of genetically modified plants is grown in Ukraine. But today, genetically modified (GM) food products are not uncommon and the range of their application in the food industry is quite wide. Genetically modified soybeans, potatoes, corn, zucchini, tomatoes, rice, sugar beets, melons, etc. have found widespread use in the food industry, some of them are also grown in the fields of agricultural formations in Ukraine. Some experts believe that about one million hectares of Ukrainian land are occupied by GM crops, of which more than 50 % are soybeans, 20 % are corn, and the rest are potatoes, sugar beets, and rapeseed. Therefore, there is a high probability of encountering GMOs in food products made from the above-mentioned plants[1, 2].

To more deeply clarify the situation regarding the production, circulation and consumption of food products produced with the participation of GM crops, we conducted a sociological survey of two categories of the population: producers and consumers of these products. In particular, among the surveyed respondents, the majority believes that the situation regarding the production, use and circulation of GMOs in food technologies at the legislative level is insufficiently regulated – 31.9 %, another 29.9 % – rather partially, 8.5 % – do not pay due attention to this issue, 27 % – are unaware and only 10.6 % believe that this issue is fully regulated. The majority of respondents (55.3 %) expressed their opinion on the need to test products for GMO content at the stage of production, import and export and other areas of circulation, 19.1 % – selectively at different stages of circulation, 10.6 % – at the stage of import and export, 6.5 % – rather partially and only 8.5 % – inappropriate. At the same time, a significant part of the respondents (76.7 %) noted that it is advisable to introduce an effective system of tracking and labeling of food products containing GMOs at the level of the Law, 17 % – believe that such tracking is advisable for individual products, 4.2 % – on a voluntary basis and only 2 % – inappropriate.

In addition, a significant part of the population has reservations about the safety of food products containing GMOs for human health (22 %), another 35.3 % – partially and 36.7 % said that food products created with GMOs are safe. The opinion of the surveyed respondents regarding whether they have enough information about the sale of food products containing GMOs in retail establishments is also noteworthy. In this context, the answers were distributed as follows: 56 % of the respondents said that they were aware, 19.2 % – rather partially, 13.2 % – not enough, 7.2 % – do not pay due attention to this issue and 4.4 % – emphasized that they are not aware at all. Regarding the answer to the question about the effectiveness of advertising in Ukraine about the dangers of GMOs in food, the answers of the respondents were distributed as follows: only 10.4 % of respondents believe that such advertising exists and is quite effective, another 11.8 % – rather partially, but 58.8 % noted that there is no such advertising at all, at the same time 11.8 % do not pay attention to this issue at all and 7.2 % of respondents are unaware. At the same time, a certain part of the respondents indicates that in

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1 Юлевич О. І. Біотехнологія : навчальний посібник / О. І. Юлевич, С. І. Ковтун, М. І. Гиль ; за ред. М. І. Гиль. Миколаїв : МДАУ, 2012. 476 с.

2 Теплоухов Б. П. Зброя масового знищення та захист від неї. Київ : Скіф, 2023. 100 с.

Ukraine more attention should be paid to the production of organic products, to conduct extensive explanatory work among the population regarding the harmfulness of GMOs, or to ban their production and circulation altogether. Therefore, the question arises, should Ukraine legalize or not legalize the production of genetically modified products? If we objectively assess the situation, it is obvious that it is worth abandoning the production and consumption of genetically modified products for several good reasons: the lack of in-depth research in Ukraine on the usefulness or harmfulness of food products created with the participation of GMOs; the deterioration of the population's health; a fairly high level of agricultural production, which has made Ukraine one of the largest exporters of plant raw materials. Possessing a huge agricultural potential, among such developed countries of the world as the USA, Canada, Great Britain, France, Germany, Italy and Poland, Ukraine occupies key positions in the production of agricultural products per person (2015): grain and leguminous crops – 1403 kg, sunflower – 261 kg, potatoes – 486 kg, sugar beet – 241 kg, vegetables – 215 kg and eggs – 392 pieces. However, the indicators for milk and meat production have significantly decreased compared to previous years, of which 248 and 54 kg were produced, respectively. At the same time, in terms of food consumption, Ukraine lags behind a number of developed countries of the world, especially in terms of the range and quality of food products. Taking into account the above arguments, it is more expedient in Ukraine to develop organic farming, which is one of the methods of producing ecological products, which is gaining increasing popularity in the countries of the world community. Organic farming is a system of crop and livestock farming that refuses or significantly limits the use of chemical agents, primarily pesticides, artificial mineral fertilizers, growth regulators and food additives for the preparation of feed for cattle, pigs, poultry, fish, etc. This system is based on scientifically based crop rotations, the use of organic fertilizers, soil-protective tillage, agrotechnical and biological means of protecting cultivated plants from pests, diseases and weeds in order to form a stable crop yield with high quality indicators of crop products. In this context, permaculture deserves special attention, which is actively implemented in private farms. This direction is especially worthy of attention for the development.

2. The GMO problem and risks

The GMO problem and the risks of using transgenic plants for human health have not yet been finally proven. There is no consensus among world scientists on the negative impact of GMOs. Some believe that GMOs are safe, others that transgenic plants cause allergic reactions, cancer, gastrointestinal disorders, etc. Recently, the EU has been paying more and more attention to assessing the risk of using GMOs in the human food chain. In 2014, studies were conducted with the participation of the European organization EFSA, aimed at assessing the risk of GMOs to the human body. The studies were conducted in 6 European countries for three months. For this, 50 g of corn in the form of pastries and flakes, which contains GMOs in an amount of 5.07 mg/kg, was introduced into the daily diet of people of different age groups (from 3 months of age to 75 years). The results of the studies showed that with daily consumption of GM corn in the diet by people of different age groups during the specified period, a chronic 16 risk develops. What could this indicate? If people who did not suffer from allergic reactions before consuming GM corn, then they may be at risk of developing allergies in the future. What is the situation in Ukraine regarding GMOs? Today, according to the Law of Ukraine "On the State Biosafety System in the Creation, Testing, Transportation and Use of Genetically Modified Organisms", the industrial production and introduction into circulation of GMOs, as well as products produced with the use of GMOs, is prohibited until their state registration. However, despite the ban, GM feed, raw materials and products have begun to appear on the Ukrainian market. Given this fact, there is a need to create and monitor raw materials, feed and food products for the presence of GMOs. The aim of the work was to analyze the results of research on grains and feed for the period 2016–2017 on the presence of GMOs and the spread of GM lines in Ukraine. Materials and methods. The research was conducted during 2016–2017 using the real-time polymerase chain reaction (PCR-RF) method on the basis of the research department for GMO detection of the State Research Institute for Laboratory Diagnostics and Veterinary and Sanitary Expertise (DNILDVSE), Regional State Laboratories of the State Service for Food, Agriculture and Food Safety (RDL), branches of DNILDVSE and other laboratories. Diagnostic kits for screening, identification of GM lines and determination of their quantitative content (R-Biophapm AG, Germany) were used for the research: SureFood GMO Screen 35S+NOS+FMV, SureFood GMO Screen 4plex BAR/NPTII/PAT/CTP2:CP4 EPSPS, SureFood GMO ID RR Soya, SureFood GMO ID RR2Y Soya, SureFood GMO QUANT RR-Soya, SureFood GMO QUANT GT73 Canola. Reference standards of different percentage concentrations of soybean, corn, and rapeseed (ERM, Belgium) were used as positive controls. Biorad CFX96 amplifier. Research results. Today, the State Service for Food and Consumer Protection has 9 fully functioning accredited laboratories that conduct GMO analysis: DNDILDFSE, Kharkiv branch of DNDILDFSE, Poltava, Cherkasy, Dnipropetrovsk, Khmelnytskyi, Lviv, Kirovohrad, Ivano-Frankivsk regional state laboratories. During 2016, 2,599 samples of plant raw materials were examined, of which GM lines of soybean and rapeseed were detected in 177 samples. In 2017, 4,371 were examined, of which 329 samples were positive. In positive samples of compound feed, soybeans, oilcake and soybean meal, GM lines MON 40-3-2 and MON 89788 were identified in an amount of more than 10 %, in samples of rapeseed and rapeseed oilcake, GM line GT-73 was detected in an amount of more than 10 %[3].

The main reason for controlling the circulation of GMOs is to provide the consumer with the right to choose when consuming food products containing components of GM plants. In Ukraine, the main regulatory document regulating the circulation of GMOs in Ukraine is the Law of Ukraine No. 1103 dated May 31, 2007 "On the State Biosafety System for the Creation, Testing, Transportation and Use of Genetically Modified Organisms", adopted with the aim of implementing the basic principles of the Cartagena Protocol on Biosafety into the legislation of Ukraine. However, as practice shows, an effective mechanism for regulating GMOs, especially in terms of their registration, is actually absent. Despite the existence of four State Registers, currently in Ukraine there is only one product registered and permitted in the production of feed for farm animals, namely "soybean meal of the GMO line MON 40-3-2". However, as the results of research by our and other laboratories show, other GMOs are also present in circulation on the agricultural market of our country.

3. GMOs as medicines

In recent decades, biotechnology has been rapidly developing in the pharmaceutical industry. With their help, fundamentally new drugs (drugs) (cytokines, hormones, blood clotting factors, vaccines, monoclonal antibodies, etc.) are created, which more effectively and selectively affect pathological processes. The use of drugs of biotechnological origin (BTP) is revolutionary in the treatment of viral diseases and such severe chronic diseases as diabetes mellitus, rheumatoid arthritis, oncological diseases, anemia in chronic kidney disease, tuberculosis, etc. BTP drugs are produced, in particular, by genetic engineering (or recombinant DNA technology), which is based on the construction of DNA fragments in vitro with the subsequent introduction of new (recombinant) genetic structures into a living cell and their expression. The first to be synthesized using this technology were insulin, growth hormone, α- and β-interferons in 2004, recombinant epoetin-α, granulocyte colony-stimulating factor in 2006, and follicle-stimulating hormone

[3] Півень О. Без ГМО: правда і страшилки про генну інженерію. Київ : Віхола, 2022. 178 с.

in 2007. Among the drugs of BTT origin is recombinant Interferon alpha-2b, synthesized by Escherichia coli cells based on a gene encoding a product identical to human alpha-2b interferon, using phage-dependent genetic engineering biotechnology. The drug, like natural leukocyte interferon, has three main types of biological activity: immunomodulatory, antiviral, and antitumor. Filgrastim is a highly purified non-glycosylated protein consisting of 175 amino acids, and is also produced by Escherichia coli bacteria, into whose genome the human granulocyte colony-stimulating factor gene was introduced by genetic engineering. Human granulocyte colony-stimulating factor is a glycoprotein that regulates the formation of functionally active neutrophils and their release into the blood from the bone marrow. Among the drugs synthesized by cells of higher organisms is recombinant human erythropoietin (EPO), which contains 165 amino acids in which the human erythropoietin gene has been transfected. The product contains an amino acid sequence identical to natural erythropoietin. Erythropoietin is a glycoprotein that has a stimulating effect as a hormonal factor of mitosis and differentiation of erythroid precursor cells in the bone marrow. The first recombinant erythropoietin preparation (epoetin-α) was developed in the mid-1980s. Currently, several recombinant human EPO preparations have been obtained by genetic engineering for clinical medical use. In world medical practice, the most widely used are recombinant EPO-alpha and EPO-beta, which differ in the level of glycosylation. Their amino acid sequence is the same (165 amino acids). Alpha and beta EPO differ only in the number of carbohydrates, but have approximately the same biological activity. Purified commercial alpha and beta EPO are a mixture of isoforms from 9 to 14. The two products are synthesized in a culture of Chinese hamster ovary cells, into which the cDNA of the human EPO gene was inserted. Omega EPO is produced in a culture of kidney cells of young Chinese hamsters. Another EPO that has received approval from the European Medicines Agency is delta EPO, which is synthesized in a culture of human fibrosarcoma cells (HT – 1080 line). Among the most significant problems of quality, efficacy, safety and production of BTP drugs are: – the complexity of the structure of the active substance (peptides or proteins, glycoproteins, which consist of many macromolecules of complex structure); – the complexity of production and the presence in the technological chain of “capricious” microorganisms (viruses, bacteria, fungi), or animal cells (kidney fibroblasts (VNK line), ovaries (CHO line); – imperfection of quality control methods for this group of drugs; – lack of a long clinical history. The process of manufacturing BTP drugs can be divided into six main stages: – synthesis of cDNA of the active substance; – selection of a vector for transfection and its combination with cDNA; – selection of producer cells and modification of their genome using the resulting vector-cDNA construct (transfection); growth of transfected producer cells and obtaining a supernatant containing the biotechnological product; – purification of the product using highly efficient biochemical methods; – creation of a dosage form (stabilization, packaging, standardization by dosage). Therefore, when studying the stability of drugs of BT origin, the term "purity" is quite conditional, since it is extremely difficult to determine the absolute purity of such products due to the effects of glycosylation, deamidation or other heterogeneities. Therefore, the purity of these drugs should generally be determined by more than one method, taking into account that the results obtained will largely depend on the analytical method used. Pharmacovigilance is a very important tool for collecting and evaluating data on the safety of biosimilars. Key activities in pharmacovigilance of BTP drugs are: risk identification, using knowledge of the reference drug, taking into account potential differences in safety profiles, and efferent drug and biosimilar. In this case, special attention should be paid to the detection and assessment of cases of immunogenicity, including lack of efficacy[4, 5].

4. GMOs – harm or benefit?

The growth of the population on the Earth and the emergence of factors that affect the reduction of crop yields are forcing humanity to look for ways to solve the global food problem. Today, one of these ways is to use scientific achievements in the field of genetic engineering. With the help of biotechnology, various "genetically modified organisms" (GMOs) are obtained, resistant to various pests, diseases, changes in the habitat, climate. Many scientists see genetic engineering as a way to solve the food problem in developing countries. Almost a third of food products in European countries are "genetically modified", in the USA this figure reaches 60 %. This term is understood as any living organism in which the natural set of genes has been artificially changed. As a result, new varieties of plants are created and grown that are resistant to environmental influences and that give high yields. In animal husbandry, animals that are characterized by accelerated growth are more productive. And yet, is the widespread use of genetically modified products dangerous for human health and the environment? Supporters of the use of genetic engineering in agriculture are sure that eating transgenic food poses no greater danger to humans than eating conventional products.

[4] Paul Knoepfler GMO Sapiens: The Life-Changing Science of Designer Babies. NY : WSPS, 2015. 282 p.

[5] Wunderlich S., Gatto K. A. Consumer Perception of Genetically Modified Organisms and Sources of Information. *Adv. Nutr*. 2015. Vol. 6. P. 842–851.

Their main arguments are as follows: genetically modified crops allow for the production of food products in larger quantities, cheaper and tastier than traditional crops; plants can be modified so that they contain more nutrients and vitamins; genetically modified plants can be adapted to 57 extreme conditions (drought, cold, etc.); the use of genetically modified crops that are resistant to pests will allow fields to be treated with pesticides less; food products containing genetically modified ingredients can become beneficial for health if vaccines against infectious diseases are added to them. The possible harm of genetically modified products was first announced in 2000. Then a statement by world scientists on the dangers of genetic engineering was published, and then their open letter to the governments of all countries on GMOs, signed by 828 scientists from 84 countries of the world. In December 2004, the European Union banned the sale of GMOs using antibiotic-resistant genes, and the World Health Organization (WHO) recommended that manufacturers refrain from using these genes. However, even large corporations do not fully comply with WHO recommendations. At an international conference dedicated to the topic of GMOs, experts from the All-Ukrainian Ecological League expressed the opinion that the unauthorized distribution of such products is a dangerous experiment on the population and soils of Ukraine. There is a category of supporters and individuals interested in exaggerating the potential danger of genetically modified organisms. First of all, these are molecular geneticists who support the horror story of possible GMO problems in order to obtain funding for scientific research, which, in fact, contributes to the development of the topic of genetic engineering. Religious motives for rejecting products created from modified organisms due to the disruption of the natural process of formation of a particular organism are quite understandable and acceptable. Giant corporations – manufacturers of herbicides, pesticides, insecticides, are also interested in lobbying the topic of GMOs in order to preserve their huge capacities, since they lose the market for their products if transgenic plants do not need it. But the most interested are manufacturers and importers of food additives and products with synthetic additives, who are most satisfied with the fact that due to the inflated problem of GMOs in the food industry, claims to less. As for GMO itself, as such, according to the followers of genetic engineering, any genetic information, modified or not, is encoded in the form of a sequence of nucleotides consisting of a nitrogenous base, pentose sugar and phosphoric acid, which are the absolute norm for all living things. Genetic modification itself is a change in the order of this sequence. However, in the process of preparing such a product for food, as well as in the process of digestion itself, this sequence is hydrolyzed, that is, it breaks down into its constituent parts – nucleotides, which are naturally absorbed by the body. At the same time, the information of the modified genome does not pose any danger, since it disappears in the pan and stomach in the literal sense of the word. This is the same as preparing and eating a dish from a sheet of paper with some text, fearing that this information in the form of a certain sequence of letters of the alphabet may have harmful consequences. GMOs are a real breakthrough in providing food for the world's rapidly growing population. And this is the main argument of supporters of the spread of transgenes. There are many scientific works devoted to the issue of genetically modified organisms, but none of them directly answers the question of whether they are harmful or beneficial. In the near future It is unlikely that scientists will give a specific answer to the questions that the results of experiments in the field of genetic engineering entail, and first of all, this is because they did not set such a goal. After all, as always, there are two sides of the coin, that is, there are both opponents and supporters of GMOs, and each of them will try to prove their rightness and lobby their interests, using all possible and available means for them. Perhaps genetically modified organisms really carry harm due to combinations of genes that have never combined in nature. On the other hand, perhaps genetically modified products are another great discovery, which, like most sensational breakthroughs in science, has been unrecognized for a long time, and humanity has not yet realized its benefits. Opponents of GMOs cannot substantiate their fears at a more or less decent scientific level, since the number of correct scientific works that relate to the topic of GMO safety is quite limited. Scientists – biochemists, physiologists and molecular biologists from scientific communities around the world – argue that from a scientific point of view there is no difference between plants obtained using genetic engineering and plants bred by traditional breeding methods when cultivated in the fields and used in production, since the method of obtaining transgenic plants itself does not raise any concerns. That is why the problems of safety and use of GMOs should be resolved at the level of an individual product – using various tests that confirm the compliance of the studied products with existing standards and norms [6].

5. Distribution of genetically modified soybean in Ukraine

Soybean is a unique feed, food, technical and medicinal crop, the beans of which contain 35–45 % crude protein, 18–25 % fat, 22–35 % carbohydrates, enzymes, vitamins, minerals. Soy protein has a full set of amino acids

[6] Guidance on the EU menu Methodology / European Food Safety Authority. *EFSA Journal.* 2014. Vol. 12 (12) 3944. 77 pp. DOI: 10:2903/ j.efsa. 2014. 3944.

necessary for the human and animal body, which is easily digestible and is equal in biological value to the proteins of meat, milk, eggs. Soy protein, flour and oil can be found on the shelves of supermarkets in developed countries of the world as one of the components of more than 1000 food products – margarines, mayonnaise, meat substitutes, imitation dairy products, bread, bakery and confectionery products, chocolate, soy drinks, soy sauce and seasonings. In terms of soybean seed cultivation, Ukraine ranks first in Europe and is among the top ten countries in the world. Soybean is one of the most common biotech crops. The total area of its crops in the world is constantly growing and in 2016 amounted to 33.87 million hectares. Over 90 % of this area is occupied by genetically modified soybean with Roundup Ready herbicide resistance. Research results indicate the presence and cultivation of GM crops in Ukraine as well. Given the number of samples of agricultural crops containing GMOs, the constant growth of GM crop areas in the world and the geographical location of our country, the problem of the safety of using GM crops in food production arises. The aim of this study was to study the impact of traditional and genetically modified soybean on the postnatal development of rats of three generations. The experiment was conducted on 3 generations of Wistar rats: parental, first and second. The initial group was females and males, age 3-3.5 months. The animals were divided into three groups: control group – intact animals, group "Experimental 1" – animals that received a standard diet with 35 % of its protein content replaced by natural soybeans, group "Experimental 2" – animals that received a standard diet with a similar part replaced by transgenic soybeans "Roundup Ready" line GTS 40-3-2. The diets of all groups of animals met standard requirements and accepted norms. Before feeding, soybeans were heat treated to neutralize antinutrients and reduce urease activity. Intact animals received standard vivarium feed in compliance with the established diet. Animals of all groups consumed water ad libitum throughout the entire research period. Puppies were weaned from their mothers on the 30th day of life and transferred to the diet that the parental group received. To continue the experiment, offspring from different females were selected in order to randomize the studies and prevent incest. Intact and experimental animals were in identical conditions, the collection and processing of the material was carried out in parallel. The experiment was conducted in compliance with the requirements for experiments on animals (Strasbourg, 1985; Ukraine, 2001). A study of the development of first-generation rat pups showed that the average litter size in the "Experimental 2" group was 8.6 ± 1.5 heads, in the "Experimental 1" group – 8.0 ± 2.1 heads, in the control group – 9.4 ± 2.4 heads. No visible defects were found in any experimental groups. Analysis of the physical development of the rat pups did not reveal any deviations from the norm. Postnatal development of first-generation rats in the control and experimental groups is characterized by high survival. In the period from 1 to 5 days of life, the survival rate of the offspring of the "Experimental 1" group was 93.8 %, in the period from 6 to 30 days of life – 91.7 %, in the "Experimental 2" group – 91.7 and 87.3 %, in the control group – 94.7 and 95.8 %, respectively. Postnatal development of rats of the second generation is also characterized by high survival in the experimental groups. In the period from 1 to 5 days of life, the survival rate of the offspring of the "Experimental 1" group was 93.9 %, in the period from 6 to 30 days of life – 91.9 %, in the "Experimental 2" group – 91.1 and 83.6 %, in the control group – 93.3 and 92.7 %, respectively. There is a tendency to decrease in the number of suckling rats in the group of animals that received genetically modified soybeans as part of the diet. The average size of the litter in rats of the experimental groups of the second generation was slightly lower compared to the size of the litter of female rats of the first generation, but was within physiological values. Comparison of the average weekly body weight gain between male and female rats of the experimental groups did not establish a significant difference between animals that consumed natural soybeans and GTS 40-3-2 soybeans, which coincides with the results obtained by Chinese scientists when animals consumed soybean flour. Comparison of the mass indices of the main organs of rats of both sexes of three generations showed that the indicators do not differ significantly. A study of the liver mass index of animals revealed that in the "Experimental 2" group, an increase in this indicator was observed compared to the control group in females of the parental generation by 23.5 %, in males – by 15.7 %. In animals of the next two generations, the trend was maintained to the increase in this indicator, but less pronounced. Since the liver plays the role of a detoxification center, it can be assumed that the response of the rat organism to the influence of certain components of the diet is activated. The results of the conducted studies indicate the absence of a probable negative or positive effect of thermally processed genetically modified soybeans on the reproductive functions of rats and the development of offspring of the first and second generations. Thus, the relevance of long-term multilateral studies remains to create a clear idea of the long-term consequences of the impact on living organisms of transgenic plants and food products containing them[7, 8].

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6. Genetically modified rice

Rice, corn, and wheat are the world's most important crops. Rice is the main food source for nearly half of the world's population, mostly in Asia. Farmers have been growing and breeding rice for thousands of years. Modern breeders are still trying to improve rice's ability to resist disease. Genetic engineering is increasingly being used to achieve these goals. Genetic engineering is one method that can be used to achieve breeding goals, namely, the creation of resistant, high-yielding varieties that require little or no spraying, bred "tailor-made" for the specific conditions of a particular region. Genetic engineering offers the opportunity to increase resistance to viral, bacterial, and fungal pathogens. Other important goals include tolerance to drought and soil salinity. Rice is grown in tropical and subtropical regions around the world. Rice cultivation is primarily concentrated in China, India, and Southeast Asia. These regions account for 90 % of the world's rice production, which is largely produced by smallholder farmers. Thailand is the world's leading rice exporter. The most important rice producer in Europe is Italy. Weed and pest control are the main reasons why 80 % of the world's rice fields are flooded. Rice was not originally an aquatic plant. Rather, it has been adapted through breeding for "flooded" conditions. Rice breeding is taking place in many countries, including projects conducted at international agricultural research centers. In 2000, the first two GM rice varieties, both herbicide-tolerant, called LLRice60 and LLRice62, were approved in the United States. These and other herbicide-resistant GM rices were later approved in Canada, Australia, Mexico, and Colombia. However, none of them reached the commercialization stage. Reuters reported in 2009 that China had granted pest-resistant GM rice biosafety status, but the line had not been commercialized. As of December 2012, GM rice was not widely available for production or consumption. China is leading the way in rice breeding research, with high hopes for new, insect-resistant rice varieties. The Chinese government is currently conducting systematic field trials of these new varieties. Results show that most farmers using GM rice have been able to stop tilling their fields altogether. In contrast to GM rice, conventional rice varieties are sprayed, on average, 3–4 times during their growing season. GM rice cultivation is expected in the near future in China, India, Indonesia and the Philippines.

Golden rice is a genetically modified variety of rice (Oryza sativa L.). Two genes were taken to modify the rice: the psy gene from the daffodil (Narcissus pseudonarcissus) and the crtl gene from the soil bacterium (Erwinia uredovora). In 2003, the concentration of beta-carotene in laboratory plants reached 1.6 μg/g. The first outdoor harvest was obtained in 2004 in the city of Crowley, Louisiana, USA, as it is one of the few countries that has not banned the genetic modification of food plants. In 2005, the biotech company Syngenta created an improved variety called Golden Rice 2 – a rice variety with an increased content of beta-carotene, a metabolic precursor of vitamin A. The content of beta-carotene in it was increased times compared to the first version. Since 2012, golden rice has already begun to be harvested in China and the Philippines. The year 2014 is considered a turning point in the spread of this crop and, thanks to the help of the Bill and Melinda Gates Foundation, three and a half million farmers have already grown rice with the Sub1 gene. As is known, rice contains a small amount of iron and vitamin A. In regions where rice is a staple food, vitamin A deficiency is observed in the indigenous population, which leads to vision problems and, in some cases, blindness. According to WHO data from 2009 and 2012, 190 to 250 million preschool children worldwide each year still suffered from vitamin A deficiency. Studies have shown that vitamin A supplementation can reduce mortality among children under 5 years of age by 24–30 %. This means that the availability of vitamin A in 8 million children of late childhood and preschool age in malnourished families could prevent 1.3 to 2.5 million child deaths per year. An average serving of "golden" rice can cover half of the daily requirement of the vitamin for a young child[9].

In Japan, work is underway to develop varieties of rice that will pose less of a problem for people with rice allergies. To achieve this, researchers are trying to reduce the activity of the gene that leads to the formation of an important allergen (AS-albumin). So far, researchers have not been able to completely eliminate traces of albumin. In the UK (Department for International Development), a rice variety resistant to yellow spot virus has been developed. In Zurich, a rice variety resistant to yellow spot virus has been developed. resistant to Tungro virus and various fungi. Ventria Bioscience has developed rice varieties that can produce human proteins. For example, one of these varieties synthesizes human lactoferrin and lysozyme. These two proteins are present in breast milk and are widely used in the production of baby food and rehydration products. Several insect-resistant rice varieties have been developed and tested in large quantities in China. To make rice varieties resistant to insect pests, the same technologies were used as for corn – the introduction of genes from the bacterium Bacillus thuringiensis to synthesize entomootoxins in rice plants. These varieties can resist a wide range of pests, while other rice varieties need to be treated with insecticides three to four times during the growing season. Bt rice has been widely grown

[9] W.-D. Fessner Biocatalysis: From Discovery to Application. 2000. 268 p.

in Chinese fields since 2009. 140 In addition, many field trials are underway in India with insect-resistant Bt rice. A number of research projects are related to the development of new rice varieties that can survive with less water and can grow in saline soil. In China, salt-tolerant varieties have already been developed, into which a gene has been transferred from Suaeda salsa, a plant that also grows in saline soil. A similar rice variety is also undergoing field trials in Europe, the USA and India. Scientists at the University of California have developed a type of GM rice that can withstand flooding for more than two weeks. In Japan, work is underway to develop a hypoallergenic type of rice in which the formation of allergens (AS-albumin, glutenin) is suppressed. In other GM rice varieties, the starch composition (amylose) or protein content has been changed. Sake producers could be potential buyers. Therefore, new achievements in genetic engineering are of great importance for agriculture, since some varieties of plants bred using new technologies are already finding their place in the sown areas of various countries[10, 11, 12].

7. Food safety and genetics

Food safety problems are complex, and their solution requires numerous efforts from scientists, manufacturers, sanitary and epidemiological services, government agencies, and consumers. The relevance of this problem is growing every year, since food safety directly affects not only human health, but also the preservation of the gene pool of humanity as a whole. Genetics, molecular biology, and molecular genetics use a number of common methods and approaches, which together constitute a methodology – a certain way of studying hereditary material (DNA). An important applied value of the methods used in these subject areas is their use for assessing dangerous factors for human life and health. In view of this, the development of a methodology for assessing the safety and quality of agricultural raw materials of animal and plant origin, as well as ready-to-eat food products based on molecular genetic approaches is of scientific interest and has practical significance. The last decades have been marked by significant progress in the development and application of approaches to determining DNA polymorphism and the selection of appropriate molecular genetic marker systems that would contribute to the wider implementation of modern molecular genetic methods and assessment technologies to improve the safety and quality of products in the agricultural

[10] Lilia Alberghina Protein Engineering For Industrial Biotechnology. 2003. 374 p.

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sector. Today, the following main areas of development of DNA technologies for the needs of the agri-food sector are distinguished: development of molecular methods for diagnosing and controlling the safety and quality of agricultural raw materials of animal and plant origin; diagnostics of infectious diseases of agricultural animal species and phytosanitary quarantine control; detection of genetic diseases of animals at early stages of development; genotyping of organisms to create genetic passports of breeds, species, taxonomic groups; marker-associated selection (MAS). In Ukraine, over the past twenty years, numerous studies have been conducted on the application of modern achievements in molecular genetics and varieties of molecular genetic markers in a wide variety of branches of domestic animal husbandry, plant breeding, and food microbiology[13, 14]. Despite this, there is a significant shortage of work on the practical application of modern achievements in genetics and developments in the selection of high-yielding animal breeds, obtaining plant varieties with improved properties, and developing systems for monitoring the safety and quality of agricultural raw materials and food products at all stages of their production.

Food safety and quality are among the most important factors determining the health of nations. Recent decades have been characterized by a steady deterioration in the health indicators of our country's population. Of course, this is primarily due to a decrease in the quality of life, a low level of social protection, and a poor healthcare system. As a result, life expectancy in Ukraine is one of the lowest in Europe and is on average 76.0 years for women and 66.2 years for men. According to WHO and the State Statistics Service of Ukraine, mortality per 1,000 people increased from 12.10 in 1990 to 25.2 in 2020. Among the causes of high morbidity and mortality, cardiovascular and oncological diseases occupy a leading place, the development of which is associated, among other reasons, with nutrition. Every person has an inalienable natural right to the security of his life. One of the important elements of life safety is food safety[15, 16].

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[14] Димань Т. М., Козловська М. В., Облап Р. В., Дубін О. В., Кравченко О. І. Генетично модифіковані сільськогосподарські культури: прогрес, проблеми, перспективи : монографія / за ред. Т. М. Димань, Л. Г. Шморгун. Серія: Імплементація європейських норм і практик. Регулювання ринків та дослідництво в умовах СОТ. Київ : Проблеми інноваційно-інвестиційного розвитку, 2013. 158 с.

[15] Кошкалда І. В. Актуальні питання продовольчого забезпечення. *Вісник Сумського національного аграрного університету.* 2017. Вип. 4 (71). С. 207–212.

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After all, it is well known that the consequences of consuming low-quality and unsafe food products can be a danger to human health of varying degrees, up to and including fatal cases. Food poisoning, in addition to harming the health of a particular consumer, causes significant losses to the economy and the image of the state, manufacturing enterprises, trade, tourism, etc. To prevent these adverse consequences, each state implements certain principles of state policy to ensure the safety and quality of food products and food raw materials.

Trends in world economic policy have placed Ukraine in the need to make radical decisions regarding the harmonization of legislation in the field of food production with international standards and the adaptation of national food safety standards to world requirements. In modern conditions, the successful process of Ukraine's integration into world economic cooperation is impossible without coordinating efforts to ensure the production of safe and high-quality food products. To this end, food industry enterprises are developing and implementing safety and quality management systems, for the successful use of which it is necessary to adhere to the general principles of food hygiene. The modern attitude towards food safety has been formed relatively recently. The increase in environmental pollution, the introduction of new food production technologies, the use of genetic engineering and biotechnology, the globalization of modern food production and the strengthening of international trade relations between countries have prompted the introduction of new international food legislation in order to introduce stricter requirements for the safety and quality of food products. In view of this, in 1963, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) established the Codex Alimentarius Commission. The main objective of the Commission was to create a set of internationally recognized standards for food products. This became the starting point for the development of requirements for ensuring the safety and quality of food products at the national levels[17, 18].

The crisis in the food industry, associated with outbreaks of infectious diseases of farm animals (foot-and-mouth disease, transmissible spongiform encephalopathy of cattle, avian influenza), the detection of hormones in pork, antibiotics in honey, dioxins in poultry, etc., led to the development and justification of new approaches to risk management in the field of food safety. These approaches were included in the Green Paper (1997) and the

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[17] Безпека продовольчої сировини і харчових продуктів / за ред. Т. М. Димань, Т. Г. Мазур. Київ : ВЦ «Академія», 2011. 520 с.

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White Paper (2000) on food safety, and later transformed into a number of regulatory documents of the main EU legislation[19]. Today, a global and integrated approach to the food safety system includes a number of fundamental points, such as, among others, the recognition of animals as sentient beings; mandatory state control over all links in the food production and consumption chain; differentiation of responsibility for compliance with safety principles; the right to objective and timely information; increasing public trust in food producers; introduction of effective systems for monitoring and evaluating the effectiveness of national authorities. Today, ensuring the quality of food raw materials and food products in production is achieved by introducing and adhering to product quality management systems, as well as standards that regulate the requirements for them. International organizations have developed and implemented a number of systems to ensure the quality and safety of food products. One of such systems is the HACCP system. HACCP is the most common method of ensuring the safety and quality of food products. This system is based on such basic principles as conducting a risk analysis, determining critical control points, determining critical limits, creating a monitoring system for critical control points, describing corrective actions, determining procedures for verifying the effectiveness of the HACCP system, documenting all procedures and recording evidence[20, 21]. Food safety problems are complex, and their solution requires numerous efforts from scientists, manufacturers, sanitary and epidemiological services, government agencies, and consumers.

The relevance of this problem is growing every year, since food safety directly affects not only human health, but also the preservation of the gene pool of humanity as a whole. Food safety is primarily the absence of direct danger to human health when consuming food (food poisoning, food infections), as well as the absence of the danger of long-term consequences (carcinogenic, mutagenic and teratogenic effects). Thus, food products that do not harm the health of not only the current generation, but also the future are considered safe.

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CONCLUSIONS

With food, substances hazardous to health can enter the human body in significant quantities. Today, the issue of increasing the responsibility of producers to ensure effective mechanisms for controlling the quality of food products and guaranteeing their safety for the health of the consumer is very acute. The safety of food products is assessed according to sanitary and hygienic standards, which include biological objects, potentially dangerous chemical compounds, radionuclides and harmful plant impurities. Their presence in food products must be regulated and not exceed permissible standards. More than half of the harmful substances that regularly enter the human body come with food. Therefore, ensuring the environmental safety of food products is extremely important. In recent years, the relevance of this problem has further increased due to the widespread use of various types of food additives and new packaging materials. In addition, a large number of small enterprises have appeared, where the technological process of food production is not sufficiently controlled. Hazardous substances can enter food products at the stage of obtaining food raw materials from environmental objects, as a result of the introduction of special additives during the production of food products to improve taste, improve appearance or increase shelf life. The safety of food products can also decrease when new production technologies are used, such as genetic engineering or radiation exposure. The decrease in environmental safety at the stage of production of raw materials of plant and animal origin occurs as a result of the absorption and accumulation of chemical substances by these organisms. The accumulation process can occur through bioconcentration, biomultiplication or bioaccumulation. In the first case, the accumulation of chemicals occurs due to direct perception from the environment, in the second – during nutrition, in the third – both due to the environment and food products. Thus, in connection with global pollution of the external environment, the problem of foreign substances entering food products and raw materials acquires socio-medical and socio-economic significance. The relevance and complexity of this problem at the current stage of industrial development is determined not only by the fact that new substances enter nature every day, new combinations of chemical compounds are formed, the action of which is unstudied, but also by the fact that methods for determining foreign substances are largely cumbersome, laborious and, unfortunately, not always accurate. If at the beginning of the 20th century, thanks to the successes of medical and biological sciences, as well as preventive measures, many diseases lost their leading role, then at present, due to environmental problems, the number of diseases is increasing.

SUMMARY

The safety and quality of agricultural raw materials and food products is one of the crucial components of the economic security of each state and is determined by the country's ability to effectively control the production, export and import of food on generally recognized principles. In developed countries, there is a multi-level system of protection of the population from substandard goods, which is based on quality control. Monitoring and control of the safety and quality of agricultural raw materials and food products is impossible without the availability of appropriate analytical methods of analysis and diagnostic test systems. Therefore, today, great attention is paid to the development of modern highly effective approaches and methods for detecting safety and quality indicators.

One of the critical points during the detection of GMOs and the determination of their quantitative content for both DNA and protein analysis methods is sample preparation. In this case, it is important to take into account not only the limitations of each of the sample preparation stages, but also the specifics of the analysis. The final result is also significantly affected by the size of the sample and the procedure for its selection. An equally important stage in the development of methods for the determination of GMOs based on DNA analysis is the optimization of the DNA extraction procedure. This is primarily due to the fact that, firstly, food samples contain a fairly high amount of inhibitory agents, and secondly, the vast majority of them undergo heat treatment. Today, there are a number of approaches to the determination of transgenic organisms, but the most common are two, in particular, the enzyme-linked immunosorbent assay method and the polymerase chain reaction method. Enzyme-linked immunosorbent assay (ELISA) involves testing for the presence of specific proteins using specific binding between an expressed antigen and an antibody. Polymerase chain reaction (PCR) is based on the detection of DNA sequences introduced into a given crop. These methods can be used both for qualitative analysis, showing the presence or absence of GMOs, and for determining the quantitative (percentage) content of GMOs in the sample under study.

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