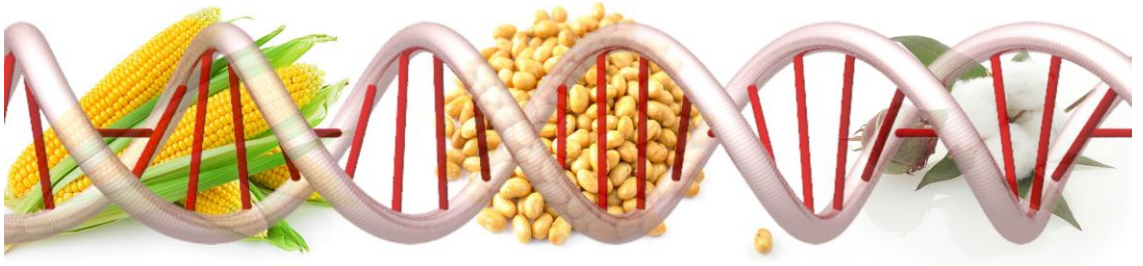


FOOD SAFETY AGENCY OF BOSNIA AND HERZEGOVINA

**GENETICALLY MODIFIED ORGANISMS
– PRESENT SITUATION AND FUTURE PROSPECTS –**



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Publishers:

Food Safety Agency of Bosnia and Herzegovina

For publishers:

Džemil Hajrić, Head of the Food Safety Agency of Bosnia and Herzegovina

2018

Printed by:

Circulation:

CIP - Katalogizacija u publikaciji
Nacionalna i univerzitetska biblioteka
Bosne i Hercegovine, Sarajevo

604.6

GENETICALLY modified organisms : present situation and future prospects /
Vojislav Trkulja ... [et al.]. - Mostar : Food Safety Agency of Bosnia and Herzegovina,
2018. - 124 str. : ilustr. ; 24 cm

Tekst na engl. jeziku. - Bibliografija: str. 108-118

ISBN 978-9926-8327-0-4
1. Trkulja, Vojislav
COBISS.BH-ID [26958854](#)

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Review excerpt – academic prof. Novo Pržulj, PhD

„...Genetically Modified Organisms – state of play and future prospects, a monograph, comes in times when long discussions are being held on genetically modified organisms (GMOs), the role of science in life and particularly in human health. Authors of this monograph tried to remain neutral - not to express their support to GMOs, but also not to negate their significance. They decided to provide comprehensive information to readers; those who oppose and those support the use of biotechnology achievements and GMOs, to explain state of play in biotechnology and GMOs, methods of risk assessment and biosafety applied before the GMOs and GM food, and to inform on future trends in producing GMOs. By discussing GMOs, the authors also point out the role of science in modern life, but also the ways to control it, in order to prevent potential negative effects of science products on human health, biodiversity and the environment.

The authors clearly put GMOs in social context, in which a GMO is just like a foreigner under different (non)scientific, bioethical, social economic, political and religious controversies.

Regardless of attitudes of countries, laws, social communities and individuals, the fact is that the public is not informed, or it is poorly informed on GMOs. Although, in this short period of time, it has not been possible to have an insight into all the aspects, it is necessary to have continuous scientific and professional discussion on this topic. The contribution of this monograph to the GMO issue is precise and articulate, and clear scientific and ethical attitude is presented, discussed by having in mind a precautionary principle, which I consider an appropriate contribution to science and profession. This monograph contributes to forming and developing modern and real scientific awareness, which shall be able to face all challenges. This makes the task of scientists to inform the public on key scientific and ethical issues regarding GMOs very difficult. And for that this monograph is so important.“

Banja Luka, 17 December 2018

Academic, prof. Novo Pržulj, PhD

Review excerpt – prof. Kasim Bajrović PhD

„...After a comprehensive analysis of the monograph and facts presented in it, it can be concluded that it provides all the necessary information on genetically modified organisms, risk assessment of GMOs, methods used for detecting GMOs, GMOs and biosafety, GMO legislation in the world, the EU and Bosnia and Herzegovina and future prospects on GMOs. The monograph provides detailed description of GMOs based on confirmed scientific evidence and it does not include any prejudice, which is usually a component of the debate on this topic. Furthermore, this monograph contributes to disseminating scientifically proven information on application of genetic engineering technologies, which are widespread in the modern world.

In conclusion, this monograph ‘Genetically Modified Organisms - State of Play and Future Prospects’ represents useful reading for all stakeholders, from BH institutions and their bodies, through legislative and executive level of the government to those who apply for authorisation, as well as consumers and interested general public. The monograph is concise, with appropriate writing style, understandable to all. Based on available information it can be concluded that this monograph is the most descriptive and concise text on GMOs in the Ex-YU region. The monograph can be very useful as an introductory concept in implementation of suitable programmes at all levels of the education system in Bosnia and Herzegovina.

According to all presented facts, opinions and feedback, it is my pleasure to propose this monograph to be published in its entirety.”

Sarajevo, 14 December 2018

Prof. Kasim Bajrović, PhD

1

CHAPTER

GENETICALLY MODIFIED ORGANISMS – *Introduction* –

The century we left behind us brought many innovations, fundamentally changing life of the humankind. When compared to previous periods, it was a century of great changes, and, certainly, a century of dramatically expansive scientific development in many fields. Now, when we are at the doorstep of a new millennium, we rightfully wonder what it will bring. It is difficult, from this perspective, to perceive how everything that was foreshadowed in the second half of the last century will mark the first century of the new millennium. Namely, it was already then certain that **Biotechnology** would do that, a science based on molecular genetics and its methods of genetic engineering, which achievements lead us to creating and using controlled and deliberately **genetically modified organisms** (GMOs).

GMOs and technology used to create them have already become, or shall increasingly become a part of our lives, which is why it is necessary to know more about them. This is important not only for scientists, but for everyone: producers, consumers and general public. In order for the general public to have the right attitude and opinion on GMOs and the technology used for their production, on all potentials and advantages, as well as on potential risks and negative consequences of such technology. They also need to know about the legislation in BiH regulating it, which fully in line with the current EU legislation, they need to have timely, easily understood and objective information, which is a primary goal of this monograph.

1.1. What are GMOs?

Genetically modified organisms (GMOs) are organisms containing one or more genes imported artificially in laboratories by using genetic engineering methods, i.e. genes are inserted from other unrelated species. The inserted gene is known as *transgene*, which is why such organisms are also known as *transgenic organisms*.

A *gene* is a part of a deoxyribonucleic acid (DNA) molecule which has a particular function, i.e. it is responsible for creating a specific protein. This means that a gene is a basic physiological and mutable unit of a chromosome structure. *Genotype* is a genetic constitution, i.e. hereditary

material in a cell and/or organism which determines physical appearance, i.e. *phenotype* of a given organism.

Genetically modified organisms (GMOs) are organisms with altered genome in a way that would have never happened through traditional reproduction, or natural recombination of existing genes within a specific species, i.e. in a way that is not possible in nature. Genetic constructions with altered host genomes most commonly originate from distant and unassociated species removing all natural barriers in natural gene migration, changing hereditary information. Therefore, GMOs in all their genetic material carry stably incorporated foreign DNA sequences, genes, present in the nucleus (or organelles) of cells of transgenic individuals passed onto progenies in accordance with the general laws of heredity.

Sources of genes inserted into the host DNA exist in plants, as well as in microorganisms, insects, animals, including human beings, and, having in mind the group they belong to, we can now talk about genetically modified microorganisms, plants and animals (Kajba and Ballian, 2007; Ballian and Kajba, 2011; Trkulja *et al.*, 2014a).

1.2. How long have GMOs existed?

Genetically modified organisms were produced for the first time in the 1970s. They were used in the production of human insulin replacing insufficient production of bovine insulin. Although this prevented a major ‘pharmaceutical’ crisis, genetically modified organisms didn’t arouse public attention because they were easily introduced into medicine, agriculture and everyday use. GMOs drew public attention and caused fear due to contaminated blood products containing HIV and Hepatitis B viruses, viruses which led to first victims. After this, there was a fear of ‘mad cow disease’. Even though GMOs were not connected in any way to these cases, general public was afraid of GMOs and genetic manipulation. Whatever the case, quality control, food safety and availability, as well as health protection are among the highest priorities today, which is why the general public should have a special role in the process of deciding on this issue (Ballian, 2005; Trkulja *et al.*, 2014a).

1.3. How do we produce genetically modified organisms?

Genetically modified organisms (GMOs) are produced by using ‘*genetic engineering*’ method or ‘*recombinant DNA technology*’, a group of techniques used for functional gene transfer in an organism with the purpose of producing new organisms with new traits.

Genetic engineering (recombinant DNA technology or modern biotechnology) represents a range of techniques which allow identifying a gene in a genome of a specific species, isolating it, and importing it into a genome of the same or a different species. (Jelenić, 2004a; Kajba and Ballian, 2007; Ballian and Kajba, 2011).

Techniques used for the transfer of foreign DNA into the host organism can be classified as *direct* (biolistics, electroporation, microinjection, macroinjection) and *indirect* (using *Agrobacterium tumefaciens*). Transgenic plants or animals usually carry several thousand base pairs foreign DNA sequence, expressing 2-4 functional genes with specific regulatory sequences. This 'DNA insert' represents only one millionth of a genome in a modified plant or animal cell (Kajba and Ballian, 2007; Ballian and Kajba, 2011).

Genetic engineering techniques have now a broad application in scientific research in all fields of biology, as well as in human and veterinary medicine, forestry, agriculture, pharmaceutical and food industry, protection of the environment from pollution and other human activities. Biological research based on this technique usually refer to introduction and function of genes and their practical use for the benefit of humankind. Such genetically modified organisms, with specific genes inserted, produce human proteins necessary for treatment and prevention of different diseases. They are among others: insulin (for treatment of diabetes), interferon (for viral diseases), coagulation factors (for treatment of haemophilia), different vaccines, antibodies, etc.

Genetic engineering implies the use of modern and highly sophisticated methods for obtaining new traits of microorganisms, plants and animals. Unlike other methods of genetic improvement, the application of this technology is strictly regulated, which is why genetically modified organisms or food products derived from GMOs or containing GMOs, can be placed on the market only after being approved through a comprehensive procedure. This procedure is based on scientific approach to assessing the risk they pose on health of people, environment and biodiversity (Trkulja *et al.*, 2014a).

1.4. What are the advantages and the risks of cultivating GM plants?

There are many ethical and technical issues related to the GMO technology, and industry. Genetics has grown, from science dealt with exclusively by a small scientific community, to a topic discussed by many: the competent, the incompetent, professionals, amateurs, enthusiasts, sensationalists, the moderate, the passionate, the careful and the curious.

Difference of opinion is inevitable and it is part of human nature. However, there has never been a topic to divide public so much as has the issue of GMOs, dividing people to those who support it and those who bitterly oppose it. So, while some expect this technology to bring many important changes into our lives, to increase quality of our lives providing incredible perspectives, the others openly express their fear of potential consequences of transferring genes from one organism to another, by removing all natural barriers (Ballian, 2009).

The former believe it to be a revolutionary step toward well-being of humankind, since they believe GM foods to have a huge potential and are of great importance in fighting against insufficient amounts of food and hunger of the increasing world population. They also emphasise the fact that the increase in food production needs to be achieved on limited land area, since the full genetic potential for productivity of the most significant plants has already been reached in conventional selection programmes. Furthermore, the most fertile agricultural land on the Earth is constantly being reduced as a consequence of urbanisation, industrialisation, and the development of transport infrastructure, while deforestation and expansion of agriculture to new land cause severe damage to already fragile ecosystems. They argue that already in the mid 1990s the direct result of progress in genetic engineering was the first generation of genetically modified plants, tolerant to specific total herbicides, resistant to specific pests and viruses, with the increase in agricultural output. We are now working on further research and gradual introduction of so called second and third generations of genetically modified plants with improved nutritional quality and new technological and other traits, such as tolerance to drought, soil salinity and low fertility of the soil, stress tolerance, and delayed ripening. All this enables new approaches and possibilities for overcoming well known limitations of tropical agriculture, with the purpose of producing food in larger amounts. The advocates of the GM technology also argue that molecular biology and its endless possibilities in recombining genes, the most perfect forms of matter created in nature, brings humankind endless possibilities in creating new, more suitable organisms, and new varieties and hybrids of cultivated plants, as well as new varieties of useful microorganisms. Genetically modified organisms (GMOs) give us endless possibilities in repairing biological and production possibilities of numerous species of plants for the well-being of humankind. Unimaginable possibilities this technology allows us in food production, food technology, human and veterinary medicine and plant protection, as well as in bioenergy, open up possibilities for finding more efficient solutions for the burning issues of modern humankind (Ostojić, 1995). Furthermore, the possibility of creating new transgenic plants which would

provide food enriched with new nutritive ingredients, and even food which would simultaneously be a medication is being intensely explored.

Those who oppose genetically modified foods, as well as those who are not absolutely against such idea, but advocate careful treatment of the issue, argue that the influence of such food on human health hasn't been sufficiently researched, nor it has been proven that it is undeniably harmless. They also mention potential adverse impact on the environment and changes in ecosystems, as well as different 'moral' concerns. Although the advocates of genetically modified food claim there is no health risk, those who oppose it warn that not enough time has passed since the start of cultivation and use of genetically modified species and it is still uncertain what the long-term results will be. Answer to such questions cannot be neither positive nor negative, because it will take more time, perhaps even several generations for us to be able to answer these questions.

The impact on the environment and ecosystems has been researched more, and it is now possible to say that the impact can be adverse, because it can endanger natural species, whether by increased mortality, or their natural (spontaneous) cross-breeding with genetically modified species. In the USA and the Great Britain for example, it has been determined that mortality of some insects is increased near the fields where genetically modified plants are cultivated, although papers negating this have also been published.

Different 'moral' concerns of those who oppose GMOs are primarily related to danger of *'playing with boundaries set by nature or a divine hand'*, and the relation between rich and poor countries and the role which multinational corporations can have in deepening of already existing huge gap between them. Although advocates of genetic engineering argue that new species providing increased agricultural output, or more meat, are the solution for hunger and poverty, only a few absolutely believe in that. Additionally, the opposers to GMOs consider this technology a potential and real danger, threatening the environment, that possibly may create monstrous organisms. They also consider GM food products to be insufficiently sophisticated and researched, emphasizing the danger of playing with boundaries set by nature or a divine hand (Dimitrijević i Petrović, 2004). According to them, the GM products released in to the environment can threaten ecosystems, perhaps even inadvertently. They also argue that consumers worldwide should have more rights to asses advantages of accepting the GM food products compared to possible risks (Annerberg, 2003). So, they argue that several transgenic plants currently available on the market are not useful to consumers, but to producers,

which is why consumers wonder why they would accept the risk, while producers and/or multinational supply companies reap big profits.

Additionally, many non-governmental organizations pay special attention to legal and ethical aspects of ‘*patenting the living*’, ie. patenting genetically modified organisms (Egzuagher, 2001). According to Tarasjev et al. (2006) there is accord in principle that the technology can be patented. However, patenting organisms is a source of strong reactions. It is primarily pointed out that they are not inventions, but discoveries at best, and organisms used as recipients (hosts), as well as genes used for insertion, are products of evolution. They already exist, i.e. they are not newly produced, and their progeny are the result of normal reproduction, etc. The same authors argue that the situations in which farmers would be sued in case a genetically modified organism was found on their land, which could happen accidentally and against their will, they should be considered not only in regards to legal implication, but ethical as well.

For all this it seems that today, when scientists from all over the world pave new roads and ways to read, understand and manipulate this primarily fundamental alphabet of life – *genetic code* – necessary trace of our existence and the world we live in, and when we are witnessing these exciting and seemingly unlimited scientific possibilities, we need to, now more than ever, participate in the discussion on **ethics** (Baillan, 2009).

Despite all concerns, the fact is that humankind have accumulated knowledge and mastered another technique which helps them to penetrate the microcosm of genes and genetic information. The fact is that this level of knowledge allows them to erase or move natural laws and already set boundaries in horizontal gene transfer, i.e. exchange of genetic information between species. As all dramatic newly conquered scientific and technological fields, biotechnology has its own advantages, as well as potential frightening and unforeseeable consequences. For that, it is extremely important to have **comprehensive and high-quality control** over this technology (Trkulja *et al.*, 2005, 2006, 2017).

2

CHAPTER

GENETICALLY MODIFIED ORGANISMS – *Present Situation* –

2.1. What is the present situation in terms of cultivation and registration of varieties and hybrids of GM plants globally?

The first genetically modified organism, officially approved in the USA by the FDA (Food and Drug Administration) on 18 May 1994, was ‘*Flavr Savr*’ - a tomato hybrid produced by the Calgene, a California based company (*Image 1*), in which alien genes were inserted in order to preserve tomato longer after its harvesting.



Image 1. First GMO – Flavr Savr tomato hybrid produced by the Calgene, commercialized in the USA in 1994 (photo by: G. Bognanni).

In the 22-year period, from 1996 to 2017, farmers kept increasing the cultivation of GM crops, since their initial commercialization in 1996 (*Figure 1*). As a result of that, the total global area of GM plants increased

112 times in these first 22 years (1.7 million ha of land), which makes GM crops the fastest adopted crop technology in history of the world.

In 2017, 17 million growers in 24 countries worldwide (*Table 1*) planted 189.8 million ha of land by GM crops, an increase in 4.7 million ha or 3% compared to 2016 when 185.1 million ha of land was planted by GM crops.

According to Clive (2013) it is important to note that more than half of the population of 7 billion (60%, equivalent to 4 billion people) lived in 27 countries in which, in 2013, GM plants were grown, and more than half of total of 1.5 billion ha of agricultural land was in those 27 countries, the countries in which GM plants were approved and cultivated. It is also important to note that 189.8 million ha of global area of GM crops in 2017 was 12.6% out of 1.5 billion ha of total agricultural land in the world.

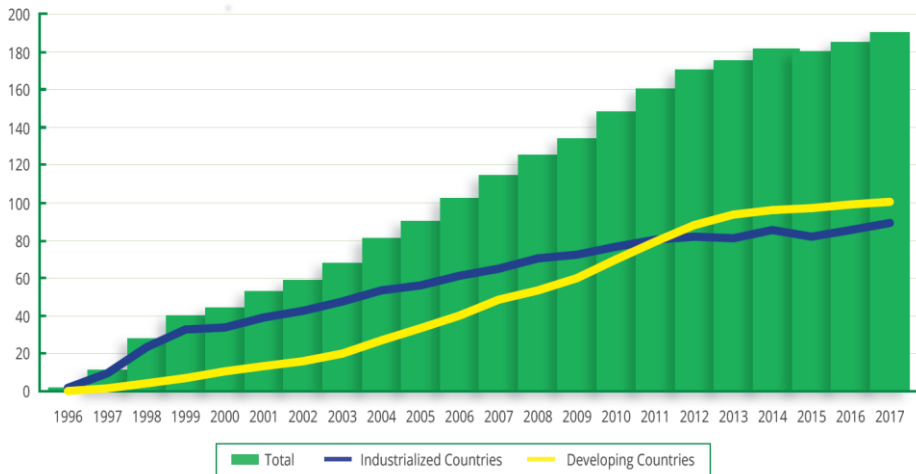


Figure 1. Overview of global area of GM crops from 1996 to 2017, and overview of total global area of GM crops in industrial and developing countries in millions ha (ISAAA, 2017a)

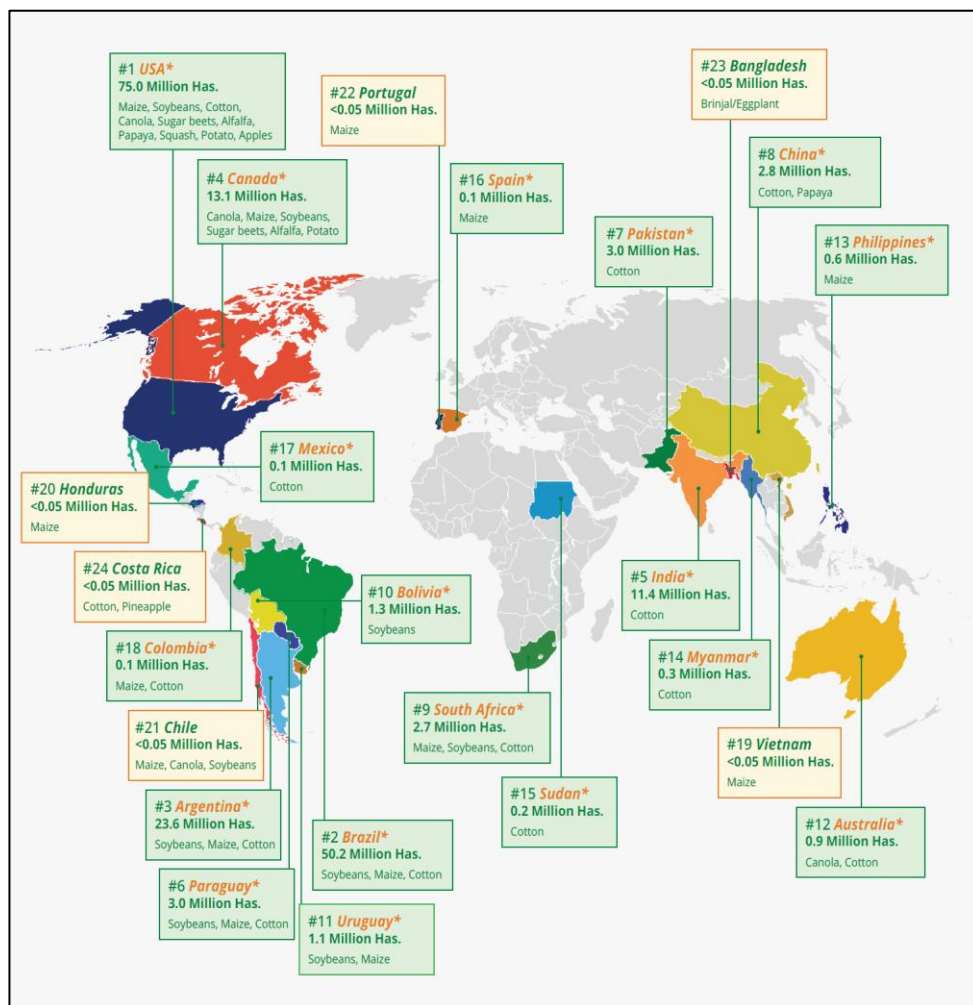


Figure 2. Overview of countries in which GM crops were grown in 2017 (ISAAA, 2017b)

In 2017, GM plants were grown in 24 countries, out of which 19 were developing countries and 5 industrial countries (Figure 2). According to number of hectares of GM plant land those countries were: the USA, Brazil, Argentina, Canada, India, Paraguay, Pakistan, China, South Africa, Bolivia, Uruguay, Australia, Philippines, Myanmar, Sudan, Spain, Mexico, Columbia, Vietnam, Honduras, Chile, Portugal, Bangladesh, and Costa Rica, 2 of which are the EU member states (Spain and Portugal) growing GM maize (Table 1).

Table 1. Land area and GM species sown in 2017 in countries globally (ISAAA, 2017b)

Red. broj	Country	Surface (million ha)	GM plants
1.*	USA	75.0	maize, soybeans, cotton, canola, sugar beet, alfalfa, papaya, squash, potato, apples
2.*	Brazil	50.2	soybeans, maize, cotton
3.*	Argentina	23.6	soybeans, maize, cotton
4.*	Canada	13.1	canola, maize, soybeans, sugar beet, alfalfa, potato
5.*	India	11.4	cotton
6.*	Paraguay	3.0	soybeans, maize, cotton
7.*	Pakistan	3.0	cotton
8.*	China	2.8	cotton, papaya
9.*	South Africa	2.7	maize, soybeans, cotton
10.*	Bolivia	1.3	soybeans
11.*	Uruguay	1.1	soybeans, maize
12.*	Australia	0.9	canola, cotton
13.*	Philippines	0.6	maize
14.*	Myanmar	0.3	cotton
15.*	Sudan	0.2	cotton
16.*	Spain	0.1	maize
17.*	Mexico	0.1	cotton
18.*	Columbia	0.1	maize, cotton
19.	Vietnam	<0.1	maize
20.	Honduras	<0.1	maize
21.	Chile	<0,1	maize, canola, soybeans
22.	Portugal	<0,1	maize
23.	Bangladesh	<0,1	brinjal/eggplant
24.	Costa Rica	<0,1	cotton, pineapple

**18 countries in which GM crops are grown on >50,000 ha of land*

In 2017, the USA, Brazil, Argentina, Canada, India and Paraguay were the six leading countries in GM crops cultivation. The USA kept the No. 1 position with 75 million ha of land area (39.5% out of total global area of GM crops), followed by Brazil with 50.2 million ha, Argentina with 23.6 million ha, Canada with 13.1 million ha, India with 11.4 million ha, and Paraguay with 3 million ha (*Table 1*).

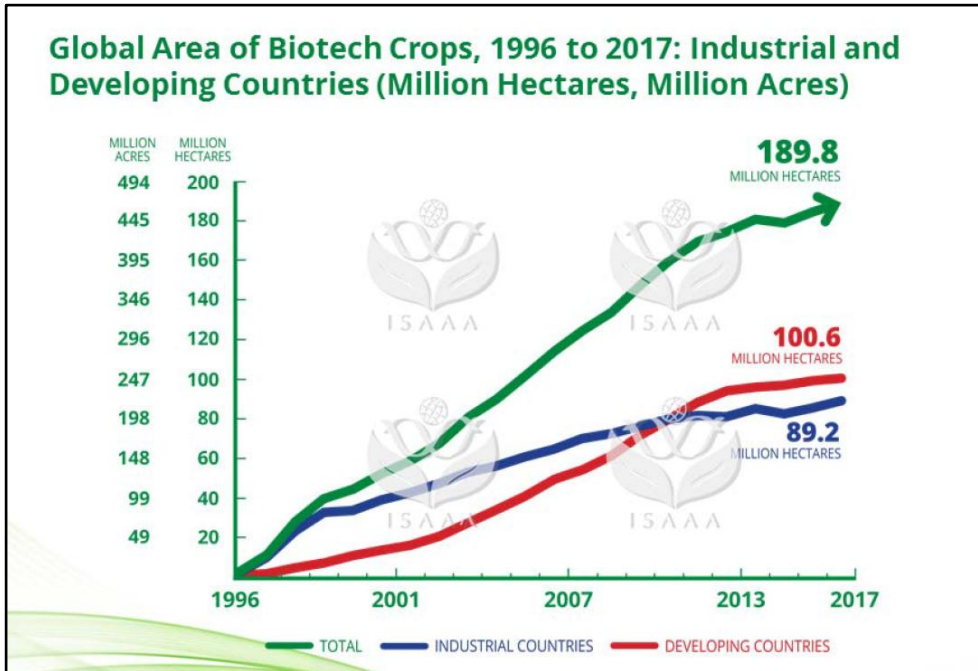


Figure 3 Global area (million ha) of GM crops in industrial and developing countries in the period 1996-2017 (ISAAA, 2017a)

For the sixth consecutive time, in 2017, developing countries planted more GM plants (53%) than industrial countries, in which 47% of total agricultural land was under GM crops (Figure 3). This contrasts the predictions of critics who had, prior to commercialization of GM crops in 1996, argued that biotechnological crops were acceptable only for industrially developed countries and they would never be accepted and adopted by developing countries.

The highest increase in agricultural land planted with GM crops in the world in 2017 was in the USA in 2.1 million ha, i.e. 3% compared to 2016 when the global land area under GM crops was 72.9 million ha.

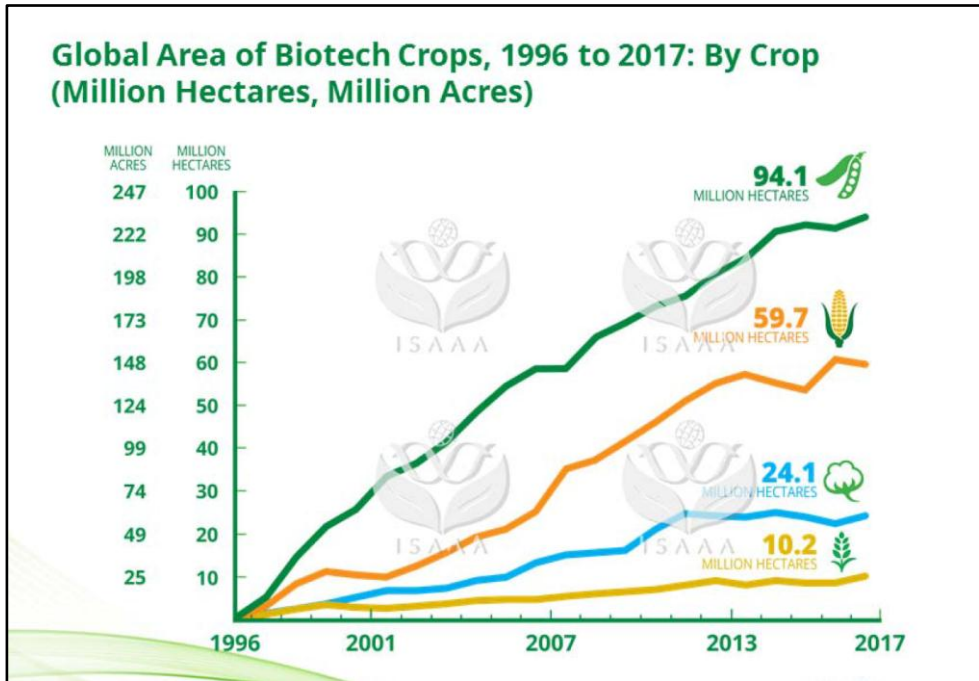


Figure 4. Global area (in million ha) of the most important GM crops in the period 1996-2017 (ISAAA, 2017)

In 2017, GM soybean was again the top GM crop in the world, planted on 94.1 million ha of land (49.6% of total global area planted to GM crops), followed by maize (59.7 million ha, or 31.5% of total global land area), then cotton (24.1 million ha, or 12.7%), and canola (10.2 million ha, or 5.4% of total global area planted to GM crops) (Figure 4).

In addition to that, Figure 5 shows that in 2017, 77% of soybean produced globally, was GM soybean (94.1 million ha out of total of 121.5 million ha of area planted to soybean). It also shows that 80% of cotton produced globally, was GM cotton (24.1 million ha out of total of 30.2 million ha), and 32% of maize produced globally (59.7 million ha of GM maize out of total of 188 million ha of area planted to GM crops), as well as 30% of total production of canola, i.e. 10.2 million ha of GM canola area out of total of 33.7 million ha of area planted to GM crops (ISAAA, 2017a).

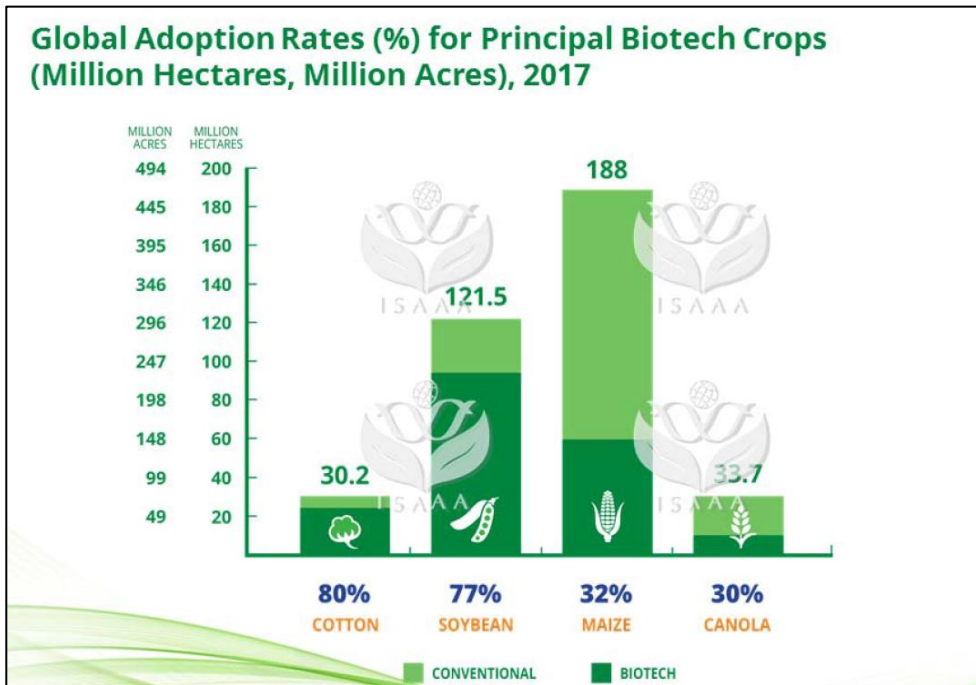


Figure 5. Global area (million ha) and % of the most important GM crops in 2017 (ISAAA, 2017a).

Furthermore, in 2017, total herbicide tolerance of GM soybean, maize, canola, cotton and alfalfa was still the most dominant trait with GM plants planted on land area of about 88.7 million ha (Figure 6), or 47% of GM crop area. However, in 2017, GM crops with so called ‘stacked traits’. i.e. with two or three new traits in one variety or hybrid were cultivated on larger areas, i.e. 77.7 million ha of land, or 41% of land planted to biotechnological crops, compared to 23.3 million ha planted to GM crops with *Bt* resistance to insects (12% of land planted to transgenic crops). In addition to that, the area of GM crops resistant to viruses, and with some other traits was less than 1 million ha of land or <1% of global area of GM crops (ISAAA, 2017a).

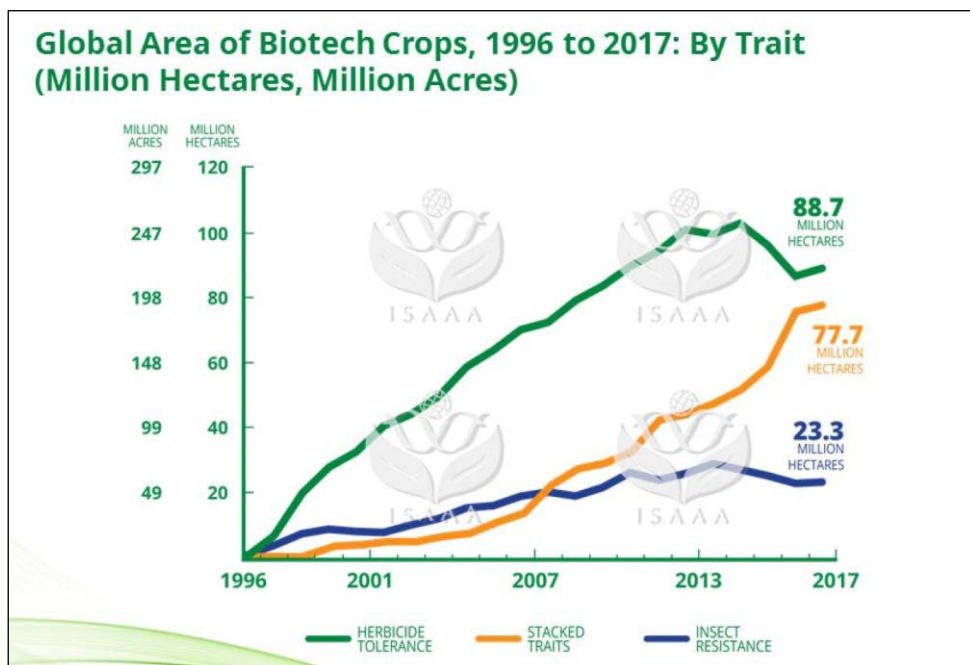


Figure 6. Global area (million ha) of GM crops by trait in the period 1996-2017 (ISAAA, 2017a)

In 2017, 24 countries planted GM crops, and 43 more issued authorisations for the import of different varieties and hybrids of GM crops intended for food and feed, which makes 67 countries in total to issue regulatory approvals for importing GM crops and their use for food and feed, or deliberate release into the environment, i.e. growing, since 1994. The fact is that 75% of world's population live in these 67 countries which have authorised importing GM crops intended for food and feed, or cultivation (ISAAA, 2017a).

According to the ISAAA report (2017a), by December 2017, these 67 countries have issued 4,133 authorisations for the total of 476 GM varieties and hybrids (GM events) with 29 different cultivated plants. 1,995 of the authorisations were for the use of different varieties and hybrids of GM crops for food, and 1,338 for feed and 800 for cultivation. Out of these 29 plants top four are: soybean (*Glycine max* (L.) Merr.), maize (*Zea mays* L.), cotton (*Gossypium hirsutum* L.) and canola (*Brassica napus* L.). Additionally, different countries worldwide issued authorisation for different varieties and hybrids and other crops, such as: wheat (*Triticum aestivum* L.), rice (*Oryza sativa* L.), potato (*Solanum tuberosum* L.),

tomato (*Lycopersicon esculentum* Mill.), pepper (*Capsicum annuum* L.), melon (*Cucumis melo* L.), squash (*Cucurbita pepo* L.), beans (*Phaseolus vulgaris* L.), lentil (*Lens culinaris* Medikus), chicory (*Cichorium intybus* L.), tobacco (*Nicotiana tabacum* L.), sunflower (*Helianthus annuus* L.), sugar beet (*Beta vulgaris* L.), polish canola (*Brassica rapa* L.), creeping bentgrass (*Agrostis stolonifera* L.), carnation (*Dianthus caryophyllus* L.), petunia (*Petunia x hybrida*), rose (*Rosa x hybrida*), plum (*Prunus domestica* L.), papaya (*Carica papaya* L.), poplar (*Populus* sp.), apple (*Malus domestica* Borkh.) and pineapple (*pineapple comosus* (L.) Merr.).

Table 2 represents revised list (Trkulja *et al.*, 2014b) of plant species with existing genetically modified varieties, or hybrids approved in some of the countries worldwide.

Table 2. Plant species list (including Latin name and name in five world languages) with existing genetically modified varieties or hybrids, approved by some of the countries worldwide

Plant species (Latin name)	English	Russian	Spanish	German	Italian
(<i>Glycine max</i>)	Soybean	соя	haba de soybeans	soybeansbohne	di semi di soia
(<i>Zea mays</i>)	Maize	кукуруза	maíz	mais	mais
(<i>Brassica napus</i>)	Argentine Canola	аргентинское рапса	Argentina Canola	argentine canola	Argentina Canola
(<i>Brassica rapa</i>)	Polish Canola	польский рапса	Pulir Canola	polnisch canola	Polacco di canola
(<i>Oryza sativa</i>)	Rice	рис	arroz	reis	riso
(<i>Solanum tuberosum</i>)	Potato	картофель	patata	kartoffel	patata
(<i>Triticum aestivum</i>)	Wheat	пшеница	trigo	weizen	grano
(<i>Lycopersicon esculentum</i>)	Tomato	помидор	tomate	tomate	pomodoro
(<i>Cucumis melo</i>)	Melon	дыня	melón	melone	melone
(<i>Cucurbita pepo</i>)	Squash	сквош	calabacín	squash	squash
(<i>Helianthus annuus</i>)	Sunflower	подсолнечник	girasol	sonnenblume	girasole
(<i>Beta vulgaris</i>)	Sugar Beet	сахарная свекла	remolacha	zucke-rrübe	barbabietola da zucchero
(<i>Medicago sativa</i>)	Alfalfa	люцерна	alfalfa	alfalfa	erba medica
(<i>Nicotiana tabacum</i>)	Tobacco	табак	tabaco	tabak	tabacco
(<i>Linum usitatissimum</i>)	Flax	Лен, льняное	Lino, linaza	flachs, leinsamen	Di lino, semi di lino
(<i>Cichorium intybus</i>)	Chicory	цикорий	achicoria	chicoree	cicoria
(<i>Lens culinaris</i>)	Lentil	чечевица	lenteja	linse	lenticchia

<i>(Gossypium hirsutum)</i>	Cotton	хлопок	algodón	baumwo-lle	cotone
<i>(Agrostis stolonifera)</i>	Creeping Bentgrass	Ползучая полевицы	bentgrass	creeping bentgrass	agrostide
<i>(Dianthus aryophyllus)</i>	Carnation	гвоздика	clavel	nelke	garofano
<i>(Prunus domestica)</i>	Plum	сливовый	ciruela	pflaume	prugna
<i>(Carica papaya)</i>	Papaya	папайя	papaya	papaya	Papaia
<i>(Capsicum annuum)</i>	Pepper	перец	pimienta	pfeffer	pepe
<i>(Phaseolus vulgaris)</i>	Beans	фасоль	haba	bohne	fagiolo
<i>(Petunia x hybrida)</i>	Petunia	петуния	petunia	petunie	petunia
<i>(Rosa hybrida)</i>	Rose	роза	rosa	rose	rosa
<i>(Populus sp.)</i>	Poplar	тополь	álamo	pappel	pioppo
<i>(Malus domestica)</i>	Apple	яблоко	manzana	apfel	mela
<i>(Ananas comosus)</i>	Pineapple	ананас	piña	pineapple	pineapple

Majority of cultivated GM plants today belong to a so called ‘first generation GM crops’ genetically modified with the purpose to make growing for farmers easier, and dominant GM events are tolerant to specific total herbicides, and resistant to harmful organisms (insects and phytopathogenic fungus, bacteria and viruses which cause crop diseases).

Often, a smaller amounts of pesticides are used for these crops compared to the amounts used in growing conventional varieties and hybrids, which toxicologically and environmentally is better, i.e. smaller amounts of pesticides with favourable ecological and toxicological properties are used (glyphosate) compared to some conventional herbicides used for the protection of soybean crops from weed.

In order to protect crops from insects different varieties of soil-dwelling bacteria *Bacillus thuringiensis* (*Bt*) are used, a bacteria characterized by the presence of protein crystals, i.e. **Cry-proteins**. Different varieties of this bacteria contain different combinations of Cry-proteins, such as: Cry1Ab, Cry2A, Cry3Bb, Cry 9C, etc., which are toxic for certain insect pests. These proteins are also known as **Bt toxins**. These proteins cause digestion discomfort and death of certain insect pests (European corn borer, corn rootworm, Colorado potato beetle, etc.) when they feed on them, but they are not dangerous for humans and animals (Sanvido *et al.*, 2006).

In ecological farming *Bacillus thuringiensis* is used as a biological insecticide for suppressing insect pests. Scientists have transferred the gene

for synthesis of ‘Cry-proteins’ from different varieties of this bacteria into maize, soybean, cotton, potato and other crops, after which such genetically engineered crops produce this protein independently. Insect pests and their larvae feed on roots, leaves, stems or seeds of these plants and die. Farmers are satisfied because they don’t need to buy insecticides, nor come into contact with them. Consumers are satisfied because they need not to worry about the residues of synthetic insecticides in food. Additionally, insects not feeding on *Bt* toxin will not die, and it has been determined that a larger number of different insects can be found in these fields than in the fields planted to traditional crops, where pesticides are used for the suppression of insect pests (Trkulja *et al.*, 2014a).

2.2. What is the present situation in terms of cultivation and registration of varieties and hybrids of GM plants in the EU?

Two EU member states (Spain and Portugal) continued growing biotechnological crops in 2017. Total area planted in these two countries was 131,535 ha, which represents decrease of 4% compared to area of 136,363 ha in 2016 (ISAAA, 2017a).

Neither Check Republic, nor Slovakia grew biotechnological crops in 2017 due to strict requirements for reporting on cultivation of biotechnological crops and preference of producers for non-GMO raw materials.

In the EU, total of 111 approvals for using GM events in five plant species (cotton, maize, canola, soybean and sugar beet) were issued and all 111 approvals were for food and feed, and only 1 (MON810 maize) for cultivation.

The European Union has issued authorisations for **19 soybean events**. 17 of them are with total herbicide tolerance trait, alone or in combination with other traits, one soybean event has *cry1Ac* gene inserted which confers resistance to certain lepidopteran insect pests, and one has modified nutritive content as a result of the inserted *Pj.D6D* gene, allowing the conversion of linoleic acid into α -linoleic acid, and the *Nc.Fad3* gene causing conversion of α -linoleic acid into stearidonic acid. 12 out of total of 17 herbicide tolerant GM soybean events are with imported genes which confer tolerance to one or more herbicides, one expresses *cry1Ac* gene conferring insect resistance and a cp4epsps gene conferring glyphosate tolerance, while the other 4 soybean events have a combination of herbicide tolerance and modified nutritional composition (Trkulja and Mihić-Salapura, 2018).

By December 2018, the European Union issued approvals for **74 maize hybrids** for food and feed, and only one MON810 maize with the inserted *cryIA(b)* gene which confers protection against certain lepidopteran insect pests. Out of 74 authorized maize events, six express genes which confer tolerance to herbicides, i.e. the *mepsps* gene which confers tolerance to glyphosate herbicide, the *pat* gene which confers tolerance to glufosinate-ammonium, the *aad-1* gene inserted to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides. Three hybrids are insect resistant, the first is inserted with *cry1A.105* and *cry2Ab2* genes which confer resistance to certain lepidopteran insect pests, the second expresses a modified *cry3A* gene which confers protection from specific insects from *Coleoptera* family, with *pmi* gene as a selection marker, and the third expresses the *vip3Aa20* gene which confers resistance to insects. The most common trait with genetically modified maize hybrids is combined insect resistance and tolerance to herbicides from the glyphosate and glufosinate-ammonium group existing in 63 hybrids (Trkulja and Mihić-Salapura, 2018). The same authors argue that the purpose of a hybrid inserted with the *cspB* gene to reduce crop losses caused by drought, and with the *nptII* gene, a selection marker.

Furthermore, by December 2018, the European Union issued approvals for **12 cotton events** for food and feed, and cotton products for the use other than for food and feed, with the exception of cultivation. One cotton variety is tolerant to herbicides, and has a selection marker inserted. Two varieties are resistant to certain lepidopteran insect pests, and have selection markers inserted. Another variety expresses combined resistance to certain lepidopteran insect pests (*cry1Ac* gene), tolerance to glyphosate, (*cp4 epsps*). Three cotton events are only herbicide tolerant (one with the *pat* gene inserted, another with the *cp4 epsps* gene inserted, which confers tolerance to glyphosate herbicide – *2mepsps* gene inserted, and one with the *cp4 epsps* gene, which confers tolerance to glyphosate herbicide). Three cotton events have combined tolerance to herbicide and resistance to certain lepidopteran insect pests. One event expresses a combination of two traits – tolerance to two herbicides, while another one expresses three different traits - tolerance to glufosinate ammonium and glyphosate, and resistance to insects (Trkulja and Mihić-Salapura, 2018).

The EU has issued approvals for five canola events for food and cultivation; two of them are glyphosate tolerant, one has a combination of tolerance to glufosinate-ammonium and the Barnase-Barstar complex leading to insufficiently viable pollen and male sterility, one has a

combination of four genes – two for tolerance to herbicides and two which lead to insufficiently viable pollen and male sterility.

In the same manner, by December 2018, the European Union issued approvals for **five sugar beet events**; two events are tolerant to glyphosate, one is tolerant to glufosinate-ammonium, one expresses four different traits – tolerance to glufosinate-ammonium and *barnase* and *barstar* genes which result in lack of pollen and male sterility, and one has a combination of four genes – two confer tolerance to herbicides and two which result in insufficiently viable pollen and male sterility.

By December 2018, the European Union issued approvals for **one soybean event** tolerant to glyphosate herbicide to be used as ingredient for food and feed, and food and feed derived from it.

The EU register of authorised GM crop events with authorisation expiry dates issued in the European Union is presented in Table 3 (European Commission, 2018).

Table 3. EU register of approved GM plants with authorisation expiry dates

Genetically modifies cotton			
Plant (GM event) Unique ID [Company]	Genes introduced/ characteristics	Authorised use	Authorisation expiry date
cotton (MON1445) MON-Ø1445-2 [Monsanto]	Genetically modified cotton which expresses: cp4 epsps gene inserted to confer tolerance to glyphosate herbicides nptII and aadA genes inserted as selection markers	Food produced from MON- Ø1445-2 cotton	26/04/25
		Feed produced from MON- Ø1445-2 cotton	26/04/25
cotton (MON15985) MON-15985-7 [Monsanto]	Genetically modified cotton which expresses: cry2Ab2 and cry1Ac genes which confer resistance to certain lepidopteran insect pests uidA gene inserted as a selection marker nptII and aadA genes	Foods and food ingredients containing, consisting of, or produced from MON-15985-7 cotton	26/04/25
		Feed containing, consisting of, or produced from MON-15985-7 cotton	26/04/25

	inserted as selection markers	Products other than food and feed containing or consisting of MON-15985-7 cotton for the same uses as any other cotton with the exception of cultivation	26/04/25
cotton (MON531) MON-ØØ531-6 [Monsanto]	Genetically modified cotton which expresses: cry1Ac gene which confers resistance to lepidopteran insect pests nptII and aadA genes inserted as selection markers	Food produced from MON-ØØ531-6 cotton	26/04/25
		Feed MON-ØØ531-6ed produced from cotton	26/04/25
cotton (MON531 x MON1445) MON-ØØ531-6 x MON-Ø1445-2 [Monsanto]	Genetically modified cotton which expresses: cry1Ac gene which confers resistance to lepidopteran insect pests cp4 epsps gene inserted to confer tolerance to glyphosate herbicides nptII and aadA genes inserted as selection markers	Food produced from MON-ØØ531-6 x MON-Ø1445-2 cotton	26/04/25
		Feed produced from MON-ØØ531-6 x MON-Ø1445-2 cotton	26/04/25
Cotton (LLCotton25) ACS-GHØØ1-3 [Bayer]	Genetically modified cotton which expresses: pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting of, or produced from ACS-GHØØ1-3 cotton (including food additives)	Renewal ongoing
		Feed containing, consisting of, or produced from ACS-ACS-GHØØ1-3 cotton (feed materials and feed additives)	
		Products other	

		than food and feed containing or consisting of ACS-GHØØ1-3 cotton for the same uses as any other cotton with the exception of cultivation	
cotton (GHB614) BCS-GHØØ2-5 [Bayer]	Genetically modified cotton that expresses: 2mepsps gene inserted to confer tolerance to the glyphosate herbicides	Foods and food ingredients containing, consisting of, or produced from ACS-GHØØ1-3 cotton (including food additives)	16/06/2021
		Feed containing, consisting of, or produced from ACS-ACS-GHØØ1-3 cotton (feed materials and feed additives)	
		Products other than food and feed containing or consisting of ACS-GHØØ1-3 cotton for the same uses as any other cotton with the exception of cultivation	
Cotton (281-24-236x3006-210-23) DAS-24236-5xDAS-21Ø23-5 [Dow AgroSciences]	Genetically modified cotton that expresses: cry1Ac and cry1F genes which provide protection to certain lepidopteran insect pests pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting of, or produced from DAS-24236-5xDAS-21Ø23-5 cotton (including food additives)	21/12/2021
		Feed containing, consisting of, or produced from DAS-24236-5xDAS-21Ø23-5	

		cotton (feed materials and feed additives)	
		Products other than food and feed containing or consisting of DAS-24236-5xDAS-21023-5 cotton for the same uses as any other maize with the exception of cultivation	
<p>cotton (T304-40) BCS-GH004-7 [Bayer]</p>	<p>Genetically modified cotton which expresses:</p> <p>pat gene which confers tolerance to herbicide glufosinate-ammonium</p> <p>cry1Ab gene which confers protection against certain lepidopteran insect pests</p>	Foods and food ingredients containing, consisting of, or produced from BCS-GH004-7 cotton	26/04/25
		Feed containing, consisting of, or produced from BCS-GH004-7 cotton	
		Products other than food and feed containing or consisting of BCS-GH004-7 cotton for the same uses as any other cotton with the exception of cultivation	
<p>cotton (MON 88913) MON-88913-8 [Monsanto]</p>	<p>Genetically modified cotton which expresses:</p> <p>cp4 epsps gene which confers tolerance to glyphosate herbicides</p>	Foods and food ingredients containing, consisting of or produced from MON-88913-8 cotton	26/04/25
		Feed containing, consisting of, or produced from MON-88913-8	

		<p>cotton</p> <p>Products other than food and feed containing or consisting of MON-88913-8 cotton for the same uses as any other cotton with the exception of cultivation</p>	
<p>cotton (GHB614xLLcotton25) BCS-GH002-5xACS-GH001-3 [Bayer]</p>	<p>Genetically modified cotton which expresses:</p> <p>pat gene which confers tolerance to herbicide glufosinate-ammonium</p> <p>cp4 epsps gene which confers tolerance to glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from BCS-GH002-5xACS-GH001-3 cotton</p> <p>Feed containing, consisting of, or produced from BCS-GH002-5xACS-GH001-3 cotton</p> <p>Products other than food and feed containing or consisting of BCS-GH002-5xACS-GH001-3 cotton for the same uses as any other cotton with the exception of cultivation</p>	<p>26/04/25</p>
<p>cotton (281-24-236x3006-210-23xMON88913) DAS-24236-5xAS-21023-5xMON-88913-8 [Dow AgroSciences]</p>	<p>Genetically modified cotton which expresses:</p> <p>pat gene which confers tolerance to herbicide glufosinate-ammonium</p> <p>CP4EPS protein which confers tolerance to glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from DAS-24236-5xAS-21023-5xMON-88913-8 cotton</p> <p>Feed containing,</p>	<p>03/07/27</p>

	Cry1F and Cry1Ac proteins which confer resistance to certain lepidopteran insect pests	consisting of, or produced from DAS-24236-5×DAS-21023-5×MON-88913-8 cotton	
		DAS-24236-5×DAS-21023-5×MON-88913-8 cotton in products containing it or consisting of it for any other than (1) and (2), with the exception of cultivation	
cotton (GHB119) BCS-GH005-8 [Bayer CropScience]	Genetically modified cotton which expresses: pat gene inserted to confers tolerance to herbicide glufosinate-ammonium cry2Ae gene inserted to confer resistance to certain lepidopteran insect pests.	Foods and food ingredients containing, consisting of, or produced from BCS-GH005-8 cotton Feed containing, consisting of, or produced from BCS-GH005-8 cotton (feed materials and feed additives) Products, other than food and feed, containing or consisting of BCS-GH005-8 cotton for the same uses as any other cotton, with the exception of cultivation	03/07/27
Genetically modified maize			
Plan (GM event) Unique ID [Company]	Genes introduced/ characteristics	Authorised use	Authorisation expiry date
Maize (Bt11) SYN-BT 011-1	Genetically modified maize which expresses:	Foods and food ingredients containing,	Renewal ongoing

<p>[Syngenta]</p>	<p>the cry1A (b) gene inserted to confer resistance to lepidopteran insect pests the pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p>	<p>consisting of, or produced from SYN-BT011-1xMON-00021-9</p> <p>Feed containing, consisting of, or produced from SYN-BT011-1xMON-00021-9 maize</p> <p>Products other than food and feed containing or consisting of SYN-BT011-1xMON-00021-9 maize</p>	
<p>Maize (DAS59122) DAS-59122-7 [Pioneer and Dow AgroSciences]</p>	<p>Genetically modified maize which expresses: the cry34Ab1 and cry35Ab1 genes inserted to confer resistance to certain coleopteran insect pests pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p>	<p>Food containing, consisting of, or produced from DAS-59122-7 maize</p> <p>Feed containing, consisting of, or produced from DAS-59122-7 maize</p> <p>Products other than food and feed containing or consisting of DAS-59122-7 with the exception of cultivation</p>	<p>05/08/28</p>
<p>Maize (DAS1507xNK603) DAS-01507-1xMON-00603-6 [Pioneer and Dow AgroSciences]</p>	<p>Genetically modified maize which expresses: cry1F gene inserted to confer resistance to certain lepidopteran insect pests such as the European corn borer (<i>Ostrinia nubilalis</i>) and species belonging to the genus <i>Sesamia</i></p>	<p>Foods and food ingredients containing, consisting of, or produced from DAS-01507-1xMON-00603-6 maize (including food additives)</p> <p>Feed containing,</p>	<p>Renewal ongoing</p>

	<p>pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p> <p>cp 4epsps gene inserted to confer tolerance to the glyphosate herbicide</p>	<p>consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation</p>	
<p>Maize (DAS1507) DAS-Ø15Ø7-1 [Pioneer and Dow AgroSciences]</p>	<p>Genetically modified maize which expresses:</p> <p>cry1F gene inserted to confer resistance to the European corn borer and certain other lepidopteran insect pests</p> <p>pat gene inserted to confer tolerance to the glufosinate-ammonium herbicide</p>	<p>Foods and food ingredients containing, consisting of or produced from maize 1507</p> <p>Feed containing, consisting of or produced from maize 1507</p> <p>Products other than food and feed containing or consisting of maize 1507 with the exception of cultivation</p>	<p>20/12/2027</p>
<p>Maize (GA21) MON-ØØØ21-9 [Syngenta]</p>	<p>Genetically modified maize which expresses:</p> <p>mepsps gene inserted to confer tolerance to glyphosate herbicide</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-ØØØ21-9 maize (including food additives)</p> <p>Feed containing, consisting of, or produced from</p>	<p>05/08/28</p>

		MON-00021-9 maize (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-00021-9 maize for the same uses as any other maize with the exception of cultivation	
Maize (MON810) MON-00810-6 [Monsanto]	Genetically modified maize which expresses: cry1A (b) gene inserted to confer resistance to lepidopteran insect pests	Foods and food ingredients produced from MON810 (including food additives)	03/07/27
		Pollen produced from MON810 maize	05/11/23
		Feed containing or consisting of MON810 maize	03/07/27
		Feed produced from MON810 maize (feed materials feed additives)	03/07/27
		Seeds for cultivation	Renewal ongoing
Maize (NK603) MON-00603-6 [Monsanto]	Genetically modified maize which expresses: cp4 epsps gene inserted to confer tolerance to the glyphosate herbicides	Foods and food ingredients containing, consisting of, or produced from MON-00603-6 maize	26/04/25
		Feed containing, consisting of, or produced from MON-00603-6	

		maize	
		Products other than food and feed containing or consisting of MON-00603-6 maize for the same uses as any other maize with the exception of cultivation	
Maize (NK603 x MON810) MON-00603-6 x MON-00810-6 [Monsanto]	Genetically modified maize which expresses: cp4 epsps gene inserted to confer tolerance to glyphosate herbicides and cry1A(b) gene inserted to confer resistance to certain lepidopteran insect pests (<i>Ostrinia nubilalis</i> , <i>Sesamia</i> spp.)	Foods and food ingredients containing, consisting of, or produced from MON-00603-6xMON-00810-6 maize (including food additives)	Renewal ongoing
		Feed containing, consisting of, or produced from MON-00603-6xMON-00810-6 maize (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-00603-6xMON-00810-6 maize for the same uses as any other maize with the exception of cultivation	
Maize (T25) ACS-ZM003-2 [Bayer]	Genetically modified maize which expresses: pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting of, or produced from ACS-ZM003-2 maize	26/04/25

		Feed containing, consisting of, or produced from ACS-ZMØØ3-2 maize	
		Products other than food and feed containing or consisting of ACS-ZMØØ3-2 maize for the same uses as any other maize with the exception of cultivation	
Maize (MON88017) MON-88Ø17-3 [Monsanto]	Genetically modified maize which expresses: modified cry3Bb1 gene inserted to confer protection to certain coleopteran insect pests cp4 epsps gene inserted to confer tolerance to glyphosate herbicides	Foods and food ingredients containing, consisting of, or produced from MON-88Ø17-3 maize (including food additives)	Renewal ongoing
		Feed containing, consisting of, or produced from MON-88Ø17-3 maize (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-88Ø17-3 maize for the same uses as any other maize with the exception of cultivation	
Maize (MON89034) MON-89Ø34-3 [Monsanto]	Genetically modified maize which expresses: cry1A.105 and cry2Ab2 genes inserted to confer resistance to lepidopteran insect pests	Foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3 maize (including food additives)	Renewal ongoing

		Feed containing, consisting of, or produced from MON-89Ø34-3 maize (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-89Ø34-3 maize for the same uses as any other maize with the exception of cultivation	
<p>Maize (MIR604) SYN-IR6Ø4-5 [Syngenta]</p>	<p>Genetically modified maize which expresses: modified cry3A gene inserted to confer resistance to certain coleopteran insect pests pmi gene inserted as selection marker</p>	Foods and food ingredients containing, consisting of, or produced from SYN-IR6Ø4-5 maize (including food additives)	29/11/19
		Feed containing, consisting of, or produced from SYN-IR6Ø4-5 maize (feed materials and feed additives)	
		Products other than food and feed containing or consisting of SYN-IR6Ø4-5 maize for the same uses as any other maize with the exception of cultivation	
<p>Maize (MON88017xMON810) MON-88Ø17-3xMON-ØØ81Ø-6 [Monsanto]</p>	<p>Genetically modified maize that expresses: the cry1Ab gene which confers protection against certain lepidopteran insect</p>	Foods and food ingredients containing, consisting of, or produced from MON-88Ø17-	27/07/20

	<p>pests</p> <p>the cry3Bb1 gene which provides protection to certain coleopteran insect pests</p> <p>the cp4 epsps gene which confers tolerance to glyphosate herbicides</p>	<p>3xMON-00810-6</p> <p>Foods and food ingredients containing, consisting of, or produced from MON-88017-3xMON-00810-6</p> <p>Feed containing, consisting of, or produced from MON-88017-3xMON-00810-6</p>	
<p>Maize (MON89034 x MON88017)</p> <p>MON-89034-3x MON-88017-3</p> <p>[Monsanto]</p>	<p>Genetically modified maize that expresses:</p> <p>cry1A.105 and cry2Ab2 genes which provide protection to certain lepidopteran insect pests</p> <p>cry3Bb1 gene which provides protection to certain coleopteran insect pests</p> <p>cp4 epsps gene which confers tolerance to glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-89034-3x MON-88017-3 maize (including food additives)</p> <p>Feed containing, consisting of, or produced from MON-89034-3x MON-88017-3 maize (feed materials and feed additives)</p> <p>Products other than food and feed containing or consisting of MON-89034-3x MON-88017-3 maize for the same uses as any other maize with the exception of cultivation</p>	<p>16/06/21</p>
<p>Maize (Bt11 x MIR162 x MIR604 x GA21)</p> <p>SYN-BT011-1 x SYN-IR162-4 x</p>	<p>Genetically modified maize which expresses:</p> <p>cry1Ab and vip3Aa20</p>	<p>Foods and food ingredients containing, consisting of, or</p>	<p>18/09/2026</p>

<p>SYN-IR604-5 × MON-00021-9 and</p> <p>four related GM maizes combining three different single GM events:</p> <p>(Bt11 × MIR162 × MIR604) SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5,</p> <p>(Bt11 × MIR162 × GA21) SYN-BT011-1 × SYN-IR162-4 × MON-00021-9,</p> <p>(Bt11 × MIR604 × GA21) SYN-BT011-1 × SYN-IR604-5 × MON-00021-9,</p> <p>(MIR162 × MIR604 × GA21) SYN-IR162-4 × SYN-IR604-5 × MON-00021-9</p> <p>and</p> <p>six related GM maizes combining two different single GM events:</p> <p>(Bt11 × MIR162) SYN-BT011-1 × SYN-IR162-4,</p> <p>(Bt11 × MIR604) SYN-BT011-1 × SYN-IR604-5,</p> <p>(Bt11 × GA21) SYN-BT011-1 × MON-00021- 9,</p> <p>(MIR162 × MIR604) SYN-IR162-4 × SYN-IR604-5,</p> <p>(MIR162 × GA21) SYN-IR162-4 × MON-00021-9,</p> <p>(MIR604 × GA21) SYN-IR604-5 × MON-00021-9</p> <p>SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × MON-00021-9</p> <p>[Syngenta]</p>	<p>genes inserted to confer resistance to certain lepidopteran insect pests,</p> <p>cry3A gene inserted to confer resistance to certain coleopteran insect pests,</p> <p>mepsps gene inserted to confer tolerance to the glyphosate herbicide,</p> <p>pmi gene inserted as selection marker</p>	<p>produced from the GMOs, specified in column 1 (including food additives)</p> <p>Feed containing, consisting of, or produced from the GMOs, specified in column 1 (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of the GMOs, specified in column 1, for the same uses as any other maize, with the exception of cultivation</p>	
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<p>Maize (MIR162)</p> <p>SYN-IR162-4</p> <p>[Syngenta]</p>	<p>Genetically modified maize which expresses:</p> <p>vip3Aa20 gene inserted to confer resistance to lepidopteran insect pests</p>	<p>Foods and food ingredients containing, consisting of, or produced from SYN-IR162-4</p> <p>Feed containing, consisting of, or produced from SYN-IR162-4</p> <p>Products other than food and feed containing or consisting of SYN-IR162-4</p>	<p>18/10/2022</p>
<p>Maize (MON 89034×1507×MON88017×59122)</p> <p>MON-89034-3xDAS-01507-1xMON-88017-3xDAS-59122-7</p> <p>and</p> <p>four related GM maizes combining three different single GM events:</p> <p>(MON89034×1507×MON88017) MON-89034-3xDAS-01507-1xMON-88017-3,</p> <p>(MON89034×1507×59122) MON-89034-3xDAS-01507-1xDAS-59122-7,</p> <p>(MON89034×MON88017×59122) MON-89034-3xMON-88017-3xDAS-59122-7,</p> <p>(1507×MON88017×59122) DAS-01507-1xMON-88017-3xDAS-59122-7</p> <p>and</p> <p>four related GM maizes combining two different single GM events:</p> <p>(MON89034x1507) MON-89034-3xDAS-01507-1,</p> <p>(MON89034x59122) MON-89034-3xDAS-59122-7,</p>	<p>Genetically modified maize which expresses:</p> <p>Cry1A.105, Cry2Ab2, Cry1F genes inserted to confer resistance to certain lepidopteran insect pests such as the European corn borer (<i>Ostrinia nubilalis</i>) and species belonging to the genus <i>Sesamia</i>,</p> <p>Cry3Bb1, Cry34Ab1 and Cry35Ab1 genes inserted to confer resistance to certain coleopteran insect pests such as corn rootworm larvae (<i>Diabrotica</i> spp.)</p> <p>pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p> <p>cp4 epsps gene inserted to confer tolerance to the glyphosate herbicide</p>	<p>Foods and food ingredients containing, consisting of, or produced from the GMOs, specified in column 1 (including food additives)</p> <p>Feed containing, consisting of, or produced from the GMOs, specified in column 1 (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of the GMOs, specified in column 1, for the same uses as any other maize, with the exception of cultivation</p>	<p>05/11/2023</p>

<p>(1507xMON88017) DAS-Ø15Ø7-1xMON-88Ø17-3,</p> <p>(MON88017x59122) MON-88Ø17-3xDAS-59122-7</p> <p>[Monsanto and Dow AgroSciences]</p> <p>MON-89Ø34-3xDAS-Ø15Ø7-1xMON-88Ø17-3xDAS-59122-7</p>			
<p>Maize (MON89034x1507xNK603)</p> <p>MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6</p> <p>[Monsanto and Dow AgroSciences]</p>	<p>Genetically modified maize which expresses:</p> <p>Cry1A.105, Cry2Ab2, Cry1F genes inserted to confer resistance to certain lepidopteran insect pests such as the European corn borer (<i>Ostrinia nubilalis</i>) and species belonging to the genus <i>Sesamia</i>,</p> <p>pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p> <p>cp4 epsps gene inserted to confer tolerance to the glyphosate herbicide</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize (including food additives)</p> <p>Feed containing, consisting of, or produced from MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation</p>	<p>05/11/2023</p>
<p>Maize (MON 87460)</p> <p>MON 8746Ø-4</p> <p>[Monsanto]</p>	<p>Genetically modified maize which expresses:</p> <p>cspB gene inserted to reduce yield loss caused by drought stress</p>	<p>Foods and food ingredients containing, consisting of or produced from MON 8746Ø-4 maize</p>	<p>26/04/2025</p>

	nptII gene inserted as selection marker	Feed containing, consisting of, or produced from MON 87460-4 maize	
		Products other than food and feed containing or consisting of MON 87460-4 maize for the same uses as any other maize with the exception of cultivation	
Maize (NK603 × T25) MON-00603-6 × ACS-ZM003-2 [Monsanto]	Genetically modified maize which expresses: cp4 epsps gene which confers tolerance to glyphosate herbicides pat gene which confers tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting of or produced from MON-00603-6 × ACS-ZM003-2 maize	03/12/2025
		Feed containing, consisting of, or produced from MON-00603-6 × ACS-ZM003-2 maize	
		Products other than food and feed containing or consisting of MON-00603-6 × ACS-ZM003-2 maize for the same uses as any other maize with the exception of cultivation	
Maize MON 87427 MON-87427-7 [Monsanto]	Genetically modified maize which expresses: cp4 epsps gene which confers tolerance to glyphosate herbicides The cp4 epsps expression is absent or limited in male reproductive tissues, which	Foods and food ingredients containing, consisting of, or produced from MON-87427-7 maize	03/12/2025
		Feed containing, consisting of, or produced from	

	<p>eliminates or reduces the need for detasseling when MON-87427-7 is used as female parent in hybrid maize seed production.</p>	<p>MON-87427-7 maize</p> <p>Products other than food and feed containing or consisting of MON-87427-7 maize for the same uses as any other maize with the exception of cultivation</p>	
<p>Maize (1507 × 59122 × MON 810 × NK603)</p> <p>DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6</p> <p>and</p> <p>four related GM maizes combining three different single GM events:</p> <p>(1507 × 59122 × MON 810) DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6,</p> <p>(59122 × 1507 × NK603) DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6,</p> <p>(1507 × MON 810 × NK603) DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6,</p> <p>(59122 × MON 810 × NK603) DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6</p> <p>and</p> <p>four related GM maizes combining two different single GM events:</p> <p>(1507 × 59122) DAS-Ø15Ø7-1 × DAS-59122-7,</p> <p>(1507 × MON 810) DAS-Ø15Ø7-1 × MON-ØØ81Ø-6,</p> <p>(59122 × MON 810)</p>	<p>Genetically modified maize which expresses:</p> <p>the Cry1Ab and Cry1F proteins which confer resistance to certain lepidopteran insect pests,</p> <p>The Cry34Ab1 and Cry35Ab1 proteins which confer resistance to certain coleopteran insect pests,</p> <p>the pat gene, which confers tolerance to glufosinate-ammonium based herbicides,</p> <p>the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides.</p>	<p>Foods and food ingredients containing, consisting of, or produced from the GMOs specified in column 1</p> <p>Feed containing, consisting of, or produced from the GMOs specified in column 1</p> <p>Products, other than food and feed, containing or consisting of the GMOs specified in column 1, for the same uses as any other maize, with the exception of cultivation</p>	<p>04/08/2028</p> <p>04/08/2028</p> <p>04/08/2028</p>

<p>DAS-59122-7 × MON-00810-6, (59122 × NK603) DAS-59122-7 × MON-00603-6 DAS-01507-1 × DAS-59122-7 × MON-00810-6 × MON- 00603-6 [Pioneer]</p>			
<p>Maize (DAS-40278-9) DAS-40278-9 [Dow AgroSciences]</p>	<p>Genetically modified maize which expresses: aad-1 gene inserted to confer tolerance to 2,4-D-based and AOP-based (aryloxyphenoxypropionate) herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from DAS-40278-9 maize (inFoods and food ingredients containing, consisting of, or produced from the GMOs specified in column 1 cluding food additives)</p> <p>Feed containing, consisting of, or produced from DAS-40278-9 maize (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of DAS-40278-9 maize, for the same uses as any other maize, with the exception of cultivation</p>	<p>03/07/2027</p>

<p>Maize (Bt11 × 59122 × MIR604 × 1507 × GA21)</p> <p>SYN-BT011-1 × DAS-59122-7 × SYN-IR604-5 × DAS-01507-1 × MON-00021-9</p> <p>and</p> <p>five related GM maizes combining four different single GM events:</p> <p>(Bt11 × MIR604 × 1507 × GA21) SYN-BT011-1 × SYN-IR604-5 × DAS-01507-1 × MON-00021-9,</p> <p>(Bt11 × 59122 × 1507 × GA21) SYN-BT011-1 × DAS-59122-7 × DAS-01507-1 × MON-00021-9,</p> <p>(Bt11 × 59122 × MIR604 × GA21) SYN-BT011-1 × DAS-59122-7 × SYN-IR604-5 × MON-00021-9,</p> <p>(Bt11 × 59122 × MIR604 × 1507) SYN-BT011-1 × DAS-59122-7 × SYN-IR604-5 × DAS-01507-1,</p> <p>(59122 × MIR604 × 1507 × GA21) DAS-59122-7 × SYN-IR604-5 × DAS-01507-1 × MON-00021-9</p> <p>and</p> <p>nine related GM maizes combining three different single GM events:</p> <p>(Bt11 × 59122 × MIR604) SYN-BT011-1 × DAS-59122-7 × SYN-IR604-5,</p> <p>(Bt11 × 59122 × 1507) SYN-BT011-1 × DAS-59122-7 × DAS-01507-1,</p> <p>(Bt11 × 59122 × GA21)</p>	<p>Genetically modified maize which expresses:</p> <p>cry1Ab and cry1F genes inserted to confer resistance to certain lepidopteran insect pests, cry3A, cry34Ab1 and cry35Ab1 genes inserted to confer resistance to certain coleopteran insect pests,</p> <p>mepsps gene inserted to confer tolerance to the glyphosate herbicides,</p> <p>pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium s,</p> <p>pmi gene inserted as selection marker</p>	<p>Foods and food ingredients containing, consisting of, or produced from the GMOs, specified in column 1 (including food additives)</p> <p>Feed containing, consisting of, or produced from the GMOs, specified in column 1 (feed materials and feed additives)</p> <p>Products, other than food and feed, containing or consisting of the GMOs, specified</p>	<p>03/07/2027</p>
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<p>SYN-BT011-1 × DAS-59122-7 × MON-00021-9,</p> <p>(Bt11 × MIR604 × 1507) SYN-BT011-1 × SYN-IR604-5 × DAS-01507-1,</p> <p>(Bt11 × 1507 × GA21) SYN-BT011-1 × DAS-01507-1 × MON-00021-9,</p> <p>(59122 × MIR604 × 1507) DAS-59122-7 × SYN-IR604-5 × DAS-01507-1,</p> <p>(59122 × MIR604 × GA21) DAS-59122-7 × SYN-IR604-5 × MON-00021-9,</p> <p>(59122 × 1507 × GA21) DAS-59122-7 × DAS-01507-1 × MON-00021-9,</p> <p>(MIR604 × 1507 × GA21) SYN-IR604-5 × DAS-01507-1 × MON-00021-9</p> <p>and</p> <p>six related GM maizes combining two different single GM events:</p> <p>(Bt11 × 59122) SYN-BT011-1 × DAS-59122-7,</p> <p>(Bt11 × 1507) SYN-BT011-1 × DAS-01507-1,</p> <p>(59122 × MIR604) DAS-59122-7 × SYN-IR604-5,</p> <p>(59122 × GA21) DAS-59122-7 × MON-00021-9,</p> <p>(MIR604 × 1507) SYN-IR604-5 × DAS-01507-1,</p> <p>(1507 × GA21) DAS-01507-1 × MON-00021-9</p> <p>SYN-BT011-1 × DAS-59122-7 ×</p>		<p>in column I, for the same uses as any other maize, with the exception of cultivation</p>	
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SYN-IR604-5 × DAS-01507-1 × MON-00021-9 [Syngenta]			
Maize (MON 87427 × MON 89034 × NK603) MON-87427-7 × MON-89034-3 × MON-00603-6 and the three related GM maizes combining two different single GM events: (MON 87427 × NK603) MON-87427-7 × MON-00603-6, (MON 89034 × NK603) MON-89034-3 × MON-00603-6, (MON 87427 × MON 89034) MON-87427-7 × MON-89034-3 MON-87427-7 × MON-89034-3 × MON-00603-6 [Monsanto]	Feed containing, consisting of, or produced from the GMOs specified in column 1	Foods and food ingredients containing, consisting of, or produced from the GMOs specified in column 1	04/08/2028
		Feed containing, consisting of, or produced from the GMOs specified in column 1	
		Products, other than food and feed, containing or consisting of the GMOs specified in column 1, for the same uses as any other maize, with the exception of cultivation	
Genetically modified canola			
Plant (GM event) Unique ID [Company]	Genes introduced/ characteristics	Authorised use	Authorisation expiry date
Canola (GT73) MON-00073-7 [Monsanto]	Genetically modified canola which expresses: cp4 epsps and goxv247 genes inserted to confer tolerance to the glyphosate herbicide	Foods and food ingredients containing, consisting of, or produced from MON-00073-7 canola with the exception of isolated seed protein	26/04/2025
		Feed containing and consisting of MON-00073-7 canola	Renewal ongoing

		Feed produced from MON-00073-7 canola	26/04/2025
		Other products containing or consisting of MON-00073-7 with the exception of cultivation	Renewal ongoing
<p>Canola (MS8, RF3, MS8xRF3) ACS-BN005-8, ACS-BN003-6, ACS-BN005-8 x ACS-BN003-6 [Bayer]</p>	<p>Genetically modifieds canola which expresses:</p> <p>a bar (pat) gene inserted to confer tolerance to herbicide glufosinate-ammonium s</p> <p>barnase gene inserted to leads to lack of viable pollen and male sterility</p> <p>barstar gene inserted to leads to lack of viable pollen and male sterility</p>	Foods and food ingredients containing, consisting of, or produced from ACS-BN005-8ACS-BN003-6ACS-BN005-8 x ACS-BN003-6 oilseed- rape (including food additives)	24/06/2023
		Feed containing or consisting of ACS-BN005-8ACS-BN003-6ACS-BN005-8 x ACS-BN003-6 oilseed- rape	Renewal ongoing
		Feed produced from ACS-BN005-8ACS-BN003-6ACS-BN005-8 x ACS-BN003-6 oilseed-rape	24/06/2023
		Other products containing or consisting of ACS-BN005-8ACS-BN003-6ACS-BN005-8 x ACS-BN003-6 oilseed- rape with the exception of cultivation	Renewal ongoing
<p>Canola (T45) ACS-BN008-2</p>	<p>Genetically modified canola which expresses:</p> <p>pat gene inserted to confer</p>	Foods and food ingredients containing or produced from	Renewal ongoing

<p>[Bayer]</p>	<p>tolerance to glufosinate-ammonium herbicides</p>	<p>ACS-BN008-2 canola (including food additives)</p> <p>Feed containing or produced from ACS-BN008-2 canola (feed materials and feed additives)</p> <p>Products other than food and feed</p>	
<p>Canola (MON 88302)</p> <p>MON-88302-9</p> <p>[Monsanto]</p>	<p>Genetically modified canola which expresses:</p> <p>cp4 epsps gene which confers tolerance to glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-88302-9 canola</p> <p>Feed containing, consisting of, or produced from MON-88302-9 canola</p> <p>Products other than food and feed containing or consisting of MON-88302-9 canola for the same uses as any other canola with the exception of cultivation</p>	<p>26/04/2025</p>
<p>Canola (MON88302 x Ms8 x Rf3, MON88302 x Ms8 and MON88302 x Rf3)</p> <p>MON-88302-9 x ACSBN005-8 x ACS-BN003-6; MON-88302-9 x ACSBN005-8; MON-88302-9 x ACS-BN003-6</p> <p>[Bayer CropScience and Monsanto Europe]</p>	<p>Genetically modified canola which expresses:</p> <p>cp4 epsps gene which confers tolerance to glyphosate herbicides</p> <p>bar (pat) gene inserted to confer tolerance to glufosinate-ammonium based herbicides</p> <p>barnase gene inserted to leads to lack of viable pollen and male sterility</p> <p>barstar gene inserted to</p>	<p>Foods and food ingredients containing, consisting of, or produced from canolas MON88302 x Ms8 x Rf3, MON88302 x Ms8 and MON88302 x Rf3</p> <p>Feed containing,</p>	<p>20/12/2027</p>

	leads to lack of viable pollen and male sterility	<p>consisting of, or produced from canolas MON88302 x Ms8 x Rf3, MON88302 x Ms8 and MON88302 x Rf3</p> <p>Products, other than food and feed, containing or consisting of canolas MON88302 x Ms8 x Rf3, MON88302 x Ms8 and MON88302 x Rf3, with the exception of cultivation 20/12/2027</p>	
Genetically modified soybean			
Plant (GM event) Unique ID [Company]	Genes introduced/ characteristics	Authorised use	Authorisation expiry date
Soybean (A2704-12) ACS-GM005-3 [Bayer]	Genetically modified soybean which expresses: pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium	<p>Foods and food ingredients containing, consisting of, or produced from ACS-GM005-3 soybean (including food additives)</p> <p>Feed containing, consisting of, or produced from ACS-GM005-3 soybean (feed materials and feed</p>	Renewal ongoing

		additives)	
		Products other than food and feed containing or consisting of ACS-GMØØ5-3 soybean for the same uses as any other soybean with the exception of cultivation	
<p>Soybean (MON89788) MON-89788-1 [Monsanto]</p>	<p>Genetically modified soybean which expresses: cp4 epsps gene inserted to confer tolerance to the glyphosate herbicide</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-89788-1 soybean (including food additives)</p>	<p>Renewal ongoing</p>
		<p>Feed containing, consisting of, or produced from MON-89788-1 soybean (feed materials and feed additives)</p>	
		<p>Products other than food and feed containing or consisting of MON-89788-1 soybean for the same uses as any other soybean with the exception of cultivation</p>	
<p>Soybean (MON40-3-2) MON-Ø4Ø32-6 [Monsanto]</p>	<p>Genetically modified soybean which expresses: cp4 epsps gene inserted to confer tolerance to the glyphosate herbicide</p>	<p>Food containing, consisting of, or produced from MON 40-3-2 soybean (including food additives)</p>	<p>09/02/2022</p>
		<p>Feed containing or consisting of MON 40-3-2 soybean</p>	

		Feed produced from MON 40-3-2 soybean (feed materials and feed additives)	
		Other products containing or consisting of MON 40-3-2 soybean with the exception of cultivation	
<p>Soybean (MON87701) MON-87701-2 [Monsanto]</p>	<p>Genetically modified soybean which expresses: cry1Ac gene inserted to confer resistance to certain lepidopteran insect pests</p>	Foods and food ingredients containing, consisting of, or produced from MON-87701-2 soybean (including food additives)	09/02/2022
		Feed containing, consisting of, or produced from MON-87701-2 soybean (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-87701-2 soybean for the same uses as any other soybean with the exception of cultivation	
<p>Soybean (356043) DP-356043-5 [Pioneer]</p>	<p>Genetically modified soybean which expresses: gat gene inserted to confer tolerance to the glyphosate herbicide gm-hra gene inserted to confer tolerance to the ALS-inhibiting herbicide</p>	Foods and food ingredients containing, consisting of, or produced from DP-356043-5 soybean (including food additives)	09/02/2022
		Feed containing,	

		<p>consisting of, or produced from DP-356043-5 soybean (feed materials and feed additives)</p> <p>Products other than food and feed containing or consisting of DP-356043-5 soybean for the same uses as any other soybean with the exception of cultivation</p>	
<p>Soybean (A5547-127) ACS-GM006-4 [Bayer]</p>	<p>Genetically modified soybean which expresses: pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium</p>	<p>Foods and food ingredients containing, consisting of, or produced from ACS-GM006-4 soybean (including food additives)</p> <p>Feed containing, consisting of, or produced from ACS-GM006-4 soybean (feed materials and feed additives)</p> <p>Products other than food and feed containing or consisting of ACS-GM006-4 soybean for the same uses as any other soybean with the exception of cultivation</p>	<p>09/02/2022</p>
<p>Soybean (MON87701 x MON89788) MON-87701-2 x MON-89788-1 [Monsanto]</p>	<p>Genetically modified soybean which expresses: cry1Ac gene inserted to confer resistance to certain lepidopteran insect pests cp4 epsps gene inserted to confer tolerance to the</p>	<p>Foods and food ingredients containing, consisting of, or produced from MON-87701-2 x MON-89788-1 soybean (including food</p>	<p>27/06/2022</p>

	glyphosate herbicide	additives)	
		Feed containing, consisting of, or produced from MON-87701-2 x MON-89788-1 soybean (feed materials and feed additives)	
		Products other than food and feed containing or consisting of MON-87701-2 x MON-89788-1 soybean for the same uses as any other soybean with the exception of cultivation	
Soybean (MON 87705) MON-87705-6 [Monsanto]	Genetically modified soybean which contains: cp4 epsps gene inserted to confer tolerance to glyphosate herbicides fragments of FAD2-1A and FATB1-A genes resulting in inhibition of the expression of the FAD2-1A and FATB1-A genes by RNA interference (RNAi), which leads to an increased oleic acid and reduced linoleic acid	Foods and food ingredients containing, consisting of or produced from MON-87705-6 soybean	26/04/2025
		Feed containing, consisting of, or produced from MON-87705-6 soybean	
		Products other than food and feed containing or consisting of MON-87705-6 soybean for the same uses as any other soybean with the exception of cultivation.	
Soybean (MON 87708) MON-87708-9	Genetically modified soybean which expresses: the dmo gene which confers	Foods and food ingredients containing, consisting of or	26/04/2025

<p>[Monsanto]</p>	<p>tolerance to dicamba-based herbicides</p>	<p>produced from MON-87708-9 soybean</p>	
		<p>Feed containing, consisting of, or produced from MON-87708-9 soybean</p>	
		<p>Products other than food and feed containing or consisting of MON-87708-9 soybean for the same uses as any other soybean with the exception of cultivation</p>	
<p>Soybean (MON 87769) MON-87769-7 [Monsanto]</p>	<p>Genetically modified soybean which expresses: Pj.D6D gene which results in conversion of linoleic acid to α-linolenic acid Nc.Fad3 gene which results in conversion of α-linolenic acid to stearidonic acid</p>	<p>Food containing, consisting of, or produced from MON-87769-7 soybean</p>	<p>26/04/2025</p>
		<p>Feed containing, consisting of, or produced from MON-87769-7 soybean</p>	
		<p>Products other than food and feed containing or consisting of MON-87769-7 soybean for the same uses as any other soybean with the exception of cultivation</p>	
<p>Soybean (305423) DP-305423-1 [Pioneer]</p>	<p>Genetically modified soybean which expresses: a fragment of the endogenous fad2-1 gene resulting, through RNA interference, in the silencing of the endogenous fad2-1 gene, which leads to an increased oleic acid and</p>	<p>Foods and food ingredients containing, consisting of or produced from DP-305423-1 soybean</p>	<p>26/04/2025</p>
		<p>Feed containing, consisting of, or produced from</p>	

	<p>reduced linoleic acid</p> <p>Glycine max-hra gene which confers tolerance to acetolactate synthase-inhibiting herbicides</p>	<p>DP-3Ø5423-1 soybean</p> <p>Products other than food and feed containing or consisting of 3Ø5423-1 soybean for the same uses as any other soybean with the exception of cultivation</p>	
<p>Soybean (BPS-CV127-9)</p> <p>BPS-CV127-9</p> <p>[BASF]</p>	<p>Genetically modified soybean which expresses:</p> <p>acetohydroxyacid synthase large sub-unit of Arabidopsis thaliana gene inserted to confer tolerance to the imidazolinone herbicides</p>	<p>Foods and food ingredients containing, consisting of, or produced from BPS-CV127-9 soybean</p> <p>Feed containing, consisting of, or produced from BPS-CV127-9 soybean with the exception of forage</p> <p>Products other than food and feed containing or consisting of BPS-CV127-9 soybean for the same uses as any other soybean with the exception of cultivation</p>	<p>26/04/2025</p>
<p>Soybean (FG 72)</p> <p>MST-FGØ72-2</p> <p>[Bayer]</p>	<p>Genetically modified soybean which expresses:</p> <p>the hppdPf336 gene inserted to confer tolerance to the isoxaflutole-based herbicides</p> <p>the 2mepsps gene inserted to confer tolerance to the glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of or produced from MST-FGØ72-2 soybean</p> <p>Feed containing, consisting of, or produced from MST-FGØ72-2 soybean</p> <p>Products other than food and feed</p>	<p>25/07/2026</p>

		containing or consisting of MST-FGØ72-2 soybean for the same uses as any other soybean with the exception of cultivation	
<p>Soybean (MON 87705 × MON 89788)</p> <p>MON-877Ø5-6 × MON-89788-1</p> <p>[MON-877Ø5-6 × MON-89788-1]</p>	<p>Genetically modified soybean which contains:</p> <p>the cp4 epsps gene inserted to confer tolerance to glyphosate herbicides</p> <p>fragments of FAD2-1A and FATB1-A genes resulting in inhibition of the expression of the FAD2-1A and FATB1-A genes by RNA interference (RNAi), which leads to an increased oleic acid and reduced linoleic acid</p>	<p>Foods and food ingredients containing, consisting of or produced from MON-877Ø5-6 × MON-89788-1 soybean</p>	25/07/2026
		<p>Feed containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean</p>	
		<p>Products other than food and feed containing or consisting of MON-877Ø5-6 × MON-89788-1 soybean for the same uses as any other soybean with the exception of cultivation.</p>	
<p>Soybean (MON 87708 × MON 89788)</p> <p>MON-877Ø8-9 × MON-89788-1</p> <p>[Monsanto]</p>	<p>Genetically modified soybean which expresses:</p> <p>the dmo gene inserted to confer tolerance to dicamba-based herbicides</p> <p>the cp4 epsps gene inserted to confer tolerance to glyphosate herbicides</p>	<p>Foods and food ingredients containing, consisting of or produced from MON-877Ø8-9 × MON-89788-1 soybean</p>	25/07/2026
		<p>Feed containing, consisting of, or produced from MON-877Ø8-9 × MON-89788-1 soybean</p>	
		<p>Products other than food and feed containing or</p>	

		consisting of MON-87708-9 × MON-89788-1 soybean for the same uses as any other soybean with the exception of cultivation	
<p>Soybean (305423 × 40-3-2) DP-305423-1 × MON-04032-6 [Pioneer]</p>	<p>Genetically modified soybean that expresses:</p> <p>the cp4 epsps gene inserted to confer tolerance to the glyphosate herbicide</p> <p>the glycine max-hra gene which confers tolerance to acetolactate synthase-inhibiting herbicides</p> <p>a fragment of the endogenous fad2-1 gene resulting, through RNA interference, in the silencing of the endogenous fad2-1 gene, which leads to an increased oleic acid and reduced linoleic acid profile</p>	Foods and food ingredients containing, consisting of, or produced from DP-305423-1 × MON-04032-6 soybean	20/12/2027
		Feed containing, consisting of, or produced from DP-305423-1 × MON-04032-6 soybean	
		Products, other than food and feed, containing or consisting of DP-305423-1 × MON-04032-6 soybean, for the same uses as any other soybean, with the exception of cultivation	
<p>Soybean (FG72 × A5547-127) MST-FG072-2 × ACS-GM006-4 [Bayer]</p>	<p>Genetically modified soybean which expresses:</p> <p>the pat gene inserted to confer tolerance to the herbicide glufosinate-ammonium ,</p> <p>the 2mepsps gene inserted to confer tolerance to the glyphosate herbicides,</p> <p>the hppdPf336 gene inserted to confer tolerance to the isoxaflutole-based herbicides</p>	Foods and food ingredients containing, consisting of, or produced from FG72 × A5547-127 soybean	20/12/2027
		Feed containing, consisting of, or produced from FG72 × A5547-127 soybean	
		Products, other than food and feed, containing or consisting of FG72 × A5547-	

		127 soybean, for the same uses as any other soybean, with the exception of cultivation	
<p>Soybean (DAS-44406-6) DAS-44406-6 [Dow AgroSciences]</p>	<p>Genetically modified soybean which expresses: the 2mEPSPS gene inserted to confer tolerance to glyphosate herbicides, the aad-12 gene inserted to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, the pat gene inserted to confer tolerance to herbicide glufosinate-ammonium</p>	Foods and food ingredients containing, consisting of, or produced from DAS-44406-6 soybean	20/12/2027
		Feed containing, consisting of, or produced from DAS-44406-6 soybean	
		Products, other than food and feed, containing or consisting of DAS-44406-6 soybean, for the same uses as any other soybean, with the exception of cultivation	
<p>Soybean (DAS-68416-4) DAS-68416-4 [Dow AgroSciences]</p>	<p>Genetically modified soybean which expresses: aad-12 gene inserted to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, the pat gene inserted to confer tolerance to herbicide glufosinate-ammonium</p>	Foods and food ingredients containing, consisting of, or produced from DAS-68416-4 soybean	20/12/2027
		Feed containing, consisting of, or produced from DAS-68416-4 soybean	
		Products, other than food and feed, containing or consisting of DAS-68416-4	

		soybean, for the same uses as any other soybean, with the exception of cultivation	
Genetically modified sugarbeet			
Plant (GM event) Unique ID [Company]	Genes introduced/ characteristics	Authorised use	Authorisation expiry date
Sugar beet (H7-1) KM-000H71-4 [KWS SAAT and Monsanto]	Genetically modified sugar beet that expresses: a CP4 EPSPS protein confers tolerance to glyphosate herbicides	Foods and food ingredients produced from KM-000H71-4 sugar beet Feed produced from KM-000H71-4 sugar beet	05/08/2028

2.3. What is the present situation in terms of the application of genetic engineering in forestry?

Although they have a great ecological and economic significance, a little is known about molecular mechanisms genetic engineering development is based on and their effect on growth and health of forest trees. However, a remarkable progress has been made in shedding light on biochemical and genetic mechanisms which control growth and survival of annual plants. Significant results have been achieved by applying what we now know as functional genomics. Functional genomics is analysis of genetic material (genome) of an organism and a complicated relationship between its shape and function. If in such case costs and benefits are considered, also including side effects, this affects the final choice of targeted trait. Their relation to modified traits as well as certain alternative approaches (to conventional plant breeding, growing, or growing plantation trees) are of particular importance when we compare targeted traits, (Kajba and Ballian, 2007; Ballian, 2008, 2009).

Generally speaking, there are three main goals for growing and enhancing genetically modified plants in the forest, which entail:

1) enhanced resistance to biotic factors, i.e. resistance to insects, disease agents and weeds (herbicides);

2) enhanced tolerance to abiotic stresses, and 3) achieving enhanced traits of a tree, which shall be elaborated below (Ballian, 2009; Ballian and Kajba, 2011).

1) Enhanced resistance to biotic factors. Damage on dendroflora and perennial plants caused by domestic and introduced pathogens and pests is often of global interest. The consequence of continuous biotic stress is that plants suffer and their growth and development, i.e. forest productivity, are affected. This leads to major economic consequences. For example, in 1989 in China, a significant damage of hybrid poplar trees was determined, caused by common insect defoliators such as gipsy moth (*Lymantria dispar*), and (*Apochemia cinerarius*). This joint attack resulted in significant production loss, at around 40% (Hu *et al.*, 2001). Similarly, damage on loblolly pine (*Pinus taeda*) is usually caused by *Dendrolimus punctatus* and *Crypyothelea formosicola* (Tang *et* Tian, 2003); damage on white spruce (*Picea glauca*), is often caused by insect defoliators, such as eastern spruce budworm (*Choristoneura fumiferana*) (Lachance *et al.*, 2007). There are also phytopathogenic fungi, bacteria and viruses which can affect the health of forests and significantly reduce their productivity. Accordingly, we shall discuss the results achieved by genetic modifications for the purpose of enhancing tree resistance to different pests.

1.1) Genetically modified trees expressing Bt toxins. Insect pests are a major problem for dendroflora and perennial plants in natural forests and on plantations. Thus, a genetic modification of poplars grown on plantations around the world is being worked on intensely. There are two main groups of poplar pests: *Chrysomelidae* or leaf beetle, and *Lepidoptera* or moths and butterflies harmful in caterpillar phase, which have become tolerant to insecticides. However, they are intolerant to some biopesticides derived from different varieties of *Bacillus thuringiensis* (Bt) (James, 1997). This bacteria synthesizes proteins which are activated in intestines of some insects causing lesions and finally their death. Insecticide proteins, known as *Bt toxins* have been successfully used, exogenously and endogenously, as biopesticides for protection of many plant species for years (Thompson *et al.*, 1995; James *et al.*, 1999). These *Bt toxins* are relatively selective insecticides with little effect to non-targeted insects and pathogens. Several Bt toxin varieties have been identified so far, and each of them affects only selected groups of insects, which are usually phylogenetically closely related (Grace *et al.*, 2005.). These Bt genetic modifications introduced in trees represent an attractive alternative for cultivating plantations of GM trees resistant to a broad

spectrum of insect pests (DiCosty *et al.* Whalon, 1997; James, 1997; Roush *et al.* Shelton, 1997).

Insecticide spraying should not be used for genetically modified trees expressing the Bt transgene, which may have several advantages. Firstly, the vegetation, soil and water around these plantations are not exposed to insecticides. Sensitive, useful non-targeted insects in areas around transgenic plantations shall not be exposed to chemicals from insecticides, which reduces their potential for developing tolerance to Bt toxins present in plants (Luttrell *et al.* Caprio, 1996; Roush, 1997; Gould, 1998; McGaughey *et al.*, 1998). Secondly, insecticides used for chemical treatment degrade quickly, and remain on treated tree leaves for several days at best. Unlike them, genetically modified trees can continuously produce the toxin, which enables them to be resistant to weather conditions and it reduces costs related to repeated treatments (Nwanze *et al.*, 1995; Maredia 1997; Roush, 1997). Finally, as a result of genetic modification these trees produce toxin in plant tissues, which makes it possible to affect insects living in the stem or a plant tissue, i.e. carpenter moths or leaf miners. In some cases, not even currently available insecticides can help us against some of these insect pests, nor they can target specific pests. And these insects are often the cause of greater ecological disturbances, the consequence of damage caused to living beings on plantations and in the environment. At the very start of the development of transgenic trees, the first results proved stable transformation of poplar by the Bt gene, with the continuous toxin production. One of the achieved transgenic lines is high level of resistance to specific pests, particularly to gypsy moth and some larvae of insects of *Lepidoptera* family. However, expression of the gene for Bt toxin with some new transgenic conifers, i.e. Monterey pine (*Pinus radiata*), has shown variability in resilience to damage caused by the *Teia anartoides* larvae, depending on age of needles. These research emphasize the importance of transgene expression level and specificity of the tissue they are inserted into.

1.2) Resistance without BT transgene. Despite the help provided by Bt toxins against insect pests attacks on trees, some research are focused on developing resistance to insect attacks by using different compounds derived through genetic modification (Confalonieri *et al.*, 1998). Example for that is a generated expression of trypsin proteinase in soybean (Kunitz protease inhibitor, KTi3) and black poplar. Although generic Kunitz proteins inhibit digestive proteinases in gypsy moth (*Lymantria dispar*) and moth of the *Notodontidae* family (*Clostera anastomoze*) in *in vitro* conditions. In *in vivo testing conditions* they did not show the increase in

larvae mortality rate as a result of transgenic expression (Delledonne *et al.*, 2001).

1.3) Resistance to phytopathogenic fungi. Diseases caused by phytopathogenic fungi can be extremely harmful to forest trees. In fighting them, different genetic modifications have been used by inserting genes from different bacteria with the purpose to confer resistance to phytopathogenic fungi, but with variable success (Mittler *et al.*, 1995). It was determined that by inserting the *bacterio-opsin (bO)* gene from *Halobacterium halobium* into transgenic tobacco some defence mechanisms may be induced in it. And, the expression conferring resistance to specific plant pathogens is obtained by inserting this gene, (Rizhsky *et al.*, 2001). However, the expression of synthetic bacterioopsin (bO), a synthetic gene, used with black hybrid poplars has not significantly increased defence mechanism against different phytopathogenic fungi, such as *Melampsora* spp. which leaf rust in poplars, and *Dothichiza populea* which causes canker and bark necrosis on poplars (Mohamed *et al.*, 2001). It is similar situation with genetically modified white poplars, with the inserted *stilbene synthase (StSY)* gene from grapevine, which produces resveratrol glucoside antioxidants in it. However, they haven't significantly influenced the increase of resistance to *Melampsora pulcherrima* – the agent of leaf rust in poplars (Giorcelli *et al.*, 2004). On the other hand, it has been determined that when a rabbit-alpha *defensin (NP-1)* gene (Zhao *et al.*, 1999), or *chitinase 5B (CH5B)* gene of beans is inserted into transgenic poplars (Meng *et al.*, 2004) it can increase their resistance to a broad variety of phytopathogenic fungi.

1.4) Resistance to phytopathogenic bacteria. Numerous reports on genetic modification of plants indicate that these modifications have resulted in increased resistance to phytopathogenic bacteria, causative agents of plant diseases (Haworth *et al.*, 1988; De Kam, 1984). Although majority of types of tree bacteriosis are rare, some are economically significant, particularly infections by the bacteria from *Xanthomonas* family (Mentag *et al.*, 2003). So, transgenic poplars expressing antimicrobial protein, known as *D4E1*, express mixed or incomplete resistance to phytopathogenic bacteria from *Agrobacterium* and *Xanthomonas* families. More specifically, such transgenic poplars express increased resistance to this type of bacteria, manifested in decreased formation and size of a tumour after inoculation by *Agrobacterium* sp., i.e. development of small cancer wounds or tumours after infection with *Xanthomonas* sp. However, transgenic poplars with the *D4E1* protein inserted, haven't expressed increased resistance to phytopathogenic fungi

(Mentag *et al.*, 2003). It should also be noted that resistance to one *Agrobacterium* sp. variety known as C58, has not been increased; therefore, application of *D4E1* protein is possible only in limited and specific conditions.

1.5) Results of field experiments. Practical value of genetically modified tree species can be determined only after completion of numerous and comprehensive field experiments. There are numerous field experiments for testing resistance to pests and pathogens in industrial countries, however, some of the results have been contradictory. *In one case*, resistance tested in the field was lower than the resistance tested in a laboratory, and the level of resistance may vary depending on tissue samples. For example, a three-year testing period of field testing of transgenic birch showed that plants expressed increased resistance in the greenhouse environment, while in open fields, birches expressed equal, if not higher sensitivity to fungal pathogen *Pyrenopeziza betulicola* – which causes leaf spots on birch trees (Pasonen *et al.*, 2004). *In case two*, testing the Bt-transgenic black poplars (*Populus nigra*), this was not the case, because field testing showed significant reduction of damage from insect defoliators: 10% of damaged leaves compared to 80 to 90% of leaf damage on control plants (Hu *et al.*, 2001). This research had other important implications, a number of insect cocoons reduced in soil on the land where control, non-transgenic, plants were grown, i.e. wild-type plants were better protected when they were near or among transgenic plants. *In case three*, the level of *CryIAb* protein in needles of Bt transgenic spruces in the fields was increased, which improved their resistance to pests (Lachance *et al.*, 2007). Mortality rate caused by larvae feeding on plant tissue of spruce needles in the field experiments was from 44% to 100% in transgenic plants, compared to approx. 37% in control plants.

These experiments proved specific variability in genetically modified trees, emphasizing the need for systematic long-term field testing. It is also necessary to understand all the changes caused by genetic modifications in trees, such as the effect of the Bt gene on chemical composition, quality and structure of wood of hybrid poplars. (Davis *et al.*, 2006).

1.6) Tolerance to herbicides. Enhanced tolerance of trees to herbicides would enable the reduced use of herbicides, as well as the use of environmentally friendly and toxicologically acceptable active matters, not to mention a greater flexibility with regards to time of their application (Chupeau *et al.*, 1994).

1.6.1) **Glyphosate.** Already in the late 1980s there were reports on first successful insertion of genes in trees in order to confer them tolerance to glyphosate herbicides which causes inhibition of 5-enolpyruvylshikimate-3-phosphate (EPSP) synthase in modified plants, i.e. prevents synthesis of aromatic amino acids necessary for the production of cell proteins. The first such GM plant was transgenic hybrid poplar (*P. alba* x *P. grandidentata*) in which the *aroA* gene from *Salmonella typhimurium* family was inserted in order to confer it resistance to inhibition of EPSP synthase by glyphosate (Comai *et al.*, 1983; Riemenschneider *et Haissig*, 1991; Donahue *et al.*, 1994).

1.6.2) **Chlorsulfuron.** Chlorsulfuron is herbicide from the sulfonylurea group which reacts to acetolactate synthase enzyme (ALS) and blocks biosynthesis of amino acids and isoleucine (Ray, 1984). The first GM woody plant inserted with the acetolactate synthase (*crsI-1*), a mutated gene from *Arabidopsis thaliana* plant which transfers chlorsulfuron tolerance, was a hybrid poplar (*Populus tremula* x *P. alba*). The field testing showed that control individual poplars treated with chlorsulfuron were dying out within two to three weeks from the beginning of the treatment, while the transgenic lines survived. Although the growth and root development were slower during the treatment, GM poplars would continue growing normally upon its completion (Brazileiro *et al.*, 1992).

1.6.3) **Chloroacetanilides.** Acetochlor and metolachlor are herbicide active matters from the chloroacetanilides group. Glutathione (GSH) and glutathione S-transferase (GST) enzymes have important roles in degradation of these herbicides. The first GM woody plant tolerant to these herbicides is transgenic hybrid poplar (*Populus tremula* x *Populus alba*) inserted with the *gshI* gene from *Escherichia coli* which encodes γ -glutamylcysteine synthetase (γ -ECS) which dissolves these herbicides. During field experiments with different poplar lines on soil treated by acetochlor and metochlor herbicides the growth and biomass of all tested lines was extremely reduced, however, the reduction was less dramatic with transgenic lines compared to non-transgenic poplar trees (Gullner *et al.*, 2001). It was also determined that the concentration of glutathione and γ -ECS enzyme was increased in leaves of all tested poplar lines, but was significantly higher in transgenic poplars (Edwards *et al.*, 2000).

1.6.4) **Glufosinate-ammonium.** Glufosinate-ammonium is active herbicide substance, on the market best known as Basta. This total herbicide inhibits glutamine synthetase enzyme (GS), by producing

ammonium which is accumulated, and in higher concentrations is deadly for the plant (Bishop-Hurley *et al.*, 2001). Examples of genetic modifications in trees with the *pat* gene from *Streptomyces viridochromogenes* inserted, which confers it tolerance to total herbicide glufosinate-amonium, are Monterey pine (*Pinus radiata*), spruce (*Picea abies*), and transgenic hybrid poplar (*Populus tremula* × *P. alba*) (Pascual *et al.*, 2008).

2) Improved resistance to abiotic factors. The influence and interaction of the environment may significantly affect the tree productivity. Low temperatures and high levels of salinity in soil can significantly damage plants, decrease growth, or cause plants to die (Ballian and Kajba, 2011; Cushman *et Bohnert*, 2000). It is well known that plants and bacteria are able to survive in adverse environment. With the assistance of genomic tools positions of targeted genes enabling their resistance can be identified. Based on that information they are transformed, and therefore able to protect themselves from stress, i.e. tolerance through genetic modification (Cushman *et Bohnert*, 2000). Enhanced tolerance to many types of stress has already been achieved in several plant species. Example of the use of this technology is transgenic poplar inserted with two antifreeze genes: the *PsG6PDH* gene which encodes glucose-6-phosphate dehydrogenase, and the *PsAFP* gene which encodes protein against freezing. (Georges *et al.*, 1990; Baertlein *et al.*, 1992; Murata *et al.*, 1992).

2.1) The ozone stress. Ozone is the result of photochemical reaction of nitrous oxides, hydrocarbons, and carbon monoxide, and is highly phytotoxic (Lelieveld *et Crutzen*, 1990). Higher concentration of ozone causes changes in plant biochemical and physiological processes, resulting in necrosis on leaves, accelerated ageing of plants, reduced growth and development of plants, and increased production of reactive oxygen (ROS) (Foyer *et al.*, 1994). In this case, glutathione (GSH) and ascorbate-glutathione esterase enzyme have important role in the plant protection. Reduction of glutathione immediately reflects the glutathione reductase (GR) activity, and in many plant species there is immediate enhanced tolerance to photooxidative stress, herbicides, or droughts, and by combining them the regulation of glutathione reductase, or superoxide dismutase is achieved (Foyer *et al.*, 1994).

2.2) Salt stress caused by soil salinity. Soil salinity is issue of great global importance, and it was imposed by water scarcity and osmotic stress and accumulation of ions which negatively affect biochemical

processes in plants (Tang *et al.*, 2005). A number of genes have been tested in an attempt to increase tree tolerance to salt in soil and water. So, poplars transformed by the *mtID* gene from *Escherichia coli* had higher survival rate than wild-type poplars (Hu *et al.*, 2005). However, in the environment where plant was not under salt stress, the growth rate of transgenic plants was about 50% lower than the growth rate of control plants. Some other tree species exposed to modification with the purpose of conferring the tolerance to soil salinity expressed also enhanced tolerance to salt stress when transformed by the *mtID* gene (Hu *et al.*, 2005).

2.3) Stress as a consequence of drought. Drought represents a stress primarily because it affects osmotic plant activity, and causes interruption in distribution of homeostasis ion in a cell (Serrano *et al.*, 1999; Zhu, 2001). Poplars transformed by the pine *GS1* gene responsible for cytoplasmic glutamine synthetase (GS) expressed some tolerance to drought compared to non-modified poplars (El-Khatib *et al.*, 2004). At all levels of water availability, rate of assimilation of genetically modified trees, photosynthetic activity and stomatal conductance were higher than in their control counterparts. Good results in terms of drought tolerance have been achieved with eucalyptus hybrids (*Eucalyptus grandis* x *E. urophylla*), transformed by the *DREB1A* gene (Kawazu, 2004).

2.4) Phytoremediation. The use of plants for removing pollution from the environment is known as phytoremediation (Schnoor *et al.*, 1995). This technology, recently applied, showed certain weaknesses, and indicated several environmental issues, including waste water disposal, biofiltration as well as industrial wastewater inflow, as well as still unsolved problem of land rehabilitation after industrial processes (surface mining and landfills) (Che *et al.*, 2003, 2006; Lee *et al.*, 2003; Strand *et al.*, 2005). Since the phytoremediation technology is cheaper, less aesthetically invasive on the environment and often provides usable products (e.g. biomass), it has many advantages compared to traditional methods, e.g. constructing industrial wastewater treatment plants (Rockwood *et al.*, 2004). Phytoremediation by plants can also have additional advantages in terms of the environment, i.e. atmospheric carbon binding, erosion control, conserving plant and animal life in aquatic habitats and creating protection from noise, trash and harmful dust (Rockwood *et al.*, 2004). The result of this is transgenic tobacco with the inserted new gene from *Arabidopsis thaliana*, a genetically modified variety tolerant to mercury vapours, which binds mercury ion facilitated by the *mer* gene from *Escherichia coli*, due to which these plant can survive in places contaminated by mercury. *Mer* gene encodes enzyme reductase which then catalyses transformation of

mercury ion $Hg(II)$, or its volatile derivative into $Hg(0)$. Tulip tree or yellow poplar (*Liriodendron tulipifera*) has also been transformed by the *merA18* gene from *E. coli* and the result is strong growth of plants on the land containing certain amount of mercury, which is ten times more toxic for normal control plants. The concentration of elementary mercury detected also in transgenic plants was ten times higher than the concentration detected in wild-type plants, without visible effect on their growth (Bizily *et al.*, 2000; Meagher, 2000).

Another interesting heavy metal is Zinc, because it may cause reduction of leaf mass and dry mass in different tree species (Di Baccio *et al.*, 2003). When grey poplar (*Populus canescens*) is transformed by the *gsh1* gene from *E. coli*, which encodes the γ -glutamylcysteine synthase (γ -ECS) enzyme, derived individuals contain increased concentration of glutathione. It is expected that the higher GSH level will result in increased phytochelatin production. However, when genetically modified these individuals and wild-type plants exposed to different zinc concentrations, similar results are achieved. Thus, with 10^{-1} M Zn, the symptoms are necrosis and severe phytotoxicity, while in individual with 10^{-2} M Zn, the leaves were whiter, but still growing. Unlike these, at lower Zn concentration (10^{-3} do 10^{-5} M), there were no toxic effects of zinc (Di Baccio *et al.*, 2003).

2.5) Hormones. Many research have been conducted with the purpose of changing the lignin concentration in flowering plants, and achieving resistance to abiotic and biotic factors (Akiyoshi *et al.*, 1984). The genes controlling hormone synthesis are potential candidates for deriving genetically modified trees with those traits, as well as other desirable traits. It includes reduction of terminal bud, higher density of long fibres, and better rooting and enhanced growth, because those traits are under the influence of hormones. Cytokine, a plant hormone, is very important because it affects growth and differentiation of plants. A gene for isopentenyltransferase (IPT) from *Agrobacterium tumefaciens* catalyses adenosine-5-onophosphate and isopentenyl pyrophosphate isopentenyl adenosin-5'-monophosphate transformation, which then transforms into isopentenyl-izeatinom-type cytokines. Now, poplars with increased IPT expression show increased branching, with short internodes which could not be excluded (Von Schwartzenberg *et al.*, 1994).

3) Genetic modifications for the purpose of deriving enhanced tree traits. As a consequence of fast-growing population on the planet there has been and increased pressure on global forests in order to satisfy our growing demands for production of sufficient amounts of wood for

processing and fuel. A particular problem is increasing deforestation for agricultural land. It also needs to be noted that increasingly strict environmental regulations need to be complied with, as well as increased interest in sustainability (Ballian, 2005, 2008, 2009; Boerjan, 2005).

3.1) Lignin content. Lignin content was among first to show potential in genetic engineering for lignin modification in trees intended for chemical processing. So, for example poplar (*Populus tremuloides*) is transformed by the *4CL* gene which codes coenzyme A ligase, which results in 45% reduction of lignin (Hu *et al.*, 1999). Such major reduction in lignin content, without parallel changes in lignin monomer composition, reflected positively on industrial wood processing, including cellulose and paper production, because in order to remove lignin it is necessary to have more energy and more reagent. A four-year field research was conducted on poplar hybrids (*P. tremula* × *P. alba*), designed to suppress caffeate/hydroxyferulate O-methyltransferase (COMT) and cinnamyl-alcohol dehydrogenase (CAD) enzymes (Pilate *et al.*, 2002). Suppression of the CAD in trees results in simple delignification and superior productivity, while it takes more energy to remove lignin in trees with modified COMT. On the other hand, in similar activities with transgenic tree varieties from the *Eucalyptus* family, reduced CAD expression (antisense) didn't result in change in quality of lignin, or pulp content (Tournier *et al.*, 2003).

3.2) Chemical composition of lignin. It is equally important to reduce lignin content in trees for easier chemical processing, because by changing lignin monomer composition, overall delignification process in cellulose production is improved (Chang *et al* Sarkanen, 1973; Stewart *et al.*, 2006; Mansfield *et* Weiniesen, 2007). Otherwise, lignin is not increased in the tree structure, i.e. S:G ratio of monomer, which clearly indicates that this process increases efficiency of wood pulp preparation. In the last two decades, a great effort has been made to change monomer composition. It includes significant reduction in lignin content with a parallel S monomer reduction, achieved through light suppression of COMT enzyme under control of the 35S promoter (Jouanin *et al.*, 2000).

3.3) Changing the cell wall and polysaccharide structure. The purpose of genetic modifications in different species of trees has often, directly or indirectly, been to increase concentration of cellulose. So, lignin structure in trees has been changed by genetic engineering, and the result is additional advantage in indirect increase of cellulose amount per unit of produced wood (Hu *et al.* 1999; Park *et al.*, 2004). Example is a successful

increase in cellulose amount and reduction in xyloglucan in genetically modified white poplar (*Populus alba*) through expression of inserted fungi genes responsible for xiloglucanase enzyme. The situation is similar with aspen (*Populus tremula*) transformed by the *Cell* gene from *Arabidopsis thaliana*, responsible for endoglucanase enzyme, which resulted in 10% increase in cellulose content. Recently, transgenic hybrids of poplar (*P. alba* × *P. grandidentata*) with bacteria genes responsible for UDP-glucose pyrophosphorylase enzyme inserted, significantly increasing cellulose content, simultaneously reducing lignin content. However, the growth of these trees was significantly slower than the growth of non-modified control individuals (Coleman *et al.*, 2007).

4) Future activities. Although, not all efforts resulted in improvements of trees for industrial processing, they significantly contributed to our understanding of fundamental synthesis mechanisms and cell wall formation. So, for example, 90% reduction in CCoAOMT enzyme activity in transgenic poplars resulted in 11% reduction of lignin (Anterola *et Lewis*, 2002). It indicates that CCoAOMT enzyme has little control over flow of carbon through lignin fibres. Furthermore, a gene for functional hydroxycinnamoyl-CoA, as well as the shikimate hydroxycinnamoyl transferase (HCT) enzyme have been discovered in *Pinus radiata*, in trachea elements (Wagner *et al.*, 2007). We know from before that this gene is involved in lignin biosynthesis in conifers, for which it can represent a new goal for deriving individuals genetically modified for lower lignin content in production of wood and biofuel.

3

RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS

POGLAVLJE

3.1. What is the risk assessment of GMOs, when and how is it conducted?

Risk assessment of GMOs is a range of analyses based on which assessment of health safety and environmental acceptability of each individual variety or hybrid of GM plants. Risk assessment is conducted before the contained use of GMOs or their commercial cultivation or before the placement of certain individual variety or hybrid of GM plants on the market. The fundamental principle of risk assessment is to ‘*assess individual GMO and not the technology*’, which is why it is necessary to conduct scientific risk assessment in accordance with the ‘*one case at a time*’ principle, which means that GMOs are always tested individually. Another principle to go by in preparing the risk assessment is ‘*one step at a time*’, which means that each GMO is tested in two phases: the limited-use phase, i.e. tested in closed systems, laboratories and greenhouses, after which, in case the results of risk assessment are positive, it is tested in the environment, and this includes field experiments. In case the tested GMO is positively assessed in terms of risk and is approved, the law then prescribes the obligation of constant monitoring of potential negative effects on the environment and human health after its placement on the market or release in the environment. (Trkulja *et al.*, 2015).

When determining, analysing and assessing potential negative effects on the environment and human health, it is necessary to take four types of direct effects into consideration: 1) *direct effects*, related to primary effects on human health or on the environment which are the consequence of GMOs and do not occur in cause-and-effect chains of events, 2) *indirect effects*, related to effects on human health or on the environment, which occur in cause-and-effect chains of events of mechanisms such as interaction with other organisms, transfer of genetic material or change in the use or management, 3) *immediate effects*, related to effects on human health or on the environment noticed during the period of the GMO release, which can be direct or indirect, as well as 4) *delayed (subsequent) effects*, related to effects on human health or the environment which may not be noticed during the GMO release, but when direct or

indirect effects become visible in a later phase, or after the completion of the release. Furthermore, an analysis of *cumulative long-term effects* important for releasing a GMO and placing it on the market should be conducted. Cumulative long-term effects are related to accumulated effects on human health and the environment, also including plants and animals, soil fertility, dissolution of organic compounds in the soil, nutritional value of feed, biodiversity, animal health and resistance of organisms to antibiotics. Apart from the already mentioned, a *social component* affecting the risk assessment and encompassing public opinion should be taken into consideration. It implies the lack of reliable information, negative attitude of the media, opposition of activist groups, the lack of trust in the industry, as well as economic component of the risk (Trkulja *et al.*, 2015).

Research in ‘*risk assessment*’ include: genetic modification stability analysis, analysis of potential toxicity or allergenicity of a new protein/metabolite, analysis of nutritional composition, analysis of their effect on the biochemical processes, analysis of the change in agricultural practice and its potential consequences, analysis of the effects on targeted and other organisms, analysis of their release in the environment, analysis of potential transfer of genetic modification to a genome of associated species, potential harmful consequences of it, etc.

3.2. What are the phases in risk assessment development?

Risk assessment of GMOs is conducted in five phases (Trkulja *et al.*, 2008a). **In phase one of risk assessment** for individual genetically modified organisms, specific traits of the GMOs are determined and analysed. Relevant technical and scientific data should be taken into consideration during the risk assessment with regards to traits:

- recipient or parent organism (organisms);
- genetic modifications, inserting or cutting and pasting genetic material and relevant data on vector and donor;
- planned release and use, including its scope;
- potential environment to receive it; and
- their interaction.

According to Trkulja *et al.* (2008a) **phase two of risk assessment** is a six-step process for determining and assessing potential negative effects of deliberate release of a GMO into the environment and assessing potential danger for biodiversity and human health. *Step one*: noticing characteristics

which may potentially cause damage; *step two*: assessment of possible consequences of each potential negative effect; *step three*: assessment of probability of each individual detected negative effect occurring; *step four*: assessment of risk which each of the GMO traits represents; *step five*: implementation of risk management strategies for deliberate GMO release and placement on the market; *step six*: determining overall risk of a specific GMO.

All GMO traits related to genetic engineering which can potentially cause harmful effects on human health and the environment must be identified. Comparing the GMO traits with the traits of non-modified organisms in suitable conditions for the release and use will help determining potential negative effects and consequences of genetic modification in a GMO. It is important not to ignore any of potential negative effects just because the probability of it occurring is minor.

Potential negative effects of GMOs differ from case to case, and they can include:

- diseases which represent a threat to human health, including allergic reaction or toxic effects;
- disease which represent a threat to animal and plant health, including toxic effects and, occasionally, allergic reaction;
- impact on dynamic of populations of species in the environment of hosts, and on genetic diversity of each of those populations;
- changed effects on pathogens and/or vectors which facilitate spreading of infectious diseases and/or creating new hosts or vectors;
- disruption of prophylactic or therapeutic medical, veterinary or plant protective processes, e.g. by transferring genes resistant to antibiotics used in human and veterinary medicine; and
- effects on biogeochemistry (biogeochemical cycles), particularly on carbon and nitrogen recycling through changes during decomposition of organic substances in the soil.

In phase three of the risk assessment, the conclusion of the risk assessment is made, based primarily on determined and assessed potential negative effects of deliberate release of GMOs into the environment and the assessment of risk for biodiversity and human health from the phase two of the risk assessment.

In phase four, the process of assessment development is described, and sources of data and information used for its development are listed, potential gaps and disadvantages of the assessment are noted and a potential occurrence of negative effects is determined in case real problems occur during the assessment.

In the final phase, **phase five of risk assessment**, information on the assessor and all persons involved in the risk assessment development is provided.

Assessment of safety of food derived from GMOs includes analysis of: potential direct negative effects of the new protein on health (toxicity); potential for causing allergic reactions (allergenicity); potential changes in nutritional traits, including changed concentration of existing toxins and allergens ; stability of inserted or modified genes and potential for all other non-deliberate changes which may be the result of genetic modification.

European Food Safety Authority – EFSA – prescribes a procedure for the development of risk assessment of GMO (Waigmann *et al.*, 2012), while the EFSA’s Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel, 2010) recommends seven specific areas to be analysed during the development of risk assessment of GM plants for the environment: (1) the persistence and the invasiveness of GM plants, or their compatible associate plants, including plant-to-plant gene transfer; (2) plant-microorganism gene transfer; (3) interaction of GM plants with targeted organisms; (4) interaction of GM plants with non-targeted organisms, including selection criteria for a specific species and relevant functional groups for risk assessment; (5) influence of a specific cultivation, management and harvesting technique, including consideration of production systems and acceptance by the environment; (6) effects on biochemical processes, and (7) effects on human and animal health.

The procedure for the authorisation of the release of GMOs into the environment, or the use in food or feed is extremely complicated in the EU and it requires comprehensive research for the risk assessment development. In case the occurrence of negative effects of inserted genes and their products is not determined by testing, and if the genetically modified product proves to be equivalent to non-modified product, and it meets all the requirements from the GMO risk assessments, a new GM variety of hybrid plants may be approved by a competent authority for food and/or feed, or for commercial cultivation and production (Trkulja *et al.*, 2015).

3.3. Does GM food pose a health risk for people?

If the consumption of ‘alien’ DNA or proteins is dangerous for human health, then throughout the whole evolution we have lived dangerous lives. Everything we consume contains ‘alien’ DNA and proteins. This does not necessarily mean that every GMO is safe, just like

not all natural proteins are safe. We cannot issue general authorization for GMOs, but to immediately judge the technology itself makes no sense.

Genetically modified food products have been available to consumers since 1996. Globally, and particularly in the USA, people consume it without any noticeable effects on their health, which has been recorded in numerous scientific magazines, documents and reports of regulatory bodies and agencies. However, we cannot talk about theoretical chronic effects of GM food on human health in the USA, because too little time has passed since the initial commercialisation of the GM crops. Fundamental principle of the risk assessment and GMO product safety is '**to assess individual product, not the technology**'. The risk assessment of GM food strategy includes: information on characteristics of modification, including function and traits of a new gene; safety, allergenicity and nutritional value of new substances/products of inserted gene's expression; identification and evaluation of all changes in the GM product composition, testing side effects; the impact of modification on toxicological attributes of new food; the role of new food in diet; potential effects of processing and spoilage of GM products, etc. (Trkulja *et al.*, 2014a).

The World Health Organization (WHO) have, in cooperation with other agencies, developed a specific approach to assessing safety of genetically modified and other new food products (food products derived by using new technologies). The specific approach is based on proving '*substantial equivalence*', i.e. each new food should be equal to its conventional counterpart, after which, if they are sufficiently equal, the new food product is treated as 'the original', and if not, the new food must undergo rigorous testing of safety (toxicological, allergenic, nutritional and other testing). When assessing safety of each GMO it is important to maintain **individual approach**, i.e. to assess safety of each GMO separately. The equivalence principle has been subject to criticism of one part of scientific community, where they believe that genetically modified food products should test by long-term experiments of feeding animals and double-blind experiments on volunteers.

3.4. Are GM food products assessed differently than traditional food products?

Consumers believe that food products obtained by traditional production (*Image 2*), eaten for thousands of years, are safe. However, it is known that deriving new varieties and hybrids of different agricultural plants by using traditional methods of breeding may change existing traits of food products. Although, competent institutions for food control can be

asked to test traditional food products, it is not a practice, and often, products derived from new varieties and hybrids of different plants developed by using traditional selection methods are not sufficiently tested by risk assessment methods.



Image 2. Fruits of different plants produced by traditional methods (photo: www.cameroncowan.net).

Unlike them, genetically modified organisms require specific assessments, which is why the specific systems for comprehensive analysis, assessment and testing of GMOs and food products derived from them have been established, considering the risk for human health and the environment.

Traditional food products do not undergo similar testing. For this reason, a significant difference exists in the process of assessment and safety assessment between these two food product groups prior to placing them on the market. (Trkulja *et al.*, 2014a).

3.5. How is the potential health risk of such food determined?

Food safety assessment for food products derived from GMOs includes testing of:

- a) potential direct negative effects of a new products on health (toxicity);
- b) potential for causing allergic reactions (allergenicity);
- c) potential changes in nutritional traits, including the change of concentration of existing toxins and allergens;
- d) stability of inserted and modified genes; and
- e) potential for all other non-deliberate changes which could be result of genetic modification.



Image 3. New variety of GM pineapple, Del Monte Company, with pink pulp (foto: C. S. Prakash).

Prior to commercial cultivation and/or placement on the market of each individual GM plant variety or hybrid is authorised (*Image 3*), it is legally required to conduct a ‘risk assessment’, i.e. a range of analyses based on which the health safety and environmental acceptability of each GM plant variety or hybrid is determined. According to Jelenić (2004b) such assessments always include:

- genetic modification stability analysis,

- potential toxicity and allergenicity of a new protein/metabolite analysis,
- nutritional composition analysis,
- analysis on the effect on biochemical processes,
- analysis of changes in agricultural practice and its potential consequences,
- impact analysis for targeted and other organisms (direct or indirect),
- analysis of subsequent spreading in the environment,
- analysis of potential transfer of genetic modification to genomes of all associated species,
- possible consequences, etc.

3.6. Which GMO traits cause the biggest concern of general public?

Although health safety assessment include a broad range of analyses, the most attention is paid to: allergenicity, toxicity, potential for undesired transfer of certain genes and cross-breeding of GM crops with conventional or wild-type species, since these potential GMO traits cause major concern of general public.

Allergenicity. Efforts are made to avoid transfer of genes from the organisms known to be allergenic, unless it has been proven that protein product of transferred gene is not allergenic. Although allergenicity of fruits and other edible parts of different plants produced in a traditional way (*Image 4*) is not tested, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have developed protocols for the assessment of foods produced from GMOs. According to their reports, allergic reactions to GM food products currently available on the market have not been detected. However, some food products derived from GMOs, determined to cause allergic reaction, have been withdrawn from the market. The example is withdrawal of ‘Star Link’ maize event in the USA in 2000, after determining that it had caused allergic reaction in a number of people.



Image 4. Fruits and other edible parts of different plants produced traditionally (foto: www.ebrookosteopathy.co.uk).

Toxicity. Genetic modifications cause changes in certain biochemical processes in the host. For that, it is possible that some of the metabolism products become toxic or the production of existing toxins increases uncontrollably, which is why a special attention is paid to this possibility during the health safety assessment of each GMO.

Horizontal gene transfer and potential for developing resistance to specific antibiotics. A major concern is that potential transfer of specific genes from the ‘GM foods’ into cells of our organism or into bacteria in our digestive system (*‘horizontal gene transfer’*) could negatively affect human health. In this context, genes for resistance to specific antibiotics, found in some GM plants are cause for major concern, since the antibiotics are simultaneously used for the treatment. Although, the possibility of transfer is small, the FAO and the WHO experts insist on accepting only GM plants resistant to antibiotics.

Cross-breeding of GM plants with conventional crops or associated species. Such cross-breeding, if happens, and the mixing of seed material, can have indirect impact on the environment and food health safety. This danger is real, because it has been proven that in the USA a maize event approved only for feed was mixed with maize approved for

food (the case of aforementioned *Star Link* maize, which had to be withdrawn from the market). Some countries have adopted strategies to reduce this phenomenon (*coexistence*), which includes prescribing methods for safe division of fields with GM crops from fields with conventional crops (Trkulja *et al.*, 2014a).

3.7. Why do GM food products raise concerns among consumers?

The first time GM food products were placed on the market in 1990s. Since then, this has been a source of concern of consumers and some politicians, particularly in Europe. Consumers often wonder: ‘*Why do I need that?*’. However, in case of medicaments, consumers find it easier to accept biotechnology as useful for their health. It should be noted that first GM food products, placed on the European market, didn’t represent a direct benefit or gain for consumers, they were exclusively economically viable for farmers, their growers. It should also be noted that the trust of consumers in food health safety has significantly decreased due to a number of scandals (cow madness, dioxins in chicken, etc.). These scandals were the consequence of economic interests of food producers, insufficient, or wrong information general public received, and irresponsible behaviour of competent authorities. These cases were not connected to GM foods, but they resulted in increased distrust of public to official information. The concern of consumers in the European Union has resulted in mandatory labelling of GM food and feed.

3.8. How has the concern of public affected the sale of GM food products in the EU?

Public concern for GMOs and food products derived from GMOs has had a major effect on the GMO market in the EU. So, in 1998, in the EU, due to a great public pressure, a temporary prohibition on placing GM products on the market was imposed, i.e. **moratorium**, which was in force until 2002. Sale of such products and GMOs is still a subject of strict and comprehensive legislation the EU introduced in the early 1990s. The EU GMO approval procedure is extremely complicated and demands comprehensive research and agreement between a Member State that wants to grow GM crops and the European Commission. Between 1991 and 1998, the European Commission authorized market placing (sale) for 18 GMOs, after which, since lifting the ban in 2004 until today, several more GM products have been approved, and sowing of GM maize hybrids, in

2007 grown already in 8 EU countries (Spain, France, Czech Republic, Portugal, Germany, Slovakia, Romania and Poland). Additionally, under public pressure the EU introduced mandatory labelling of products containing, consisting of or produced from GMOs. Legislation also prescribes, in case of accidental contamination of conventional food by GM material food products containing 0.09% or more GMO must be labelled as food containing GMOs, but if the concentration of GMOs is less than 0.09% the food products need not to be labelled. Identical practice is prescribed by the Law on GMO in Bosnia and Herzegovina (Trkulja *et al.*, 2014a).

4

CHAPTER

METHODS FOR DETECTION OF GENETICALLY MODIFIED ORGANISMS

4.1. How do we recognize GMOs and based on which methods do we reliably determine the presence of GMOs?

For the purpose of controlling the presence of genetic modifications in seed material and finished products (food and feed) the whole range of methods for detecting their qualitative and quantitative presence has been developed. These techniques are based on observation and analysis of three organic parameters: *presence of a new trait (phenotype)*, *presence of specific proteins*, and *nucleic acid analysis*.

4.1.1. Detection of GMOs based on phenotype

This method is based on the analysis of the expressed traits provided by transgenics, applicable only for specific traits, (e.g. tolerance to total herbicides), and requiring certain growth and development of assessed organism, which is often a long-lasting process (e.g. mature crop is treated by total herbicides which causes all non-GM plants to die).

4.1.2. Detection of GMOs based on specific proteins

The GMO detection methods include analytical techniques based on the use of antibodies as test reagents (serological methods). These methods are based on the reaction occurring after injecting test substance (antigens) in the body of an animal, when the immune system recognizes alien substance and responds to it by producing specific antibodies which bind to antigens, and this is the basis of a method used in these assays. The most common immunoassay is ELISA test (*Enzyme Linked Immunosorbent Assay*), used in laboratories for testing specific GMOs (e.g. presence of *'Roundup Ready'* protein which is a fundamental part of the enzyme responsible for tolerance to glyphosate-based herbicides). Rapid immunoassays ('Stripe' methods) which can easily be used outside laboratories for detecting GM crops have also been developed. GMO

detection techniques at the protein level are extremely sensitive and are often used for the analysis of animal samples (Trkulja *et al.*, 2014a).

4.1.3. Detection of GMOs based on nucleic acids analysis

In order to determine the presence of genetic modifications in samples of plant material, PCR (Polymerase Chain Reaction) method is applied, with a biochemical reaction allowing *in vitro* multiplication (amplification) of a specific DNA fragment, which is basically an imitation of the DNA synthesis in all living organisms.

PCR is a method for multiplying a relatively short targeted DNA region (gene, or a gene segment) into a huge number of identical copies. Basic principle of the PCR method is selective *in vitro* multiplication of a targeted DNA molecule sequence in the reaction tube up to several billion times without prior isolation from the mass of DNA molecules present in the sample. Targeted region of DNA molecule for multiplication (gene, or a gene segment) is determined by short oligonucleotide sequences – primers, complementary to the template DNA segment. These primers are catalysts for a series of reactions with the assistance of polymerase (a DNA enzyme) which based on one DNA chain synthesises a new, complementary chain, where the size of the synthesized DNA segment is complementary to the length between the selected primers.

The PCR process can be divided into three phases: extraction of a DNA from a sample and preparation of the PCR mixture, then the PCR, and finally identification of the PCR products.

In phase one (DNA extraction from a sample) a DNA is isolated (extracted) from the plant sample through a number of analytical steps. In order to extract plant DNA from analysed sample, a standard protocol for DNA extraction from plant material is used. At the end of phase one a quantification is conducted, i.e. a quantity of the DNA extracted from the sample is determined, and then, based on that quantity, the DNA sample is diluted to optimal concentration which is this way prepared for the phase two – PCR amplification.

In phase two (PCR amplification) a sample of the tested DNA (which will be a template for copying a complementary DNA chain) is added to the DNA extracted from the sample in the reaction tube, along with two suitable oligonucleotide primers, thermostable DNA polymerase, nucleotides – building blocks of DNA (dATP, dCTP, dGTP, dTTP), Mg²⁺ and reaction buffer. After mixing the components in the reaction tube, they are placed in a thermal cycler (*Image 5*), i.e. the PCR amplification

apparatus. The main characteristic of the PCR apparatus is fast, automated, cyclic and precise temperature change 30 to 50 times (depending on the tested sample and protocol used) under microprocessor controller, which is necessary for polymerisation reaction. This instrument, based on the programmed temperature regime, is used for the amplification of targeted DNA.



Image 5. Detail from the DNA detection process based on DNA analysis using standard PCR

PCR can be: 1) qualitative, and 2) quantitative. Qualitative PCR can be standard, RT_PCR, *in situ* PCR, whilst the quantitative PCR is Real Time PCR, which can also be standard and RT-PCR. For *qualitative* GMO detection a standard PCR (Image 5) is used; it can detect less than 0.01% of modified content in raw material, and this method can only confirm or negate the presence of GMOs. However, in order to quantify GMOs, i.e. to determine exact percentage of targeted DNA sequences, specific for GMO in overall sample, a quantitative Real Time PCR is used (Trkulja *et al.*, 2014a).

1) **Standard PCR** is carried out by using a pair of primers which allow the amplification of targeted DNA sequence. It is used only for detection of its presence or absence (qualitative PCR). One cycle of the PCR is conducted in three steps: 1) the *denaturation of double-stranded DNA matrix* (tearing hydrogen bonds between complementary DNA chains under the influence of temperature - 95°C - which prevents all

enzymatic reactions, e.g. extension from the PCR cycle); 2) *hybridization of primers with matrix* (forming hydrogen bonds between primers and suitable sequences on single-stranded DNA matrix) on 40-65°C, depending on nucleic sequence and the length of primers; 3) *primer elongation* (insertion of nucleotides on 3'-end of primer catalysed by DNA polymerase enzyme) on 72°C, which is optimal temperature for DNA polymerase function.

In phase three of the standard PCR (Image 6), the amplified DNA of the sample has already been prepared by using sterile pipettes, and now is inserted into agarose gel in wells of the apparatus for electrophoresis. The inserted DNA sample is then separated based on the length of base pairs under the influence of electric field. After the electrophoresis finishes agarose gel is coloured by ethidium bromide, matter which emits light under ultraviolet radiation. The gel is photographed in special apparatus for photographing gel, after which the result analysis is conducted (Trkulja *et al.*, 2014a).

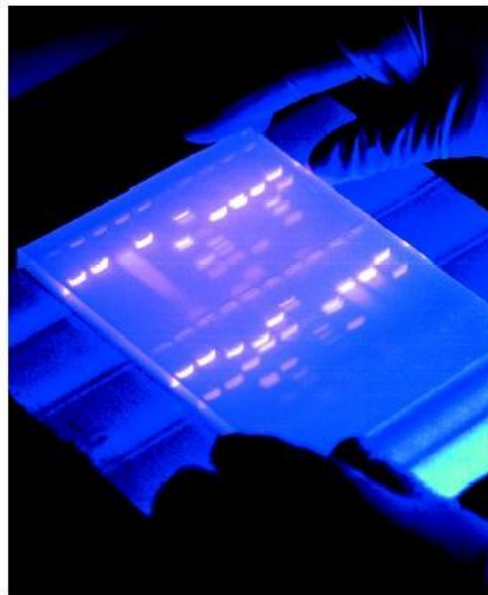


Image 6. Electrophoretic analysis of PCR products on agarose gel

2) **Real Time PCR** allows a quantitative analysis of the amplicon in the tested sample, e.g. a number of copies of a gene, as well as determining the expression level of a specific gene (quantitative PCR). E.g. when analysing the percentage of GMOs in a sample, standards with already known percentage of a specific GMO are used (0.1%, 0.9%, 3%, 5%, 10%). By comparing this amplicon the exact percentage of GMO in tested

sample is determined. By applying Real Time PCR, the expression level of a specific gene can be determined.

The Real Time PCR is a process based on the standard PCR, because a well isolated DNA, optimally selected primers for the reaction and optimal phases of PCR are necessary for it (denaturation, selection and conditions of binding primers, DNA synthesis – elongation of complementary DNA chain). Fundamental difference and a great technological improvement of the Real Time PCR compared to the standard PCR is that PCR allows detection and quantification of multiplied targeted DNA segment in real time, i.e. during the amplification of the sample (*Image 7*), which is why the visualization of the PCR products by electrophoresis on agarose gel is not necessary, and the Real Time PCR has a detection system for PCR products based on fluorescence detector (Trkulja *et al.*, 2014a).

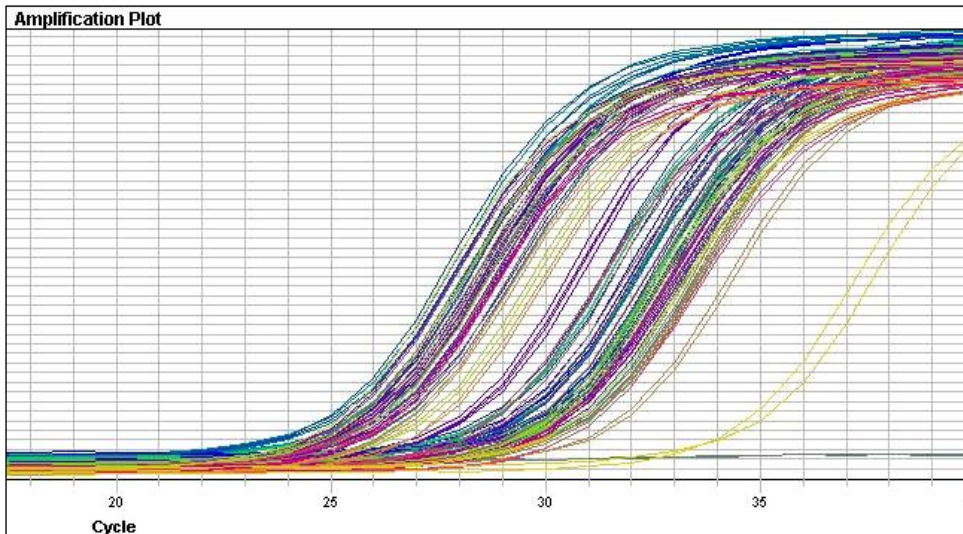


Image 7. The dynamic of the PCR in real time (Real Time PCR), or during the amplification of sample. By the 22nd cycle the PCR of product is extremely low; the PCR of product between 22nd and 32nd is increasing linear, then the increase is logarithmic; after the 35th cycle the so called 'plateau' is formed. Now, the PCR is no longer effective.

There are three variations of this system in practice in terms of final detection of quantity of the PCR products of amplification: 1) application of chemical compound (e.g. SYBR Green) which can be built between DNA double helix and emit fluorescence which fluorescence intensity is monitored; 2) application of primers marked by fluorescent compounds, so

the DNA amplification is monitored by inserting primers into the PCR product, which is how the increase of fluorescence intensity is monitored, 3) application of standard primers and special testing complementary to the targeted DNA segment and marked by different compound combinations which emit light energy and compounds which block such activity. During the PCR reaction, the dynamic of relation between the compounds changes, so the increase in radiation energy as a fluorescent light is measured as its final effect. The best known examples of such approach are TaqMan probes by the Applied Biosystems, an American company and the FRET system developed by the Roche Diagnostics (Trkulja *et al.*, 2014a).

5

CHAPTER

GENETICALLY MODIFIED ORGANISMS AND BIOSAFETY

5.1. What is biosafety?

Biosafety is the system which, in the context of modern biotechnology and genetically modified organisms, refers to protection of the environment and biodiversity, including human health and safety. Food safety represents a special aspect of biosafety. International commitments (the Convention on Biological Diversity, the Cartagena Protocol) as well as the global politics require the consideration of biosafety issues. Within the framework of famous *Agenda 21*, the Chapter 16, the following is said ‘*biotechnology promises to make a significant contribution in enabling the development of modern agriculture, health care and environment protection, but only if adequate biosafety mechanisms are defined*’.

Modern biotechnology is a system of tools used for improving plants, animals and microorganisms for the benefit of humankind. The definition from 1982 in the OECD publication *Biotechnology – International Trends and Perspectives*, describes biotechnology as application of principles of science and engineering to material processing with the assistance of biological agents with the purpose of producing goods and services. This definition is broad and refers to growing plants and animals for food, the use of microorganisms for producing food products such as yoghurt or beer, the use of microorganisms in health care. In its overall scope the definition may refer to the use of biological entities in improving industrial processes. Often, biotechnology refers to genetic engineering, although some, in that case, rather use the term ‘modern’ biotechnology, defining it as a sub-discipline. The start of biotechnology development in practical sense we can consider the era when it became well known for the cheese production and yeast activity.

Modern biotechnology promises production improvement (quality and quantity), reduction of stress on the environment, advantages in nutrition, medicine and pharmaceuticals, as well as finding alternative ways for production of necessary synthetic materials.

In addition to providing definition of biotechnology, the OECD document from 1982 recommends governments to define suitable mechanisms for safety regulation in order for the general public to trust in

modern biotechnology products. The first document responding to these recommendations was *Blue Book* by the OECD. This publication improved safety concepts for development and commercialization of GMOs, including the risk assessment, agriculture and the environment, as well as understanding genetically modified plants. However, the first consideration of mechanisms for biological control and regulation of recombinant DNA research is related to *Asilomar Conference* (Pacific Grove, California), held in the USA in 1974.

As a result of recognizing humankind as the main factor in degradation of natural ecosystems and reduction of biodiversity, and understanding that it is necessary to promptly protect and improve them, in May 1992, the *Convention on Biological Diversity* was born, at the UN Conference on Environment and Development – at the Earth Summit, held in Rio de Janeiro. The Convention was open for signing, and 156 of countries and the European Union did that. The Convention on Biological Diversity entered into force on 29 November 1993, and is currently a fundamental international agreement on issues of biological diversity. It ensures member states ‘*a comprehensive approach to conservation of biological diversity, and sustainable use of natural resources and just and equal division of benefits from the use of genetic wealth*’ (Trkulja *et al.*, 2014a).

The term *biosafety* refers to the need for protection of the environment and human health from potentially negative consequences of the modern biotechnology products. At the same time, a great potential of biotechnology in improving well-being of humankind in agriculture, protection of human health and satisfying the need for food is recognized. The Convention on Biological Diversity clearly recognizes this double aspect of modern biotechnology and, on one hand, allows the access to and the transfer of technologies, including modern biotechnology, important for protection and sustainable use of biological procedures, and, on the other hand, requires the development of appropriate procedures which will improve the modern technology safety. *Biosafety* is therefore one of the main goals of the Convention, and is achieved by reducing all potential threats to biological diversity, taking into account the potential risk for human health.

The loss of any segment of biological diversity (genetic diversity, diversity of species, as well as diversity of communities and ecosystems of those species) reduces potential of living beings, and therefore the potential of human beings to adapt to the constantly changing environment (Tarasjev *et al.*, 2006). Modern research have shown that human beings have a quality aesthetic and cultural experience, by using environment services or by

directly using plant and animal species in pharmaceutical, food and construction industry (Futuyma, 1998).

According to Tarasjev *et al.* (2006) there is a risk that the consequence of releasing and spreading genetically modified organisms into native ecosystems, in case they express modifications which would make them superior, could be negative effects on local biological diversity and beyond. For example, genetically modified plant species which synthesize Bt proteins with insecticide effect may endanger so-called ‘non-targeted’ insect species. For this, the authors emphasize that with new technologies, our environment inevitably becomes a laboratory for a broad range of experiments on and with genetically modified organisms creating room for making irreversible mistakes and raises many ethical issues.

Guided by the Convention principles and recognizing its significance, a task force was formed in 1995 to develop a Draft Protocol on Biosafety (*Cartagena Protocol*), adopted in 2000, and entered into force on 8 September 2003 for all signatory countries. The purpose of this Protocol is to contribute to establishing appropriate protection levels of the transfer, handling and use of *living modified organisms* (LMOs), products of modern biotechnology, which may have negative effects on conservation and sustainable use of biodiversity, taking into account human health (Trkulja *et al.*, 2014a).

5.2. What is the Cartagena Protocol on Biosafety?

Cartagena Protocol on Biosafety (CPB) is international agreement, legally binding for all the signatory countries, and regulating the inter-state and transboundary movement of living modified organisms (LMOs). Foods produced from GMOs fall under the Protocol only if they contain LMOs able to transfer genetic material or reproduce. The basis for the Protocol is the requirement for the exporters to ask for the consent of importers before the first shipment of LMOs intended for the release into the environment. In addition to that, the Protocol promotes biosafety determining the rules and procedures for safe transfer, handling and use of living modified organisms, with special emphasis on cross-border transfer of LMOs, and it defines time frames for decision making. It also determines a number of procedures for LMOs to be released in the environment, particularly for LMOs intended for food, feed or cultivation, and special procedures for LMOs used in closed systems. According to the Protocol, the signatory countries are required to ensure safe handling, packaging and transfer of LMOs, and the LMO shipment transported

across border should be accompanied by relevant documentation with the exact type of living modified organisms specified, and information on focal point available for any additional information.

These procedures and requirements are developed to allow countries importers to have all the necessary information based on which they can make final decision to *allow or forbid the import of LMOs* based on facts, and *safe handling of such organism*. Importing country should make its decision based on risk assessment conducted using provided scientific data. The Protocol determines principles and methodologies for developing the risk assessment. If the relevant scientific data and knowledge are insufficient the importing country may apply **precautionary principle** in decision making with regards to import of a specific LMO, taking into consideration its own socio-economic interests if they are harmonized with the country's international commitments. The precautionary principle should be based on comprehensive analysis of risks for each LMO, but it does not postpone decision making.

Signatory countries to the Protocol should also develop capacities for implementation of measures for removing negative consequences of potential risk, and measures to be taken in case of uncontrolled release into the environment of a specific LMO. In order to make the implementation of the Protocol easier, the *International Biosafety Information Exchange Mechanism - Biosafety Clearing House (BCH)* - was established for the signatory countries to the Protocol, so they can exchange information through it (Trkulja *et al.*, 2014a).

During the Earth Summit, the famous Agenda 21 was promoted as a programme for sustainable development for the 21st century, encompassing all aspects of modern science, including biotechnology. Beside already mentioned, other important documents on biosafety are the UNEP International Technical Guidelines for Safety in Biotechnology, adopted in 1995, and documents adopted at the UN International Summit on Sustainable Development (Rio Earth Summit + 10) held in Johannesburg, South Africa in 2002. The main purpose of the summit was to define national, regional and global commitments with regards to biosafety and principles of their implementation (Trkulja *et al.*, 2014a).

Despite the differences between the biosafety systems in different countries, their structure is similar and mandatory includes the following elements:

- 1) Biosafety policy;
- 2) Biosafety legislation;
- 3) System of application treatment, including:

- a) Check of completeness (administrative and technical data) and adequacy of application,
- b) Risk assessment – things to be taken into consideration: donor and host organism, vectors, inserts, LMO, LMO detection and identification, planned use, environment, etc.
- c) Decision making (lawful and transparent);
 - 4) Monitoring and inspections;
 - 5) Information for the public.

6

CHAPTER

GMO LEGISLATION IN THE WORLD, THE EUROPEAN UNION AND BIH

6.1. GMO legislation around the world

In order to be able to cultivate different varieties or hybrids of GM plants or place them on the market as food or feed they must be approved (authorised or registered) through a procedure prescribed by laws all around the world. The main objective of the GMO legislation (rules and regulations) is to protect human life and health, to protect animals health and welfare, to protect the environment and biodiversity, as well as to protect consumers' interests (Trkulja, 2015). However, there is no uniform GMO legislation in the world, different countries have different GMO regulations in place. Different approaches to labelling GMOs may be a good example of diverse legislation for individual segments in the area of GMOs. Thus, for example, GMO products labelling is not mandatory in the USA, Argentina, Canada, Uruguay, Mexico, Chile, Paraguay and Egypt, while the EU products containing >0,9% of approved GMOs must be labelled. In Brazil and Australia food with >1% GMOs must be labelled, except for GM soybean in Brazil. The threshold for GMO labelling in Japan is 5%.

According to Trkulja *et al.* (2015), different segments in the area of GMOs are regulated by numerous international conventions, protocols, agreements, instructions and guidelines, which are given in the text below.

- 1) ***The Convention on Biological Diversity (CBD)***. As a result of identifying human beings as the main factor in deterioration of natural ecosystems and reduction of biodiversity, as well as the perception of their immediate protection and improvement, the *Convention on Biological Diversity - CBD* was born in May 1992. Only a month later, during the United Nations Conference on Environment and Development – 'the Earth Summit', held in Rio de Janeiro, the *Convention* was opened for signature, and 156 countries and the European Union signed it during the Conference. The *Convention on Biological Diversity* entered into force on 29 November 1993 and is currently a fundamental international agreement treating biological diversity. The term biological safety

or *biosafety* refers to the need for protection of the environment and human health from potential adverse effects of products of modern biotechnology. At the same time, the huge potential of modern biotechnology in the advancement of human welfare through agriculture, protection of human health and satisfaction of the need for food is acknowledged. Therefore, *biosafety* as one of the Convention's main objectives is to be achieved by reducing all potential threats to biodiversity, taking into account the risk for the environment and human health. Bosnia and Herzegovina signed the Convention in August 2002.

- 2) ***The Cartagena Protocol on Biosafety - CPB***. Based on the principles of the *Convention*, and recognising its full significance, in 1995, a working group was established that developed the draft Protocol on Biosafety (the Cartagena Protocol), which was adopted in 2000 and entered into force on 8 September 2003 for all the signatory countries. By December 2018, the Cartagena Protocol on Biosafety was signed by 171 states. The main goal of this protocol is to contribute to the establishment of relevant protection levels in the area of safe transboundary transfer, transport, handling and use of *living modified organisms (LMOs* – a term adopted instead of GMOs referring only to seeds and live organisms and not to food derived from LMOs), products of modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity as well as on human health. The Cartagena Protocol on Biosafety is an international agreement binding for all the signatory countries and regulating inter-state and transboundary movement of living modified organisms. The basis of the Protocol is a requirement for exporters to ask for the consent from the importers before the first consignment of LMOs intended for releasing into the environment. Under the Protocol signatory countries are required to ensure safe handling, packing and transport of LMOs, and cross-border shipment of LMOs should be accompanied by relevant documentation. The purpose of the Cartagena Protocol on Biosafety is to ensure harmonised international legal framework for reasonable and environmentally safe application of new biotechnology. In this regard, the Protocol offers numerous tools:
 - 6) ***Advanced Informed Agreement procedure, AIA*** –This procedure must be observed before the first consignment of LMOs to be released into the environment. Before the import, the exporter must provide a detailed description of the LMOs to be imported. On the

other hand, the importer must confirm the receipt of such document within 90 days and thus authorize the consignor to complete the consignment within 270 days. The purpose of this procedure is to ensure sufficient amount of time to the importing country for assessing the risk related to LMO release.

- 7) *Biosafety Clearing House (BCH)* –The aim of the Biosafety Clearing House is to facilitate the exchange of scientific, technical, environmental and legal information related to LMOs via the Internet (WEB page). Each member state is obliged to designate a relevant institution and a focal point for this purpose.
 - 8) *Risk assessment and risk management framework* – Risk assessment and risk management is conducted scientifically, based on adopted risk assessment methods. In case of insufficient scientific knowledge on a specific LMO, the importing country may apply the precautionary principle and prohibit LMO import.
 - 9) *Capacity building* – The Protocol foresees financial support as well as international cooperation during scientific and technical training of staff and transfer of technology.
 - 10) *Public awareness* –The signatory to the Protocol is required to ensure the access of general public to information and to respect the decisions of general public regarding biosafety.
- 3) ***World Trade Organization (WTO)*** – The WTO is an international organisation which governs multilateral agreements in the area of goods trade, trade in services and trade-related aspects of intellectual property rights. Until the the establishment of the WTO in 1995, the *General Agreement on Tariffs and Trade (GTT)* was the only multilateral instrument regulating international trade since 1947, when it had been adopted. The WTO headquarters is in Geneva, and it presently includes 159 country members, which jointly account for 97% of the world trade. The WTO's main objective is to ensure conditions for obstacles-free trade, within predictable frames. In this regard, a system of the WTO rules and regulations has been established, composed of specific, multilateral agreements, which are mainly the result of the Uruguay Round (multilateral trade negotiations from 1986 till 1994). According to the WTO data, there are several agreements which these rules and regulations can be applied to genetically modified organisms (GMOs). These agreements are:
- *Agreement on the Application of Sanitary and Phytosanitary Measures – the SPS Agreement;*

- *Agreement on Technical Barriers to Trade - TBT*;
 - *Agreement on Trade-Related Aspects of Intellectual Property Rights - TRIPs*;
 - *General Agreement on Tariffs and Trade - GATT*. Furthermore, WTO accepts all the standards, recommendations and guidelines reached by the Codex Alimentarius Commission, the Office International des Epizooties (OIE) and the International Plant Protection Convention (IPPC) in their GMO-related research. The standards of these organizations, also known as the 'three sisters', have been treated by the WTO as international standards in terms of the Agreement on the Application of Sanitary and Phytosanitary Measures.
- 4) ***Codex Alimentarius Commission*** – the World Trade Organisation accepts all the standards, recommendations and guidelines regarding food safety assessment that have been developed by the Commission in its GMO-related research (FAO/WHO, 1996, 2011).
 - 5) ***Office International des Epizooties, OIE*** – the WTO accepts all the standards, recommendations and guidelines that have been developed by the OIE in its GMO-related research.
 - 6) ***The International Plant Protection Convention, IPPC*** – the WTO accepts all the standards, recommendations and guidelines that have been developed by the IPPC in its GMO-related research. This Commission operates within the IPP Convention and adopts international standards for phytosanitary measures.
 - 7) ***Organisation for Economic Cooperation and Development, OECD*** – the OECD guidelines regarding biosafety assessment of transgenic organisms (OECD, 2010) is one of the important international documents on biosafety.
 - 8) ***United Nations Environment Programme, UNEP*** – The *International Technical Guidelines for Safety in Biotechnology*, adopted in 1995 (UNEP, 1995), and intended as a contribution to the 'Agenda 21'. Namely, during the 'Earth Summit', the 'Agenda 21' was promoted as a sustainable development programme for the 21st century, which covers all the aspects of modern science, including biotechnology.

6.2. GMO legislation in the EU

The EU legislation on GMOs has been developed since the early 1990s. This specific regulations have two main objectives:

- 1) to protect human health and the environment, and
- 2) to ensure free movement of safe and healthy genetically modified products in the EU.

Today, the EU legislation on GMOs is rather complex and composed of several different directives, regulations, decisions and recommendations, such as:

- Directive 98/81/EC of 26 October 1998, amending Directive 90/219/EEC, *on the contained use of genetically modified organisms*. This Directive regulates research and the industrial framework of activities, including GMOs (e.g. genetically modified viruses or bacteria) in closed environments where there is no contact with the population and the environment. This includes activities in laboratories or other closed systems.
- Directive 2001/18/EC of 12 March 2001 on the *deliberate release into the environment of genetically modified organisms*, which is being applied to two type of activities:
 - 1) Experimental release of genetically modified organisms into the environment, i.e. GMO release into the environment for experimental purposes (for example, for field testing) is regulated by part B of the Directive;
 - 2) Placing on the GMO market (GMO is defined as a product which contains GMO or is derived from them), e.g. transformation of GMOs into industrial products, is predominantly regulated by part C of the Directive;
- Regulation (EC) No 1829/2003 of 22 September 2003 on *placing on the market of GM food and feed, or food and feed containing, consisting of or derived from GMOs*.
- Regulation (EC) No 1830/2003 of 22 September 2003 concerning the *traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs*, amending the Directive 2001/18/EC.
- Regulation (EC) No 1946/2003 of 15 July 2003 on *transboundary movements of GMOs*, which regulates the intentional and unintentional movement of GMOs between EU countries and third countries, excluding intentional movements within the EU.

- Regulation (EC) No 65/2004 of 14 January 2004 establishing a *system for the development and assignment of unique identifiers for GMOs*.
- Commission Decision 2004/204/EC of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on GMOs, provided for in Directive 2001/18/EC of the European Parliament and the Council of the EU.
- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and the Council of EU as regards the *authorization of new genetically modified food and feed, labelling of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk assessment*.
- Regulation (EC) No 882/2004 of 29 April 2004 *on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules*.
- Commission Recommendation 2004/787/EC of 4 October 2004 on *technical guidelines for sampling and detection of GMOs and GM products*, or products in the context of Regulation (EC) No 1830/2003.
- Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) 1829/2003 of the European Parliament and of the Council of EU as *regards the reference laboratories for genetically modified organisms in EU countries*.
- Regulation (EC) No 298/2008 of 11 March 2008 amending Regulation (EC) No 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred to the Commission.
- Directive 2009/41/EC of 6 May 2009 on the *contained use of genetically modified organisms*.
- Implementing Regulation of the Commission (EU) No 503/2013 of 3 April 2013 on *applications for authorisation of genetically modified food and feed* in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of EU, and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006.

- Directive (EU) 2015/412 of 11 March 2015 amending Directive 2001/18/EC *as regards the possibility for the Members States to restrict or prohibit the cultivation of genetically modified organisms on their territory*. Under this Directive, in accordance with the principle of subsidiarity, the member states will have more flexibility to decide whether or not they wish to cultivate genetically modified organisms on their territory without affecting the risk assessment provided in the system of the EU authorisations of GMOs, either in the course of the authorisation procedure or thereafter. In other words, member states will have flexibility to decide whether or not to cultivate GMOs in all or in part of their territory, and will have the freedom of choice of consumers, farmers, companies and all other stakeholders involved in the cultivation of GMOs. The member states which want to restrict or prohibit the cultivation of GMOs in all or part of their territory are obliged to inform thereof the European Commission by 1 October 2015 at the latest, and are required to harmonise their national legal frameworks as to define exemption of the geographical scope in the concerned Member State.

All the listed regulations create requirement which must be met by any company or scientific research institution before the development, use or placement of GMOs, or food products derived from GMOs on the market is authorised.

Unlike the USA legislation, which is based on the assumptions that biotechnology as a process itself does not bear any unique or special risk requiring food produced in this way to be treated under the same regulations as conventionally produced food, the EU legislation considers that food produced from genetically modified plants may bear a new risk which must be assessed and specifically regulated. This applies to direct risks, such as potential allergenicity or toxicity, but also to indirect long-term effects on the environment and consumers, which may not be anticipated today (*precautionary principle*). At the same time, GMOs or food products derived from GMOs (food and feed which contain or consist of GMOs) placed on the market must also meet the **labelling and traceability** criteria. These criteria are laid down in the Regulation (EC) No 1829/2003 and Regulation (EC) 1830/2003 as regards GMO traceability and labelling, as well as traceability of food and feed containing and/or consisting of and/or derived from GMOs, and the amended Directive 2001/18/EC (Trkulja *et al.*, 2014a).

6.3. GMO legislation in BiH

Pursuant to Article IV 4., a) of the Constitution of BiH, and following the proposal of the BiH Food Safety Agency (hereinafter: the Agency), the Parliamentary Assembly of Bosnia and Herzegovina, at its 44th session of the House of Representatives, held on 21 January 2009, and at the 25th session of the House of Peoples, held on 26 February 2009, adopted the **Law on Genetically Modified Organisms** (hereinafter: the Law on GMOs), published in the '**Official Gazette of BiH**', No 23/09. The Law on GMOs has been harmonised with all the applicable EU legislation governing this area, i.e. with all the regulations and directives adopted since 2009. The Law on GMOs stipulates a unique control system on GMO presence, from the farm to the table. The text below is a short overview of individual chapters in the Law on GMOs, with special focus on the practical aspects of this Law i.e. from the aspect of applicants and consumers, and all BH citizens.

6.4. Which principles has the Law on GMOs introduced to BiH?

The Law on GMOs has introduced the following principles:

- risk assessment principle;
- complex procedure of *mandatory registration* (authorisation) of a GMO prior its contained use, deliberate release into the environment and placement on the market;
- requirements for labelling and traceability of GMOs or products containing and/or derived from GMOs at all levels of placement on the market;
- requirements for post-market monitoring, also including long-term effects linked to the interaction with other GMOs and the environment;
- mandatory public communication;
- provision of information enabling identification and detection of GMOs in order to facilitate post-market inspection and control;
- authorization on specific GMOs limited to a maximum of ten years with the possibility for it to be revoked in case of any scientifically-based information on their adverse effects;
- mandatory approval of the Council for GMOs composed of experts from the relevant field to grant authorisation on a particular GMO, and

- mandatory consultations with the public regarding decisions on GMO authorization.

6.5. How does the Law on GMOs regulate the release of GMOs into the environment?

Under the Law on GMOs it is possible to apply for the release of a GMO into the environment for experimental purposes or for the purpose of its placement on the market.

Experimental release of a GMO into the environment is strictly regulated by this Law. It may be allowed for the purpose of research, demonstration or development of new GM plant varieties and hybrids, with strict restrictions necessary in order to limit the contact of GMOs and population or the environment, where the GMO behaviour in the environment and its interaction with other organisms and the environment is observed.

In case the results of the experimental release are positive, the company may decide to apply for **placement of the GMO on the market**, i.e. make it available to third parties with or without charging them. This is a later stage in the development and use of GMOs which includes for example a free-of-charge transfer of GMO between the commercial partners or the GMO advertizing. Thus, a GMO may be placed on the market for the purpose of *deliberate release into the environment or as a product used directly as food and/or feed or for processing and transformation into another product*. Placement of GMOs on the market is also strictly regulated by this Law.

6.6. How is the risk related to the release of GMOs into the environment assessed?

Risk assessment related to GMOs release into the environment entails an individual analysis of each GMO and its potential effect on the environment, stability in the environment and a potential effect it can have on biodiversity as well as on human health.

6.7. Concerns related to GMOs release into the environment

The main concerns related to the release of GMOs into the environment are:

- a) possibility for direct GMOs expansion in the environment;
- b) possibility of GMOs cross-breeding with associated species;

- c) possible adverse effects of GMOs on untargeted organisms, e.g. useful insects;
- d) possible long-term presence of modified genes in soil after harvesting GM crops;
- e) potential adverse effects of GMOs on biodiversity;
- f) unknown changes due to potential instability of genetic modification, and
- g) possible increased use of protective chemicals

As a result of the aforementioned, present scientific research is particularly focused on the potential adverse effects of introduced GMOs into the environment on useful insects or on the faster appearance of resistant insects, on the potential creation of new plant pathogens, on the transfer of genes which confer tolerance to total herbicides to other plants, appearance of weed tolerant to total herbicides, reduced use of crop rotation in specific local situations, potential adverse effects of a specific GMO on biodiversity, and other similar practical issues.

6.8. Correct labelling of products that contain, consist of or derived from GMOs

In addition to traceability requirements, the Law on GMOs in BiH introduces mandatory labelling of products which contain, consist of or derived from GMOs. The main objective of introducing mandatory labelling is to provide information to consumers and users about the product, so they can protect their fundamental ‘right to choose’ i.e. *they will be able to decide whether or not to buy and consume food containing GMOs.*

Thus, according to the new Law on GMOs, for all products containing or derived from approved GMOs, the food businesses must ensure the following:

- a) the product's package has to bear the following text on the label (declaration): ‘This product contains components of genetically modified organisms’, or ‘This product contains genetically modified (name of the organism)’;
- b) unpacked products offered to the end user have to bear the following text on the label: ‘This product contains genetically modified organisms’, or ‘This product contains genetically modified (name of the organism)’, either on the product itself or immediately next to it;

The same traceability and labelling requirements refer to feed (including various types of concentrated feed containing GM soybean) in order to provide farmers precise information on feed content and properties.

6.9. *Exceptions to the requirements for labelling of products containing, consisting of or derived from GMOs*

Conventional products, i.e. products without genetic modifications, may be unintentionally contaminated by GMOs during harvesting, storing, transporting or processing. This does not apply to GMOs. In this regard, the Law on GMOs in BiH foresees a *tolerance threshold* above which conventional food and feed must be labelled as products containing, consisting of or produced from GMOs (Trkulja *et al.*, 2014a).

Thus, under the new Law on GMOs in BiH, conventional products ‘contaminated’ by GMOs (but only by GMOs previously approved) are not subject to mandatory traceability and labelling *if they contain traces of GMOs below the threshold of 0,9%*, provided the presence of such GMO traces is technically inevitable.

6.10. *Is it mandatory to label meat or milk obtained from animals bred with feed containing, consisting of or produced from GMOs as genetically modified?*

In accordance with the Law on GMOs in BiH, and the EU legislation governing this area (Regulation (EC) No 1829/2013), it is not mandatory to label products, such as meat, milk and eggs, obtained from animals fed with GM feed or treated with GM medicines.

6.11. *Are the labelling rules and regulations for products consisting of, containing or being produced from GMOs, as laid down in the Law on GMOs in BiH, in compliance with the international market rules and regulations?*

The labelling rules and regulations for products consisting of or containing GMOs, as laid down in the Law on GMOs in BiH, are fully harmonised with the relevant EU regulations. In addition to that, these rules consider the BiH commitment to international trade and the Cartagena Protocol on Biosafety, in particular the obligations of BiH importers and the obligation of potential BH exporters exporting such products to third countries. Therefore, the labelling rules for products consisting of, containing or produced from GMOs are fully harmonised

with the WTO regulations because they are: clear, transparent and non-discriminatory (Trkulja *et al.*, 2014a).

6.12. Have the standards for monitoring and control of production and the certification and labelling system for ‘non-GMO’ products been established in BiH?

Bosnia and Herzegovina has established standards for monitoring and control of production and the certification and labelling system for ‘non-GMO’ products. These standards may be applied to herbal products, animal products and derivatives, *with the purpose of ensuring the consumers the right to choose food and feed.*

The rules for GMO-free production, regarding all phases in the food chain, and the use of relevant terms for labelling, presenting and advertising are defined by the *Guidelines on GMO-free production and food labelling*. In addition to that, the control ‘non-GMO’ label compliance is carried out in line with the *Guidelines on Risk-Based Control of GMO-free Production Processes*.

For food to bear ‘non-GMO’ label, or any other label implying that, GMOs and products which contain, consist of or produced from GMOs cannot be used as food or additives in food processing.

Managers and/or companies which place food and/or feed on the market, in line with the Guidelines, must ensure relevant evidence of compliance with the Guidelines. This includes accompanying documentation on preparation, treatment, processing and mixing of food or feed which proves that all relevant requirements laid down in the Guidelines have been fulfilled. Control and compliance certification may be conducted only by certified bodies which duly authorized in line with the ISO 17065 standard.

7

CHAPTER

GENETICALLY MODIFIED ORGANISMS – *Future Trends* –

7.1. *Future trends in the area of genetically modified organisms*

Today, intensified activities are underway in further research and introduction of the so-called second and third generation of genetically modified plants with improved nutritional quality and new technological and other traits, such as postponed ripening of fruit, stress resistance and tolerance to drought, salinity and low land fertility. All these allow new approach and possibilities to overcome the well known restrictions of tropical agriculture, for the purpose of producing more food (Trkulja *et al.*, 2009, 2014a; Trkulja and Mihić Salapura, 2017). Furthermore, intensified research is being conducted on the potential for creating new transgene plants which would create food not only enriched with new nutrients but also used as medicine. According to Trkulja and Rajčević (2007), genetic engineering may also have the potential to ensure special capacity of tolerance or resistance to plant disease agents.

According to biotechnology advocates, the new approach to controlling plant pathogens has the potential to prevent losses in crops and reduce the use of pesticides, and it may be very useful for the agents of plant diseases which are difficult to suppress with the existing methods.

Taking into account the huge increase of land planted with GM plants, recorded in the world during the first 22-year period of their commercialization from 1996 to 2017, further increase of land planted with GM plants is yet expected in the years to come. It is clear that biotechnology offers major advantages for increasing the efficiency of biofuel production both in industrial and developing countries. Furthermore, biotechnology will be the main factor for the development of biofuel production in the future.

However, adherence to the good practices of plant cultivation such as crop rotation and management of resistance to insects and tolerance to herbicides will remain critical points for GM plants, just as during the first decade. In addition to that, the practice of good GM crop management must

continue, particularly in the southern countries which will be leaders in the development of GM crops in the next decade.

Introduction of biotechnological innovations in cattle breeding is becoming increasingly important topic, with the following main goals: increased milk and meat production, increased number of progeny, unlimited breeding of animals with targeted traits, increased animal resistance to diseases, exclusion of unwanted traits (e.g. horns), increased growth speed (e.g. salmon), production of medicines in milk, more efficient use of food, reduced meat fat, easier acclimatisation to conditions of cultivation, etc. Such goals can be reached with the help of a range of biotechnological methods, such as: artificial insemination, embryo transfer, cloning, hybridization and genetic modifications (Veladžić *et al.*, 2008; ISAAA, 2012).

However, there is still a number of issues regarding the use of genetically modified animals as it bears lot of risks, such as: effect on animal welfare, risks related to animal cloning, the use of the growth hormone, risk of crossing the line, nature response to reduced diversity, a prion disease (mad cow disease) and others (Veladžić *et al.*, 2008). Thus, the use of genetically modified animals has not been put into practice yet.

Taking into account the aforementioned, it seems that in the period ahead us, when we are witnessing impressive and seemingly unlimited scientific possibilities, we must now, more than ever, engage in discussion about the ethics of such dramatic changes. Namely, it seems that in the coming period social and ethical justice must lead us in the fulfilment of our objectives to ensure sufficient food and energy, safe and healthy food, protection of the environment and biosafety, as well as overall welfare of humanity. In doing so, *there must be no monopoly on genes*, i.e. the most fundamental public good must remain a public good (Diouf, 2003).

7.2. *Instead of a Conclusion*

In the period ahead us, when the agriculture is at another historical turning point, foreshadowing significant and exciting possibilities for launching a new, green revolution, it seems that transparent, precise and objective assessment of GMO technology-related advantages and potential risks must be available to the public. At the same time, the ethical responsibility of scientists must be more pronounced, while communication on their findings must be clear and understandable to laymen. Thus, scientists and different scientific associations must have the most important role in terms of educating the public on GMOs technology

and its potential adverse effects, and ensuring that the control of this technology *is strict and of high-quality*. (Trkulja et al., 2005). Both for the scientists and the entire humanity, it is a big challenge which requires more thorough, transparent and engaged research including allocation of decision making and profit in a completely new way. This huge challenge requires us to follow, develop and link the areas of knowledge and connections where science, ethics, health and food safety meet (Trkulja et al., 2008).

Finally, we consider it useful to remind ourselves of a quote from the Convention on Biodiversity and the UN Environment Programme (CDB and UNEP, 2003), stating the following: ‘Since biotechnology is such a revolutionary science that has created a powerful industry, it has a huge potential to reshape the world around us. And, in doing so, it has been changing agriculture and what most of us have been consuming. However, any bigger mistake may lead to tragic and even permanent changes in the environment. Therefore, *our future generations will definitely look back at our time and will either thank us or curse us for what we have been or not been doing in relation to GMOs and biosafety*’ (Trkulja et al., 2014a).

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APPENDIX I

Council for Genetically Modified Organisms

Pursuant to Article 55 and 56 of the Law on GMO ('Official Gazette of BiH', No. 23/09), the Council of Ministers of Bosnia and Herzegovina, at the proposal of the Agency, at its 99th session held on 24 September 2009, adopted a **Decision on the Appointment of Members of the Council for Genetically Modified Organisms** (hereinafter: the Council for GMOs), which was published in the '**Official Gazette of BiH**', No. 92/09 of 30 October 2009. This Decision appoints the members of the GMO Council, its tasks and responsibilities, manner of work, requirements for work, fees and its duly reporting to the Agency on the annual work. The Agency then informs the BiH Council of Ministers accordingly. The appointed GMO Council members are:

- prof. Vojislav Trkulja, PhD;
- prof. Rifet Terzić, PhD;
- prof. Ivan Ostojić, PhD;
- prof. Kasim Bajrović, PhD;
- prof. Dalibor Ballian, PhD;
- prof. Stojko Vidović, PhD;
- prof. Đemo Subašić, PhD.

The first constituent session of the Council was held on 22 October 2009 in the premises of the BiH Food Safety Agency in Mostar. Apart from the appointed members of the Council, the session was attended by representatives of the BiH Food Safety Agency, led by its Director prof. Sejad Mačkić, PhD.

At the constituent session, the Council's Rules of Procedure were adopted, precisely and comprehensively prepared in line with the Law on GMOs ("Official Gazette of BiH", No. 23/09).

Prof. Vojislav Trkulja, PhD, was elected President of the Council, prof. Rifet Terzić, PhD, was elected as his first deputy, while prof. Ivan Ostojić, PhD as his second deputy.

All present members at the first session of the Council for GMOs agreed that it is an important day for the development and advancement of science in general, food safety and other issues yet to be opened and answered across BiH. At the same time, it is an important day for the country of Bosnia and Herzegovina on its road to EU and global integrations.

The mandate of the Council's members terminated in October 2013, but they continued working in a technical mandate until 6 August 2015.

Pursuant to Article 55 and 56 of the Law on GMOs ("Official Gazette of BiH", No. 23/09), the Council of Ministers of Bosnia and Herzegovina, at the proposal of the Agency, at its 17th session held on 30 July 2015, adopted a **Decision on the Appointment of Members of the Council for Genetically Modified Organisms**, which was published in the '**Official Gazette of BiH**', No. 67/15 of 25 August 2015. The appointed members of the Council are:

- prof. Vojislav Trkulja, PhD
- prof. Rifet Terzić, PhD
- prof. Ivan Ostojić, PhD
- prof. Faruk Čaklović, PhD
- prof. Dalibor Ballian, PhD
- prof. Stojko Vidović, PhD
- prof. Ahmed Džubur, PhD

The constituent session of the Council was held on 6 August 2015 in the premises of the BiH Food Safety Agency in Mostar. Apart from the appointed members of the Council, the session was attended by representatives of the BiH Food Safety Agency. Professor Vojislav Trkulja, PhD, was elected President of the Council, prof. Rifet Terzić, PhD, was elected as his first deputy, while prof. Ivan Ostojić, PhD as his second deputy.

By-laws

In cooperation with the Council for GMOs, the BiH Food Safety Agency has prepared a set of Rulebooks which were adopted by the Council of Ministers of BiH after passing the required drafting procedure. The following Rulebooks are published in the Official Gazette of BiH:

- Rulebook on the form and manner of keeping a unique register of genetically modified organisms ('Official Gazette of BiH', No. 17/12);
- Rulebook on the establishment of a system for the development and assignment of unique codes for genetically modified organisms ('Official Gazette of BiH', No. 68/12);
- Rulebook on the conditions and procedure for granting authorization for placing genetically modified food and feed for the first time on the BiH market, and on the requirements regarding

their traceability and labelling ('Official Gazette of BiH', No. 78/12 and 62/15);

- Rulebook on the content of the notification and the technical dossier for placing on the market, labelling and packaging requirements for genetically modified organisms or products containing and/or consisting of or deriving from GMOs ('Official Gazette of BiH', No. 78/12);
- Rulebook on the content and scope of risk assessment for placing on the market genetically modified organisms or products containing and/or consisting of or deriving from GMOs, and methodologies for making risk assessment ('Official Gazette of BiH', No. 79/12);
- Rulebook on the conditions of monitoring the environmental impact of genetically modified organisms or products containing and/or consisting of or deriving from GMOs, and their usage ('Official Gazette of BiH', No. 64/14);
- Rulebook on the procedure of assessment and authorization of laboratories for testing, control and monitoring of genetically modified organisms and products containing and/or consisting of or deriving from GMOs ('Official Gazette of BiH', No. 73/17).

These Rulebooks, among other issues, define the procedure for submitting applications for placing on the market genetically modified food and feed as well as the procedure for granting relevant approvals, taking thereby into account the opinions of the Council for GMOs, all valid regulations and other facts important for granting such approvals.

The overall process of granting approvals for placing GMO food and feed on the market will be carried out under strict control and transparency measures as well as under constant supervision by the Council for GMOs.

Protocol of Cooperation

On 20 April 2011, the **Protocol of Cooperation for Development of Authorized Testing Laboratories for Genetically Modified Organisms (GMOs) in BiH** was signed between the BiH Food Safety Agency and the Rome-based Italian Institute ‘Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscan’ (IZSLT), which incorporates the Reference Laboratory for GMO.

According to this Protocol, IZSLT will provide support to Bosnia and Herzegovina in setting up reference laboratories in BiH and will serve as confirmatory laboratory for GMO analysis, when needed. IZSLT will also provide training for decision makers, inspectors and laboratory staff, a short-term mission of a member state laboratory expert in a GMO laboratory in BiH, support in the preparation of BiH authorized official laboratories for participation to comparative testing schemes and support in drafting national control plans for GMOs. The Protocol ensures that the Institute, as EU reference laboratory for genetically modified organisms (GMOs), serves as a reference/confirmatory laboratory for BiH until one of its laboratories reaches the required reference level.

All the agreed activities will be realised through the World Bank ARDP project via three terms of reference which cover most of the necessary trainings for all stakeholders in the GMO control system in BiH, as defined in Article 3 of the Law on GMOs ('Official Gazette of BiH', No. 23/09) and also include the necessary trainings for experts in the four authorized testing laboratories in BiH.

The Council of Ministers of BiH, at its 155th session held on 13 July 2011, **considered and adopted the Agency's Report on the signed Protocol of Cooperation** for the development of authorized testing laboratories for genetically modified organisms and activities on the establishment of a control system for genetically modified organisms in food and feed in BiH.

APPENDIX 2

Authorized testing laboratories for GMOs control in BiH

Based on the Rulebook on the procedure of assessment and authorization of laboratories for testing, control and monitoring of genetically modified organisms and products containing and/or consisting of or deriving from GMOs ('Official Gazette of BiH', No. 73/17), the competent FBiH Ministry of Agriculture and the RS Ministry of Agriculture, and the Department for Agriculture of the Brčko District BiH are carrying out a procedure and issue decisions on authorization of GMOs laboratories. The BiH Food Safety Agency keeps a Unique list of laboratories in BiH for testing, control and monitoring of genetically modified organisms and products containing and/or consisting of or deriving from GMOs, which is being published in the Official Gazette of BiH and the Agency's official web page www.fsa.gov.ba.

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