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GMO AND HEALTH RISKS SELECTED ISSUES

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Abstract. *Genetically modified organisms (GMOs) is a topic of intense debate across the globe since they are widely used in several commercial products and the GMO industry counts for billions of US dollars. Genetically modified crops can assist to mitigate problems in commercial agriculture with proven case studies in Indian cotton and Australian canola [1]. The success of the GMO industry has been impeded by negative information concerning health and environmental risks. The aim of the paper is to assess the current research (from 2010-2019) on the health risk of GMOs (with a special emphasis on genetically modified plants). EBSCOhost (including Medline) and ScienceDirect databases were used for review of the literature. The paper concludes that research on GMO health risk is still lacking in sound methodology, complexity, continuity, objectivity and remains inconclusive.*

Keywords: *genetically modified organisms, public health, health risks, research on GMO, GMO plants.*

Tabl. 1. Lit. 15.

Introduction. Contemporary farming is more and more intensively using modern techniques, technology, and science in order to increase the farming productions. Genetically modified (GM) plants are widely used in several commercial products. Corn, cotton, soybean, canola, sugar beet, and other crops are the most widely consumed foods globally and their derived products have reached the global markets. Corn has the greatest diversity of approved genetically modified events globally (a total of 130 varieties approved in one or more countries) [2]. The market of genetically modified seeds alone became multibillion dollar industry [3] and the global genetically modified foods market or bioengineered foods market is estimated to grow at 5.10% CAGR during 2018-2026 [4]. This expected growth is fuelled by (among others): growing number of undernourished populace augmenting the demand for nutritional and healthy food; rise in genetically modified crops area and plantation; genetically modified foods production reduces the need for pesticides; rising demand for crop yield; increasing investment in the field of biotechnology research and development, and rising approvals of genetically modified foods across the world [4]. The major players in the genetically modified foods market are BASF SE, Bayer AG, Syngenta AG, Monsanto, KWS SAAT SE and others.

The development of GMOs market is hampered by worries regarding potential GMOs negative impact on health, environment and biodiversity.

There is no consensus about the likely effects of the GMO foods, but the fact remains that the effects on health are risky and highly unpredictable. Unintended health impacts from GMOs are related to allergens, antibiotic resistance, decreased proteins and toxins. The concerns are that they might contain allergenic substances due to the introduction of new genes into the crops or animals.

Analysis of recent publications. Since the review of the literature on GMOs and health risk constitutes the spin of the paper and will be developed below, one may acknowledge here, that the current debate on GMOs and food biotechnology allows to conclude that there is a serious conflict between two groups. One group consists of agri-biotech investors and producers and their affiliated scientists who consider agricultural biotechnology as a solution to food shortage, the scarcity of environmental resources and weeds and pests infestations. They are tempted to maintain that there is no health risk of GMOs and GM plants [5, 6]. The other group, the opponents, is built of independent scientists, environmentalists, farmers, and consumers. They claim that genetically modified food introduces new risks to food security, the environment and human health such as loss of biodiversity; the emergence of superweeds and superpests; the increase of antibiotic resistance, food allergies, and other unintended effects [7].

One may conclude that the scientifically-assessed direct hazardous impacts of GM food and feed on fauna and flora are conflicting. Although a review of literature available provides some evidence of GM environmental and health risks, the consequences of gene flow and risks to biodiversity are still debatable [8].

The aim of the paper .This paper is aimed at assessing the current research (defined as publications from 2010 until now) on the health risk of GMOs (with a special emphasis on genetically modified plants).

Desk-top analysis was chosen as a method. Two databases were explored: EBSCOhost (covering among others Medline) and ScienceDirect. The following key words were used for search: *genetically modified organisms, modern farming, health, and health risks* in various combinations. Title and abstract as search fields were used. The time span for search was: 2010-2019. The selection process had three steps. First the list of all identified sources was made and results were assessed and then selected by the title. Then the abstracts of publications fitting the best with the research were analyzed. Finally, 28 publications were chosen for in-depth analysis.

Results and discussion. The paper concludes that there were no breaking findings on the health risk of GMOs over the last ten years. This means that most publications remains inconclusive, i.e. do not provide hard facts for or against GMO and GM plants. Research providing some evidence of GM environmental and health risks [8, 9, 10, 11] is hectically debated [12,13] indicating lack of sound methodology and objectivity [14]. Consequently, one may suggest developing adequate methodology and procedures which could be used in experiments and

implemented/intensified studies on the long-term health effects of GM plants introduce long-term experiments.

GMOs and health risk. Human health can be seen as a function of dozens of factors influencing it. Human health depends from a wide spectrum of factors starting from inherited gene system and ending up with life style and diet. The nature of health determinants preclude that GMOs can be monitored as a potentially hazardous factor influencing environment, biodiversity as well as ingredients of our food products [15] in isolation from other factors. But certainly should be monitored. That is why GMOs are subjects of state regulation. There is a difference between USA and European Union in respect to GMOs. While American regulation and respective policies towards GMOs can be characterized as rather liberal, European Union seems to be more cautious, establishing institutional infrastructure in form of European Food Safety Authority (EFSA) which goal is to assess independently and provide scientific advice to risk managers on any possible risks that the use of GMOs may pose to human and animal health and the environment. Under EU legislation, case-specific monitoring may be required, on a case-by-case basis, by the European authorities as one of the conditions of marketing approval for crops containing GMOs. Whilst such crops have to undergo a rigorous pre-market assessment, post-market monitoring could serve to verify assumptions or to address any questions arisen during the previous assessment.

The publications researched and presented in Table 1 do not contain a breakthrough findings regarding proved health risks by GMOs and GM plants. This means that majority of research remains inconclusive.

There are, however, few issues worth to be commented upon.

One may start from the scope of regulation for GMOs. For example, it is debatable whether new plan breeding techniques (NPBTs), their resulting plants and their products should be covered by GMO legislation. For some people the trigger for regulation should be the single product and its phenotypic traits, while for the opponents the law should also regulate certain biotech processes used in production .

The next is the fact that research on GMOs and health risk suffers from several weaknesses. Here one may point at scarcity of information on the safety of GM foods and plants in specialist scientific journals. Also the methodology and procedures used in experiments with GMOs are being criticized [11, 14, 15], including the most detailed regulatory tests on the GMOs in European Union which are 90 day-long feeding trials of laboratory rats which are biochemically assessed [13]. One may also argue that 90 day trials are enough to assess the long-term health risk of GMOs and GM plants. It is stressed that studies on the long-term health effects of GM plants, including tests of mutagenicity, teratogenicity and carcinogenicity are necessary [15].

In research on health risk of GMOs, the core issue is operationalization of risk [10, 12] which still is a problem. Some add, that in research on health risk even such a basic issue as problem formulation remains a challenge [13]. Consequently, one may maintain that generally applicable tools and methodology for monitoring crop

species are still under development, leaving many fundamental questions, for example: which effects are already known to be associated with the consumption of GM feeds by livestock [15] or: which indicators of a potential health impact can be used to monitor for such effects of feeds in a post-market monitoring program [14] still unanswered. Weak methodology can – to some extent – explain fierce debate on findings indicating negative GMOs impact on health.

The debate is not free from conflicts of financial and professional interests of involved researchers indicated in the literature [3, 10, 11, 14].

Here the case of Séralini et al. [9,14] seems to be the most recent, the contribution of an in-depth analysis of 94 scientific articles by Diels et al. [3] notwithstanding. Séralini et al. study [9] investigated the long-term effects in rats of consumption of two Monsanto products, a genetically modified (GM) maize (NK603) and its associated pesticide, Roundup, together and separately. The findings suggested both the maize and the Roundup herbicide it is grown with, pose serious health risks.

The two-year feeding study found that rats fed both suffered severe organ damage and increased rates of tumors and premature death. The findings initiated a hectic debate, where both scientific and political arguments were in use. The latter are connected with the decision by Elsevier, the publisher of *Food and Chemical Toxicology* where the article was submitted to retract the paper. It was a few months after the appointment of a former Monsanto employee, Richard E. Goodman, as “editor for biotechnology”, a position created for him at *Food and Chemical Toxicology* [15]. Such controversial decisions started discussion about the “dangerous erosion of the underpinnings of the peer-review process” [6].

Summary The recent literature on health risk of GMOs and GM plants on health does not offer a scientifically sound, precise answer. Both scientific society and open public still do not know whether GMOs and GM plants are hazardous for

Table 1. Subjects and selected findings from publications under review

Author(s)	Subject	Selected findings
Raman, 2017	Research on GM crops	-GM crops do not harm environment
Asicioglu et al., 2017	Investigation of the taxon-specific cauliflower mosaic virus 35S promoter region (CaMV) and <i>Agrobacterium tumefaciens</i> nonpalin synthase terminator (tNOS) gene in addition to the control gene of High Mobility Group (HMG). Corn-containing foods were obtained from grocery stores in Turkey	- inconclusive* -randomized screens should be carried out by scientist in random bases
Diels et al., 2011	Research on a conflict of interests among researchers (based upon 94 articles selected through objective criteria)	- a strong association was found between author affiliation to industry (professional conflict of interest) and study outcome (p <0.001)

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Novella, 2014	The article discusses the controversy over the public safety and optimal regulation of genetically modified organisms technology in the U.S.	-GMOs are safe
Brandon, 2016,	Reflection on the results of the study conducted by the National Academy of Sciences, Engineering, and Medicine	-genetically modified crop ingredients pose no health risk
Maghari & Ardekani, 2011.	Review of the literature	-inconclusive; -there is a need for continuous vigilance for all countries involved in producing genetically engineered food to follow the international scientific biosafety testing guidelines containing reliable pre-release experiments and post-release track of transgenic plants
Tsatsakis et al., 2017	Review on scientifically-assessed direct hazardous impacts of GM food and feed on fauna and flora	- risks to the environment and ecosystems can exist; - very important is to provide precise knowledge and adequate current information to regulatory agencies, governments, policy makers, researchers, and commercial GMO-releasing companies to enable them to thoroughly investigate the possible risks
Séralini et al. , 2012	the long-term effects in rats of consumption of two Monsanto products, a genetically modified (GM) maize (NK603) and its associated pesticide, Roundup, together and separately.	- both the maize and the Roundup herbicide it is grown with, pose serious health risks; - rats fed both suffered severe organ damage and increased rates of tumors and premature death
Krimsky, 2015	Review of publications on GMOs and discussion about the treatment of scientists who have reported adverse effects in animal feeding experiments	-politics and corporate interests have had a big role in distorting an honest inquiry into the health effects of GMO crops
de Vendômois et al., 2010	The review of the major points of international debate on health risk studies for the main commercialized edible GMOs	- alimentary chronic risks may come from unpredictable insertional mutagenesis effects, metabolic effects, or from the new pesticide residues; - the test data and the corresponding results are kept in secret by the companies; - hepatorenal toxicities were possible; - longer testing was necessary -shortcomings in the experimental protocols designed by the company; - nonexistent traceability or epidemiological studies in the GMO-producing countries

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Barale, 2013	Letter to the editor: criticism of Séralini et al., 2012	-findings by Séralini et al. , 2012 can be questioned on scientific basis
Steinberg et al., 2019	Criticism on Séralini et al. , 2012	- no adverse effects related to the feeding of the NK603 maize cultivated with or without Roundup for up to 2 years were observed; -recommendations on the scientific justification and added value of long-term feeding trials in the GM plant risk assessment process are presented
Séralini et al., 2014	Debate on findings from 2012	-misinterpretation of findings from 2012; -double standards in evaluation by reviewers
de Vos & Swanenburg, 2018	Research on feeding GM crops	- inconclusive; -no clear evidence that feed composed of first generation GM crops has adverse effects on animal health; -research should be intensified
Devos et al., 2014	The role of the European Food Safety Authority (EFSA)	-EFSA plays important role in monitoring GMOS market
Domingo, 2016	Review of the literature on the safety of GM food (in 2000, 2007 and 2011)	-updated information on the potential adverse health effects of GM plants; - studies in the last six years show rather similar conclusions; - studies on the long-term health effects of GM plants are necessary
Hartung & Schiemann, 2014	Research on new plant breeding techniques (NPBT)	-the list of NPBT should be shortened; -plants developed by NPBT are not expected to possess higher risk for health and environment; -NPBT should not be regulated as GMOs
Tagliabue, 2018	Research on advanced biotechnologies in the agri-food sector("New Breeding Techniques")	-inconclusive; -misuse of the Precautionary principle -a misplaced alarm about "uncontrolled spreading" of genetically engineered cultivars
Rajan & Letourneau 2012	Research on risk assessments	-risk assessments are more complex, black boxing risk analysis should be abandoned; -it is necessary to build interdisciplinary institutions that can address the complex interactions between ecosystems and society
Herman et al., 2019	Review of the literature	-inconclusive; -a more thorough characterization of risk is needed

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Bobe & Procopie, 2015	Review of the literature	- GMO products have entered all the parts of the public food supply; - EU regulations do not apply to products derived from animals fed with genetically modified feed or treated with genetically modified medicinal products
Tepfer et al., 2013	Research on risk analysis	-research on GMOs suffers from not precise problem formulation
De Santis et al., 2018	Research on GMOs	-inconclusive but better organized research is needed
Robinson & Latham, 2013	Conflict of interests in research on GMOs	-GMOs critics are exposed to unethical practices and unfair treatment
Portier et al., 2014	Conflict of interests in research on GMOs	-unprofessional attitude towards critical findings; -double standards in reviewing
Paz, 2018	Research on opinion about GMOs; an 8-question survey with an optional comments section	-results (n = 150) suggest that most individuals are open to learning more about GMOs and believe that GMO production and research should be heavily monitored.
Aleksejeva, 2012	Consumer survey on the link between risk perception and willingness to buy-genetically modified (GM) food	- the high risk associated with GM foods as perceived by the respondents seems to be the main obstacle to the consumer's acceptance of GM food and willingness to purchase such kind of food

**inconclusive means here that no scientifically and statistically well supported findings were presented*

Source: author's own

health or not. The existence of conflicting interests between the producers and (some) researchers notwithstanding, one may maintain that development of the sound methodology and procedures for long-term research on health risk of GMOs and GM plants could considerably improve the quality of research and – consequently – findings. This in turn could provide consumers with solid knowledge allowing them either to verify their opinions about GMOs and GM plants [7] and/or make a rational consumer decisions [8].

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АНОТАЦІЯ

ГМО ТА РИЗИКИ ДЛЯ ЗДОРОВ'Я: ОБРАНІ ПИТАННЯ

Генетично модифіковані організми (ГМО) є темою інтенсивних дебатів по всьому світу, оскільки вони широко використовуються в кількох комерційних продуктах, а промисловість на ГМО заробляє мільярди доларів США. Генетично модифіковані культури можуть допомогти пом'якшити проблеми в комерційному сільському господарстві з перевіреними прикладами досліджень на бавовнах і австралійському ріпаку. Успіху промисловості ГМО перешкоджає негативна інформація щодо ризиків для здоров'я та екології. Метою статті є оцінка поточних досліджень (з 2010-2019 рр.) щодо ризику для здоров'я ГМО (з особливим акцентом на генетично модифіковані рослини). Для перегляду літератури використовувалися бази даних EBSCOhost (включаючи Medline) і бази даних ScienceDirect. У документі робиться висновок, що дослідження ризику для здоров'я ГМО все ще відсутнє в обґрунтованій методології, складності, безперервності, об'єктивності і залишається безрезультатним.

Ключові слова: генетично модифіковані організми, охорона здоров'я, ризики для здоров'я, дослідження ГМО, рослин ГМО.

Табл. 1. Літ. 15.

АННОТАЦИЯ

ГМО И РИСКИ ДЛЯ ЗДОРОВЬЯ: ИЗБРАННЫЕ ВОПРОСЫ

Генетически модифицированные организмы (ГМО) является темой интенсивных дебатов по всему миру, поскольку они широко используются в нескольких коммерческих продуктах, а промышленность на ГМО зарабатывает миллиарды долларов США. Генетически модифицированные культуры могут помочь смягчить проблемы в коммерческом сельском хозяйстве с проверенными примерами исследований на хлопке и австралийском рапсе. Успеху промышленности ГМО препятствует негативная информация о рисках для здоровья и экологии. Целью статьи является оценка текущих исследований (с 2010-2019 гг.) Относительно риска для здоровья ГМО (с особым акцентом на генетически модифицированные растения). Для просмотра литературы использовались базы данных EBSCOhost (включая Medline) и базы данных ScienceDirect. В документе делается вывод, что исследования риска для здоровья ГМО все еще отсутствует в обоснованной методологии, сложности, непрерывности, объективности и остается безрезультатным.

Ключевые слова: генетически модифицированные организмы, здравоохранение, риски для здоровья, исследования ГМО, растений ГМО.

Табл.1. Лит.15.

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