European Economic and Social Committee

NAT/513
GMOs in the EU
(additional opinion)

Brussels, 18 January 2012

OPINION

of the
European Economic and Social Committee
on
GMOs in the EU
(additional opinion)

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Rapporteur: **Martin Siecker**

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On 16 March 2011, the European Economic and Social Committee, acting under Rule 29A of the Implementing Provisions of its Rules of Procedure, decided to draw up an additional opinion on

GMOs in the EU
(additional opinion).

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 21 December 2011.

At its 477th plenary session, held on 18 and 19 January 2012 (meeting of 18 January 2012), the European Economic and Social Committee adopted the following opinion by 160 votes to 52 with 25 abstentions.

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1. Genetically modified organisms in the EU – orientation for future debate

1.1 Genetically modified organisms (GMOs) are a thorny issue. Genetic modification (GM) is a subject that arouses much interest, and much concern. The debate is often emotional and polarised: even where there is rational discussion, both supporters and opponents tend to be selective with the truth and neglect nuance in their arguments. Moreover, as well as differences of opinion over the pros and cons of GM, many ambiguities and assumptions seem to exist - even within the EESC - about matters such as the type and degree of legal regulation of GMOs in the EU. This is regrettable, since this important and politically sensitive subject merits a better quality debate.

1.2 The current EU legal framework for GMOs is undergoing change. In this context, the EESC will soon be giving its views on GM policy and legislation more often. As an orientation and preparation for this future debate, the present opinion provides a basic outline of the current situation and the discussion about GMOs, as well as their regulation in the EU. Various issues are involved here, including ethical, ecological, technological, (socio-)economic, legal and policy questions. All of these, which are raised by the almost limitless possibilities of GM and the rapid development of GM applications, must be considered in a broad societal context. This opinion aims to provide a roadmap for a balanced and pertinent political discussion of these important questions.

1.3 This opinion only highlights the main points of the discussion and mentions just a few of the most significant dilemmas surrounding GMOs and their regulation in the EU. More detailed (exploratory) opinions will be needed from the EESC on many of these issues, and it intends to conduct these studies during the coming period. Priority areas include the evaluation of the EU's current GMO legislation, its possible revision, and filling the regulatory gaps identified

in this opinion. The EESC commits to issuing follow-up opinions on these important dossiers in the near future.

2. History of genetic modification

2.1 Opinions diverge even over the history of GM. Whereas critics talk about a fundamentally novel technology involving uncertain risks and ethical issues, advocates position GM along a continuum of centuries-old plantbreeding traditions and biological processes using yeast, bacteria and fungi. However, the objective facts indicate that GM is something fundamentally novel and different from these historical applications. The definitive watershed between "old" and "modern" biotechnology is marked by the introduction of genetics. Watson and Crick's discovery in 1953 of the double-helix structure of DNA revealed the genetic code of humans and all the flora and fauna around us, enabling scientists to conduct revolutionary manipulation at the genetic level, in the very building blocks of life.

2.2 GM technique was created in 1973 when US scientists conducted the first successful recombinant-DNA (rDNA) experiments on bacteria. By being able to identify, isolate and replicate specific genes and introduce them into another living organism, scientists were for the first time able to make specific changes to the hereditary genetic properties of organisms in a way that is not possible in nature through reproduction and/or natural recombination. In traditional (cross-)-breeding, whole genomes (of a species) were crossed to then try to retain the favourable properties through reverse selection. While GM allows more precise manipulation, introducing genes into another organism (or species) is an unstable and uncertain process, with secondary effects and consequences for the recipient genome and interactions with the natural environment that are difficult to predict. The long-term effects in particular are still largely unknown.

2.3 After 1975, GM technology developed apace. The first commercial (medical) GM products were available as early as 1982. This was followed in the early 1990s by "transgenic" plants and animals. Over the years, interspecies boundaries have also been crossed. For instance, a pig gene has been introduced into a tomato species, a firefly gene into a tobacco plant, and a human gene into a bull. The crossing of interspecies boundaries, unpredictability of long-term effects and irreversibility of potential (environmental) consequences make GM a fundamentally novel, potentially risky technology. This therefore forms the basis for GMO regulation in the EU and its Member States, in many non-EU countries and in international treaties.

3. Relevant sectors and societal reception of GMOs

3.1 The main sectors for GM applications are: agriculture and food (mainly pesticide resistance), the medical and pharmaceuticals sector (medicines, genetic diagnostics, gene therapies) and the (petro-)chemicals and weapons industries. These sectors are also often respectively called "green", "red" and "white" biotechnology.

3.2 GM is not equally controversial in all these sectors. The concerns and reservations of policy-makers and the general public seem to be prompted more by particular applications than by GM technology per se. Medical applications are received in the main positively, and criticism focuses mainly on agricultural- and food applications. An important aspect of this debate is the balance between utility and need on the one hand and possible risks and reservations on the other. Thus many people see GM as making an important and promising contribution to curing serious human illnesses, whereas the consumer benefits of (current generation) agricultural- and food GMOs are much less evident (to date purely agronomic properties with producer advantages). The safety requirements and clinical studies that precede authorisation of medical applications have always been stricter and more exhaustive than procedures prior to the introduction of GMOs into the environment or food.

3.3 It is also important, from both a societal and a regulatory point of view, to distinguish between GM that takes place in closed, isolated spaces such as laboratories, factories and greenhouses, where containment and safety measures can prevent accidental release of GMOs, and applications in which GM plants or animals are released into the environment with no possibility of containment, as living organisms that can replicate, spread and proliferate in an uncontrolled and irreversible way in the biosphere, with unpredictable effects on and interactions with biodiversity.

3.4 In the case of plants introduced into an open environment, however, a distinction must be made between two different situations: firstly when cross-breeding between a cultivated plant species and a wild plant species is possible because the two are in close proximity, and secondly when cross-breeding is impossible owing to the absence in the environment of wild species close to the GM plant. This distinction must be incorporated into the regulatory framework governing the introduction of GM plants into an open field.

3.5 This is not by definition a distinction between "red" and "green" biotechnology: fundamental scientific research can also be conducted safely and innovatively in isolated laboratories in the agricultural- and food sectors, in the same way as has long been accepted in medical biotechnology. GM enzymes are also widely used in food production in isolated environments without remaining present as living organisms in the end product or being released into the environment. The distinction between contained use and release into the environment, and the distinction between basic scientific research and commercial applications, are key aspects of the policy debate and of public perception of and the consumer response to GMOs.

3.6 Many opinion surveys including Eurobarometer[1], and academic literature, consistently show that an increasing majority of the EU population feels sceptical, if not hostile, to GMOs - particularly in the food, animal feed and agriculture sectors. Diverging views and policies on GMOs are also espoused by Member State governments. On the one side are staunch opponents such as Austria, Hungary, Italy, Greece, Poland and Latvia; on the other are

1 The most recent of these is "Europeans and Biotechnology in 2010": http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf.

declared advocates such as the Netherlands, the UK, Sweden, Spain, Portugal and the Czech Republic. There are also many Member States that decline to take a position.

3.7 This dividedness has resulted in a contentious and protracted decision-making process for GMOs. Authorisations are generally granted unilaterally by the Commission, owing to the inability of the Member States to decide on GMO approvals by qualified majority through the comitology procedure. Although there was a de facto moratorium on GM approvals between 1999 and 2004, it proved impossible to use that period to have a fundamental discussion leading towards a more consensus-based approach to GMOs in the EU. The number of Member States that have banned cultivation of GMOs on their territory has risen in the past years. The latest Commission proposal for more latitude in (sub)national decision-making to prohibit GM crops has received much criticism from Member States, the EP, various civil society organisations and industry, and in a recent EESC opinion[2]. It is unsatisfactory, from all perspectives, that a political impasse looms over an issue as important as GMOs.

3.8 Various civil society organisations and stakeholders voice concerns about GMOs in connection with the environment, animal welfare, consumer interests, farming, beekeeping, rural and global development, ethics, religion, etc. The EP has also often expressed critical views about GMOs and their regulation, as has the EESC, and national, regional and local authorities, and independent scientists. The main advocates are large companies with GM patents and other stakeholders including certain GM farmers and scientists and international trading partners with a strong economic interest in more flexible regulation of GMOs in the EU. Some of the main claimed advantages of GMOs are discussed in chapter 5.

3.9 Outside the EU, there is also widespread (political and social) resistance to GMOs in food and the environment, notably in countries such as Japan, Switzerland, Korea, New Zealand, Mexico, the Philippines and various African countries. Yet, in some countries GMOs are cultivated widely: in 2010, GMO crops were cultivated by more than 15 million farmers on around 150 million hectars of land (mainly soya, maize, cotton). However, it should be noted that 90 % of the total hectarage was cultivated in only 5 countries: in the USA, Canada, Argentina, Brazil and India. Despite this uptake, GMOs are not uncontroversial in these countries. In fact public criticism seems to have been growing recently, owing largely to incidents involving unintentional spread of GMO crops such as maize and rice and judicial rulings on coexistence. It is important to note that these countries do not have mandatory labelling, meaning that consumers are unaware of the presence of GMOs and thus cannot make informed choices.

4. Economic interests, intellectual property and market concentration

4.1 The potential financial interests for GMOs in the plant-breeding sector are considerable. Annual global sales of seeds have now reached over EUR 35 billion, forming the basis for an even bigger product market, with a turnover of hundreds of billions of euros.

2 CESE 385/2010, OJ C 54, 19.2.2011, p. 51.

4.2 GM technology and commercialisation have developed at a dizzying pace, with significant implications for the constellation of the sector. For more than half a century, intellectual property in relation to plant breeding has been governed by the "plant variety rights" laid down in international agreements. One exception to this temporary exclusive right held by developers of new varieties is the "breeders' exemption". This allows other operators to use protected varieties in order to develop new, further improved varieties without the permission of the original rights-holder. This exemption is unique to the sector, based on the realisation that new varieties cannot be created out of nothing.

4.3 Developments in molecular biology, which originated outside the agricultural sector, led to patent rights being introduced in the plant-breeding sector. Patent rights and plant variety rights conflict with each other for a number of reasons. The first is that patent law does not recognise a breeders' exemption. This means that the patent-holder can lay an exclusive claim to genetic material and so prevent others from using that material or require them to pay for expensive licences. Unlike plant variety rights, patent rights do not produce open innovation or combine economic incentives for innovation, with protection of other public interests.

4.4 But the struggle for rights in this area goes even further. The 1998 EU Biotech Patents Directive[3] authorises patent protection for plant-related inventions. Plant genes or gene sequences can be patented, but not plant varieties. This interpretation is not undisputed. Leading multinationals in plant-breeding claim that if genetic characteristics are patentable then the varieties concerned are themselves covered indirectly by patent law[4]. If this is the case, then varieties covered by a patent may no longer be used by others for further innovation. This is detrimental to agricultural biodiversity and means that plants with interesting properties are not available for further innovation by others. Developments in medical biotechnology demonstrate the potential negative implications: rigid defence of patents and high prices result in new products only being sold to people who can afford them, and not being available to the disadvantaged people who need them most. The same undesirable effects might occur in the plant-breeding sector.

4.5 The past few decades have seen extreme market concentration in the plant-breeding sector, mainly as a result of patent protection and regulatory requirements. Whereas hundreds of businesses were operating previously, the global market is now dominated by only a handful of major players. In 2009, only ten corporations controlled nearly 80% of the global seeds market, and the biggest three even 50%. The same multinationals also controlled about 75% of the global agro-chemicals industry. These are no longer companies that are involved only in plant-breeding, but global corporations that are also active in the food, pesticide, chemicals, energy and pharmaceuticals sectors. Also, they often produce tied products, such as GM plants that have been made resistant to a specific pesticide sold by the same company. This consolidation means that a select group of multinationals have extensive control over the

3 Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, p. 13).

4 Cf. Case C-428/08, Monsanto Technology.

whole production chain for food and related products, which may undermine consumer choice, affordability, open innovation and genetic diversity. This degree of market concentration and monopoly is by any means undesirable, particularly in key sectors like agriculture and food production, and merits priority attention from the EESC and the EU.

5. Other issues surrounding GMOs

5.1 There are many different issues surrounding GMOs. Opinions about pros and cons are very divergent, and the debate is highly polarised and emotionally charged. This opinion is too short to explore the debate in detail, but a number of key points merit attention. Arguments that are often advanced in favour of GM include the fight against hunger and supplying food to the fast-growing world population, as well as climate change. There is a great need for independent scientific research in all these areas, and the EESC stresses the importance of (continuing) EU structural funding for such research, not only to promote scientific and commercial innovation but also to study socio-economic, environmental and other impacts of technological advances.

5.2 GM plants will never be able to solve problems relating to hunger and poverty. Simply increasing productivity will not necessarily lead to improved food distribution. Unfortunately, in order to tackle the serious problem of food security effectively, it is essential to improve access to land, promote a fairer distribution of wealth, bolster the sustainability of trade agreements and reduce volatility in commodity prices. Although biotechnology is certainly no panacea, the FAO has indicated in its recent reports that biotechnology offers important agricultural and economic benefits for farmers from third countries, mainly smallholder farmers. However, from the very inception of GM technology its advocates have suggested that GM plants are essential to combat global problems of hunger and poverty. Predictions were made that plants fortified with vitamins or nutrients would help mitigate hunger and disease in the third world. Potential properties such as tolerance for drought, salt, frost or other stress factors would make it possible to cultivate crops in areas where they could not previously be grown. Larger yields were also predicted. However, despite decades of promising suggestions, to date none of these output properties of crops have been commercially developed. The financial incentive for developing such crops is also limited, given that their benefits are intended for the most disadvantaged and vulnerable groups of the world population. Even if future generations of GMOs fulfil the promise of higher yields and better stress tolerance, this does not provide a solution to world hunger since most farmland in developing countries is used to produce luxury export goods for the rich world. In addition, the vast majority of GM crops that are now on the market are used for animal feed to support our western consumption of meat and dairy products (90% of EU soy imports), or for biofuels and plastics. As a result of the increasing use of food crops for non-food uses, global commodity and food prices have been driven up, thereby only exacerbating global food insecurity and poverty[5].

5 As was raised in the Hearing on *"The Agricultural biotechnology: genetically modified food and feed in the EU"*, EESC, Brussels, 20 October 2011.

5.3 Thus, the global food crisis is a problem of distribution rather than production (global production is equivalent to over 150% of global consumption), and therefore requires a political and economic solution more than agricultural innovation. The EESC recognises that global food security will become further strained by rapid population growth. International organisations like the UN Food and Agriculture Organisation (FAO), major NGOs such as Oxfam, and the recent report of the authoritative UN agri-science body, the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) panel, all point to the importance of sustainable agriculture as a solution to the problem of food security and sovereignty. These authoritative assessments stress the need for sustainable and ecological agricultural practices and techniques, and do not necessarily foresee a role for GMOs but rather for alternative techniques. The most prominent example of such alternative techniques cited by the IAASTD and others is marker-assisted selection, which uses genetic markers to specifically and efficiently select traits, but does not involve any risky or unpredictable genetic manipulation or transfer of genes. Since this technology is demonstrably effective and less expensive than GM, it could provide an uncontroversial alternative to GMOs, while the lower cost may create fewer patent and market concentration issues. Although the future potential of GMOs should not be excluded, a deliberate decision to develop non-GM techniques and sustainable farming practices could give the EU a considerable competitive edge where it does not have one in the GM context. Investing intensively in sustainable agriculture could give the EU a unique and innovation-driven leadership position worldwide, with positive effects for the economy and employment, innovation and the competitive standing of the EU. Moreover, this would be more in line with the EU farming model, which has a positive impact on biodiversity and is envisaged in the future CAP.

5.4 Advocates of GM also see it as a potential tool in both adapting to and mitigating the effects of climate change. But here too, the current generation of commercialised GM crops does not offer any useful properties. In fact, one of the most high-profile applications, production of biofuels from GM crops, is already negatively impacting the global price and supply of raw materials and food, and still involves heavy dependence on fossil fuels.

5.5 That GMOs could potentially help in addressing global perils such as hunger, poverty, climate change and environmental problems should certainly not be ruled out, but the reality is that the current generation of GMOs is not suited or designed for this purpose. Their properties are to date limited to "input" benefits for producers, such as pesticide resistance. It is a matter of (scientific) contention whether such crops have led to less, rather than more, use of pesticides, but the contribution of GMOs does not appear to have been indubitably positive. Studies are accumulating that reveal their longer-term effects, which include an increase in intensive monoculture, development of pesticide resistance, contamination of groundwater, serious reduction of local biodiversity, and risks to human health caused by long-term exposure to certain pesticides used in conjunction with GMOs. Although some of these effects may be attributable to poor farming practices per se, since the current generation GMOs are sold as

tied package products with the pesticides on which they depend, these products and their environmental and societal impacts must equally be assessed in conjunction[6].

5.6 Another major issue with GM is the choices available to consumers and farmers. This concerns both EU and non-EU countries. In the developing world, the high price of patented seed, together with exclusive purchasing obligations and banning of the traditional practice of saving seeds from previous seasons, create major socio-economic and cultural dilemmas for farmers, in particular poor smallholder farmers. In countries where GMO cultivation is prevalent, notably the USA, Canada, Argentina and Brazil, crop diversity has drastically declined. Globally, nearly 80% of all soya produced is GM, in addition to 50% of cotton, over 25% of maize, and over 20% of canola. In the EU, consumer and farmer choice is supposed to be safeguarded by labelling requirements. However, maintaining this freedom of choice both for farmers and consumers requires complete and reliable segregation of the GM and non-GM production chains. One important aspect for this segregation is the introduction of stringent co-existence legislation, including effective liability and redress rules for environmental and/or economic loss resulting from unintentional contamination, product chain certification and segregation schemes, as well as purity and labelling requirements for the presence of GM material in non-GM seed and derived products.

6. Legislation and policy review

6.1 Since 1990 the EU has developed a detailed legislative framework for GMOs, which just like the technology itself, is constantly evolving, having undergone many revisions. This has resulted in a complex patchwork of directives and regulations, the most relevant being:

- Directive 2001/18/EC on the deliberate release into the environment of GMOs[7];
- Regulation (EC) No 1829/2003 on GM food and feed[8];
- Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs[9];
- Regulation (EC) No 1946/2003 on transboundary movements of GMOs (implementation of the international Cartagena Protocol on Biosafety to the Convention on Biological Diversity)[10];
- Directive 2009/41/EC on the contained use of GM micro-organisms[11].

6.2 The current rules for approval and use of GMOs are based on a series of (legal) principles, namely:

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6 See footnote 5.

7 OJ L 106, 17.4.2001, p. 1.

8 OJ L 268, 18.10.2003, p. 1.

9 OJ L 268, 18.10.2003, p. 24.

10 OJ L 287, 5.11.2003, p. 1.

11 OJ L 125, 21.5.2009, p. 75.

- independent, scientifically founded approval before introduction;
- a high level of protection of human, animal and environmental health and well-being, in accordance with the precautionary principle and the polluter pays principle;
- freedom of choice and transparency along the whole food chain, and protection of other consumer interests, for instance through public information and participation;
- consideration of the internal market and of international obligations;
- legal certainty;
- subsidiarity and proportionality.

6.3 However, some lacunae remain, with specific EU legislation or policy still lacking on important aspects related to GMO introduction, in particular the following:

- co-existence of GMO with organic and conventional agriculture;
- liability and redress rules for environmental and/or financial damage resulting from the release of GMOs or the unintentional contamination of organic or conventional products, and compensation schemes for costs incurred for coexistence and chain certification to prevent comingling;
- purity and labelling requirements for the presence of GMO material in non-GMO seed and propagating material;
- labelling requirements, particularly for meat and dairy products derived from animals fed with GMO animal feed, and harmonised standards for GMO-free labelling;
- general strengthening of GMO labelling requirements to safeguard consumer choice, including legal clarification of 'adventitious presence' and possible tightening of threshold values;
- rules on transgenic or cloned animals and (food) products derived from them, particularly with regard to approval and labelling;
- a robust legal right for the Member States and/or autonomous regions to apply a partial or full ban on GMO cultivation on various grounds, including environmental, socio-economic, ethical and other concerns.

6.4 Although the Commission put forward a legislative proposal in July 2010 to permit (sub)national limits or bans on GM cultivation, that proposal seems to have raised rather more questions than it has answered, mainly due to several legal ambiguities and contradictions in the text, and the exclusion of environmental problems among others as justification for restrictions. Whilst the basic idea of increasing (sub)national sovereignty on GMO cultivation has been widely supported, the currently flawed text of the proposal has prompted a critical first reading with major amendments by the EP, following a critical opinion from the EESC[12]. The Council is currently deliberating on the proposal, but has been unable to reach a common position to date. The EESC considers this to be a very important dossier, which deserves priority and certainly must be taken into account in any future revision of the general legal

12 See footnote 2.

framework for GMOs. The EESC urges the Commission to work actively, through constructive dialogue with the EP and the Council, to produce a robust legal basis for (sub)national decision-making about GM cultivation founded on legitimate justifications that include broad environmental, social and economic, ethical and cultural considerations. This should be accompanied by a legal obligation for Member States and/or regions to adopt binding co-existence rules to avoid unintended contamination between GM and non-GM crop zones.

6.5 The EESC has over the past years repeatedly called for EU legislation to be adopted on co-existence, liability and more comprehensive labelling for GM products[13]. Moreover, the importance of closing these remaining legislative gaps with a harmonised EU policy was recently reiterated by the EU Court of Justice, in a judgment of 6 September 2011 relating to the coexistence issue. In this case, where honey was unintentionally contaminated by pollen from GM maize, the Court confirmed that EU law applies absolute zero tolerance for such unauthorised GMO presence[14]. This judgment underlines the importance of having an effective, coherent and stringent co-existence and production chain segregation policy to prevent mixing of GMO with non-GMO products, together with appropriate liability and redress rules for damage and compensation for costs incurred by coexistence measures and supply chain certification, as well as the option to prohibit GMO cultivation in open fields by means of zoning in certain regions (e.g. for honey production).

6.6 Although the Commission's Recommendation on coexistence of July 2010 is more flexible than its previous Recommendation of 2003, the EESC stresses explicitly that neither Recommendation is legally binding; they cannot thus impose any enforceable limits on the broad national competence for coexistence policy, but neither do they impose the necessary legal obligations for coexistence standards. The forthcoming introduction of non-food GM crops alongside GM food crops - e.g. with pharmaceutical, biofuel or industrial applications – will even further increase the need for effective coexistence and liability legislation, and the EESC believes it is important to anticipate and address these issues now, at an early stage.

6.7 In December 2008, the Environment Council called for the current legal framework for GMOs to be reinforced and better applied. Improvements were deemed necessary above all in relation to: EFSA assessments of environmental risks and post-introduction control and monitoring protocols, with a greater role for external expertise from Member States and independent scientists; evaluation of the socio-economic impacts of introduction and cultivation of GMOs; labelling thresholds for notifying traces of GMO content in seeds; and better protection for sensitive and/or protected areas, including the option of establishing GM-free zones at local, regional or national level.

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13 See for example CESE 385/2010, OJ C 54, 19.2.2011, p. 51; CESE 1656/2004, OJ C 157, 28.6.2005, p. 155; CES 358/2002, OJ C 125, 27.5.2002, p. 69; and CES 694/2001, OJ C 221, 17.9.2002, p. 114.

14 Case C-442/2009, Bablok et al. v Freistaat Bayern and Monsanto.

6.8 Although the Commission has taken action in some of these areas, the Council's demands have still been insufficiently addressed by concrete results. The EESC underscores the importance of taking concrete, substantive steps to introduce appropriate legislation and policy on each of these points and the above-mentioned legislative lacunae as soon as possible. In relation to revising the risk assessment and risk management procedures and authorisations for GMOs, the EESC echoes the Council and Parliament in recommending that not just natural scientists but also social scientists, lawyers, ethicists and representatives of civil society interest groups should be involved, so that decision-making is informed not only by scientific evaluation of risks to humans and the environment, but also by 'other legitimate factors' including for example socio-economic, cultural and ethical considerations and societal values. This might also help to address the societal controversy about GMOs and the political impasse in decision-making.

6.9 An important project that is delayed is the evaluation of the current legal framework for GMOs and GM foods and animal feed, initiated by the Commission at the Council's request in 2008, the results of which were supposed to be presented at the beginning of this year. The Commission has promised the Council that by 2012 initiatives will be taken to review the legislation, and the EESC stresses the importance of this target being met. The above regulatory lacunae must in any event be addressed in this review. As a first step, the Commission must organise a comprehensive public consultation on the basis of the now published evaluation report[15], to ensure societal input in the review of the legislative framework. This will certainly help address public concern and may improve public trust in regulators.

6.10 One aspect that will inevitably be on the future agenda is the definition of GMOs. Although GM science and applications have evolved very rapidly over the past decades, the legal definition of GMOs has remained unchanged since the first EU legislation was adopted in 1990. That legislation defines a GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"[16]. However, certain GM techniques were explicitly excluded, and therefore exempted from the provisions of the legal framework governing GMOs.

6.11 Over the years, however, many new plant-breeding techniques have been developed that were not foreseen when the current legislative framework was laid down. One example is cisgenesis, in which genes are transferred between organisms of the same species, using recombinant DNA. The question arises for such new techniques of the extent to which they fall within the current definition of GM, and thus also the question of whether organisms obtained in this way are governed by the current legal framework for GMOs. In view of administrative burdens, not to mention the political and public stigma of GMOs, exemption

15 http://ec.europa.eu/food/food/biotechnology/index_en.htm.

16 Article 2(2) of Directive 2001/18/EC and Article 2(b) of Directive (2009/41/EC. An organism is defined as "any biological entity capable of replication or of transferring genetic material".

from this legislation is very important for the plant-breeding industry in financial terms. It will allow such innovations to be brought to market sooner, without the possibility of labelling requirements provoking negative reactions from consumers. However, the same ethical, ecological, socio-economic and political concerns arise with these techniques, as is the case with the current generation of GMOs, since they use essentially the same GM technology, while experience is still limited and uncertainty high.

6.12 To guarantee a uniform regulatory approach in all the Member States to these new plant-breeding techniques and the products resulting from them, in 2008 the Commission set up a scientific working group to be followed by a policy group to make recommendations about the legal approach. The reports of both working groups were supposed to be ready by the summer of 2011 and must be taken into account in the 2012 review of the legal framework. The EESC deems it essential to maintain the EU's current process-based regulatory approach, and hence that these new plant-breeding techniques should in principle be governed by the EU legal framework for GMOs on account of the (rDNA) GM technique used, even where the resulting plants or derivative end products as such are not perceptibly different from conventional equivalents.

Brussels, 18 January 2012.

The President
of the
European Economic and Social Committee

Staffan Nilsson

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N.B.: Appendix 1 overleaf.

APPENDIX I

to the Committee opinion

The following amendments, which received at least a quarter of the votes cast, were rejected during the discussion:

Point 3.8

Replace entire point:

~~*Various civil society organisations and stakeholders voice concerns about GMOs in connection with the environment, animal welfare, consumer interests, farming, beekeeping, rural and global development, ethics, religion, etc. The EP has also often expressed critical views about GMOs and their regulation, as has the EESC, and national, regional and local authorities, and independent scientists. The main advocates are large companies with GM patents and other stakeholders including certain GM farmers and scientists and international trading partners with a strong economic interest in more flexible regulation of GMOs in the EU. Some of the main claimed advantages of GMOs are discussed in chapter 5.*~~ *The supporters and opponents of biotechnology in farming are highly divided in this emotional and passionate debate, which from the scientific point of view, often lacks technical expertise. A large majority within the scientific community strongly argues that the use of GMOs in the production of foodstuffs presents no risk to human health; in fact, GMOs are present in our daily lives and are fully accepted in areas beyond the confines of agriculture. The European Commission's Joint Research Centre has pointed out on a number of occasions that the risks inherent in transgenic foodstuffs are certainly no greater than in organic or traditional products. Some sections of civil society, however, primarily environmental groups and consumer representatives, are raising legitimate concerns regarding the environment, co-existence among crops, ethics and the monopoly of the large multinationals, which require us to approach these issues objectively. The EESC has acknowledged that biotechnology is a key tool for meeting the food challenge*[17] *but has decided to further develop the debate on the pros and cons of biotechnology in the EU.*

Result of the vote

For	91
Against	122
Abstentions	19

[17] See the conclusions of the president, Mr Nilsson, at the EESC's conference entitled "Food for Everyone", held jointly with the European Commission as a contribution to the G20 summit on food security.

Point 5.3:

Replace entire point:

~~*Thus, the global food crisis is a problem of distribution rather than production (global production is equivalent to over 150% of global consumption), and therefore requires a political and economic solution more than agricultural innovation. The EESC recognises that global food security will become further strained by rapid population growth. International organisations like the UN Food and Agriculture Organisation (FAO), major NGOs such as Oxfam, and the recent report of the authoritative UN agri-science body, the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) panel, all point to the importance of sustainable agriculture as a solution to the problem of food security and sovereignty. These authoritative assessments stress the need for sustainable and ecological agricultural practices and techniques, and do not necessarily foresee a role for GMOs but rather for alternative techniques. The most prominent example of such alternative techniques cited by the IAASTD and others is marker-assisted selection, which uses genetic markers to specifically and efficiently select traits, but does not involve any risky or unpredictable genetic manipulation or transfer of genes. Since this technology is demonstrably effective and less expensive than GM, it could provide an uncontroversial alternative to GMOs, while the lower cost may create fewer patent and market concentration issues. Although the future potential of GMOs should not be excluded, a deliberate decision to develop non GM techniques and sustainable farming practices could give the EU a considerable competitive edge where it does not have one in the GM context. Investing intensively in sustainable agriculture could give the EU a unique and innovation-driven leadership position worldwide, with positive effects for the economy and employment, innovation and the competitive standing of the EU. Moreover, this would be more in line with the EU farming model, which has a positive impact on biodiversity and is envisaged in the future CAP.*~~ *As stated in earlier EESC opinions on agriculture and research, innovation, modernisation and new technologies in the agricultural sector should play a fundamental role with a view to the development of sustainable and more productive agriculture, managing natural resources such as water and the land in a more sustainable manner. Biotechnology can, in some cases, play a part in the fight against hunger but the European agricultural model must guarantee the co-existence of organic farming, conventional agriculture and GM agriculture. The FAO, G20, World Bank and the EESC itself have recognised that, in view of the drive to increase food security, research must be directed at the development of more drought-resistant varieties which give a higher yield, make better use of the land and consume less energy. It appears to be beyond doubt that GM can make a useful contribution to this.*

Result of the vote

For	83
Against	139
Abstentions	13