LEGAL PROTECTION OF PUBLIC HEALTH THROUGH CONTROL OVER GENETICALLY MODIFIED FOOD

ABSTRACT (second language):

Prawna ochrona zdrowia publicznego poprzez uzyskanie kontroli nad żywnością genetycznie modyfikowaną

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ABSTRACT

Introduction: Science is constantly being developed which leads to both positive and negative changes in public health and the environment. One of the results of scientific progress is introduction of food based on genetically modified organisms whose effects on human health, to date, remain scantily studied and are ambiguous.

The aim: to determine how human health can be influenced by food production based on genetically modified organisms.

Materials and methods: international acts, data of international organizations and conclusions of scientists have been examined and used in the study. The article also summarizes information from scientific journals and monographs from a medical and legal point of view with scientific methods. This article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

Conclusions: Genetically modified organisms are specific human-made organisms being a result of using modern biotechnology techniques. They have both positive and negative effects on human health and the environment. The main disadvantage is not sufficient study of them in various spheres of public life.

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INTRODUCTION

Human health is substantially influenced by various factors [1,2,3,4], but recently, considerable attention of scientists around the world has been given to effects of food produced using genetically modified organisms on human organism and the natural environment. It is believed that when consuming food containing GMOs, people are at increased risk of getting various diseases and ultimately, their health deteriorates and their quality of life becomes lower. This means that introduction of the latest food production technologies and developments does not always guarantee positive changes in the system of public health, each person's health and the environment.

THE AIM

Aim to describe effects of food produced using GMOs on human health.

MATERIALS AND METHODS

According to Art. 3 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity [5], "living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Under Art. 2 of Directive 2001/18/EC [6]: genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. GMOs are organisms whose genetic material (DNA) has been altered not by reproduction and/or natural recombination but due to introduction of a modified gene or a gene of a different kind or biological species [7, p. 111]. A genetically modified organism is any organism other than a

human organism that has a novel combination of genetic material which is different from natural one and has been obtained using modern biotechnological techniques [8, p. 25]. In other words, based on the mentioned above, it can be noted that emergence of genetically modified organisms is associated with interference in functioning of respective natural processes which leads to emergence of novel combinations of genes. There are different attitudes to emergence and existence of such organisms and, accordingly, to food produced using them from legal, economic, ethical and other perspectives. But in spite of diversity of opinions, an insight into what these objects are and what effects they have on human health and the environment is of vital importance in this context.

The main potential benefits and costs attributed to GMOs: potential benefits: – promoting efficiency in farming – for example by reducing labour costs of herbicide or insecticide spraying and less tillage; – increased yields – by reducing losses from pests and disease, hence reduced pressure for more farmland; – providing altered product characteristics to aid in food processing – such as tomatoes which soften more slowly and therefore have lower water content facilitating processing into paste; – controlling fertility – to improve the purity of hybrid seed, hence higher yields; – reducing fertiliser inputs through nitrogen fixation; – reduced pesticide use [9, p. 250].

The development of a growing number and range of GMOs has opened up significant potential for many useful applications in agriculture and food-processing, pharmaceuticals and diagnostics, environmental clean-up, chemicals production and the development of new materials and energy sources. At the same time, however, there are some concerns about the potential risks to human health and the environment associated with the use and the release of these novel organisms into the environment, and in particular in relation to longer-term effects which are very difficult to predict. The need to undertake environmental risk assessments and to implement risk management measures as required has been recognised by the EU, and also by the USA and the other industrialised countries who are members of the OECD. Many non-OECD countries are also realising the need to take a preventative approach, especially as a result of the discussions at the UNCED in Rio de Janeiro in 1992 and the implications for biotechnology of the UN Biological Diversity Convention [10].

Thus, among the most important positive results of using GMOs, it is possible to highlight increase in productivity of certain areas, in particular, agriculture, which is expressed both as a direct result of such activity (growth of yields) and simplification of procedural characteristics of its implementation (reduction in labour costs, decrease in an amount of fertilizers and pesticides that are applied).

Among negatives of using GMOs, there are direct environmental effects: – if there is gene transfer from the GMO to native flora or fauna – leading to new pests as a result of hybridisation; – unexpected behaviour of the GMO in the environment if it escapes its intended use and becomes a pest; – disruption of natural communities – through competition or interference; – food web effects through harm to non-target species; – harmful effects on ecosystem processes – if products of GMOs interfere with natural biochemical cycles [9, p. 250]. Indirect environmental effects are the second type of negative consequences of using GMOs that, namely, mean – continuation of intensive agricultural systems – as a result of the requirement for high levels of external inputs; – impacts on biodiversity as a consequence of changes in agricultural practice; – cumulative environmental impacts from multiple releases and interactions; – alterations in agricultural practices, for example, to manage any direct environment impacts such the evolution of insect, herbicide or disease resistance in weeds. Moreover, food containing GMOs can have significant influence on human health: – new allergens being formed through the inclusion of novel proteins which trigger allergic reactions

at some stage; – antibiotic resistance genes used as 'markers' in the GM food being transferred to gut microorganisms and intensifying problems with antibiotic-resistant pathogens; – the creation of new toxins through unexpected interactions between the product of the GM and other constituents [9, p. 250]. There are several types of potential health effects that could result from the insertion of a novel gene into an organism. Health effects of primary concern to safety assessors are production of new allergens, increased toxicity, decreased nutrition, and antibiotic resistance [11]. Here are seven ways that GMOs may adversely affect health: 1. Food allergy – According to the Organic Consumers Association, "The list of GM food products intersect with the eight most common food allergens: eggs, milk, fish, peanuts, shellfish, soy, tree nuts, and wheat." OCA states that protein in foods is what triggers allergic reactions and "most of the foreign proteins being gene-spliced into foods have never been eaten by humans before or tested for their safety."

2. Toxicity. 3. Infertility – According to the American Academy of Environmental Medicine, "There is more than a casual association between GM foods and adverse health effects. 4. Gluten Disorders – In a 2013 report released by the Institute for Responsible Technology, internist Emily Linder MD states, "Based on my clinical experience, when I remove genetically modified foods as part of the treatment for gluten sensitivity, recovery is faster and more complete. 6. Birth defects – Glyphosate is the active ingredient in the herbicide RoundUp. According to Andres Carrasco, head of the molecular Embryology Lab at the University of Buenos Aires glyphosate "is responsible for causing birth defects, infertility, sperm destruction, and cancer." 7. Cancer [12].

In other words, negative effects of using GMOs are both general and derived. General negative effects of using GMOs manifest themselves in harming the environment, its components and processes occurring in it. Effects that are directly related to the environment in which GMOs are used and its impact on human health are among derivative ones.

According to provisions of Art. 4 of the preamble of Directive 2001/18/EC, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible. The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs) (para. 4). In other words, firstly, the purposes of emergence of such organisms may be different, secondly, their release into the environment is intentional and, thirdly, their ability to adapt to the environment and therefore affect other objects and processes can be of different character, including negative one.

Art. 11 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity establishes a procedure for living modified organisms intended for direct use as food or feed,or for processing. Under Annex III of the above mentioned Protocol, the objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health. In accordance with Art. 2 of Directive 2001/18/EC, «environmental risk assessment» means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.

It is also important to pay attention to types of GMO effects on human health and the environment. In Annex II of Directive 2001/18/EC, the following kinds of effects are distinguished: direct, indirect, immediate, delayed effects. The term 'direct effects' refers to

primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events (para. 2). The term 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management (observations of indirect effects are likely to be delayed). The term 'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect. The term 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release. Furthermore, such a mentioned term as 'cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including inter alia flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

The latter concept correlates in a certain way with the concept of delayed effects in the time spectrum of possibilities of occurrence of corresponding consequences, but the difference between them is that the concept of cumulative long-term effects is a corresponding complex collective concept and its essence is in accumulating results of interaction of relevant objects with GMOs. Such accumulation may have certain manifestation and be a prerequisite or cause of changes of certain objects as well as human health and the environment.

In other words, the Directive specifies a classification of potentially possible effects of GMOs on human health and the environment which may be manifested in varying intensity, a degree of spontaneity and time intervals of the influence concerned. By the criterion of intensity, effects of GMOs can be classified as direct and immediate, related to direct interaction of an object with GMOs and insignificant short term manifestations of such effects. By a degree of spontaneity, the effects can be defined as direct and indirect, and by time intervals – as immediate and delayed.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity and Directive 2001/18/EC also provide general principles on which the specified assessment of GMOs effects relies. Namely, it is a scientific character that is expressed in committing corresponding actions which are conditioned by certain scientifically grounded techniques, have transparent research methods and a case-by-case basis that is determined by data which may differ in character and level of detail in each particular case, depending on a corresponding living modified organism, its intended use and the likely potential receiving environment. Each time before GMOs are released into the environment, the environmental risk assessment shall be carried out on a case-by-case basis. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment (para. 19 of preamble to Directive 2001/18/EC).

Along with the provisions stipulated above, the principles of the environmental risk assessment (hereinafter e.r.a.) are also given in Annex II of Directive 2001/18/EC. In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

– identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

– the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

– the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;

– if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:

– determine whether the risk has changed;

– determine whether there is a need for amending the risk management accordingly.

The aforementioned principles of Directive 2001/18/EC are in line with those mentioned in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Annex III General principles). Firstly, all of them are combined by the precautionary principle, whose essence is expressed in preventing occurrence of negative effects on human health and the environment or minimizing them. Secondly, individualization is important both in the context of defining the negative character of GMOs effects and their essential features that are inherent in one type of GMOs in comparison with others (a case-by-case basis). Thirdly, scientific approaches to the e.r.a. shall be applied (a scientific sound manner). Fourthly, there shall be responding to the data received to identify detectable novel combinations of such organisms in the relevant objects and application of necessary preventive measures (a transparent manner).

It is important to study the experience of legal regulation regarding the issue of the permissibility of GMOs in food production in different countries in view of their possible negative effects on human health and the environment.

REVIEW AND DISCUSSION

Techniques of genetic modification listed in Annex I A of Directive 2001/18/EC are among important aspects of study of GMOs and their effects on human health. Among the following techniques, one can determine the following:

1. recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

2. techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

3. cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

These techniques and their effects on human health have become the subject of repeated scientific studies. Thus, recombination is understood as emergence of novel combinations of genes leading to a novel combination of signs in the offspring [13]. The following techniques are characterized by certain processes associated with different ways of introducing the material into the organism. Namely, they are carried out by means of micro-injection, macro-injection and micro-encapsulation. In turn, micro-injection is understood as introduction of a substance into microscopic objects (cells, nuclei, etc.) with a micro-capillary pipette [14]. With regard to the latter methods, they are based on merger of two or more cells with methods that are not found in natural conditions.

In recent years, the development and use of new techniques of genetic engineering have profoundly changed the traditional methods and scope of biotechnology. These sophisticated techniques enable the identification of many genes which confer desirable characteristics, and

the transfer of these genes to organisms which did not possess them before. Traditional selection and breeding techniques have been used for a long time in industry and agriculture to produce organisms with more desirable characteristics. However, the new, more powerful tools of molecular biology allow biological barriers to be bypassed and novel organisms with new or enhanced properties to be created. For example, a gene from a microbe responsible for expressing a certain natural toxin against insects can be introduced into the genetic material (DNA) of crop plants, which can then protect themselves from insect attack without the need for application of pesticides [10, p.6].

Despite different attitudes towards food containing GMOs, such food still dominates on a global scale. Nearly two-thirds of all genetically modified crops are grown in the United States because of relatively favourable regulation of GMOs there, moreover, the country is not a party to the Cartagena Protocol on Biosafety [16]. GMOs in the USA are generally recognized as safe, they are equated with conventional products. In addition, labeling of GMO-containing products is not obligatory at all [15], but in case of a GMO product that is noticeably different in structure, function, etc., premarket approval of the product is binding [16]. Something similar is observed in Canada. However, in Japan, all food containing GMOs is subject to mandatory labeling. In African countries, in the last few years, a ban was introduced on import of food containing genetically modified components [15].

CONCLUSIONS

In view of the above, it can be noted that genetically modified organisms are objects that have artificial origin associated with emergence of novel combinations of genes, based on the relevant principles, techniques. Moreover, there are different purposes of their emergence and risks of their effects of human health and the environment. On the one hand, such emergence is associated with relevant processes occurring both in the world in general and in certain countries in particular, but on the other hand, their effects on human health and the environment have been studied insufficiently, and, accordingly, it is difficult to determine a ratio of benefits associated with genetically modified organisms to their negative effects (both real and potential). Furthermore, the above-mentioned set of problems requires not only additional study and research based on the available data, but also more effective legal regulation. In particular, along with the use of such legal devices as mandatory labeling, certification of food containing GMOs, it would also be expedient to tighten control over effects of such food on human health by introducing additional measures, for example, accreditation of producers of such food, creation of scientific and expert laboratories to monitor the effects of food containing GMOs and others.

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