

THE CULTIVATION OF GMOS IN THE EUROPEAN FRAMEWORK AFTER THE 2015/412 DIRECTIVE

The regulation of transgenic crops (Genetically Modified Organisms GMOs) is of great significance for both farmers and consumers, and has also had relevant legal effects on the area of coexistence, that being so, in the past fifteen years, international rules, Community legislation and national regulations have succeeded each other with the aim to ensure coexistence of genetically modified crops with conventional and organic farming. And at the same time, strategies have been developed based on the principle of freedom: freedom to cultivate as a farmer's right and freedom of choice as a consumer's right, in order not to restrict any form of agriculture and therefore not to contravene economic policies, but increasing the obligations and responsibilities of the farmer¹, bearing a disproportionately heavy burden in comparison with companies that sell genetically modified seeds and with the Administration that authorizes, controls and monitors its use. Furthermore, from a consumer perspective, freedom of choice was based on the fulfillment of facilitating a truthful information under existing legislation, but that is not always adjusted to reality. Regarding States or regions, it depended on the era we focus on, as in the last ten years we have had from a moratorium to the admission of certain seeds for cultivation, linked to some surveillance and control systems that were connected with national regulations, as it happened in Spain, where some buffer zones were established (to isolate GM crops from others and to prevent possible contamination in ecological production systems).

In this context, The Protocol on Biosafety entered into force in the year 2003, as one of the most important international instruments of biodiversity due to its binding nature (but respecting States²) and due to the inner complexity of the subjects covered; where the potential adverse impacts were minimized avoiding damage resulting from transboundary movements of living modified organisms³, in relation to the conservation and sustainable use of biological diversity, and human health. We understand it did so,

¹ CAZORLA GONZÁLEZ, M.J.: "Obligaciones del agricultor de OGMs y su responsabilidad frente al medio ambiente y fincas colindantes". Págs. 89 y ss. En el libro HERRERA CAMPOS, R., y CAZORLA GONZÁLEZ, M.J. (Coordinadores y coautores), *Agricultura transgénica y medio ambiente: perspectiva legal*. Madrid: Reus, 2009.

² Article 2, paragraphs 3 and 4 of the Cartagena Protocol on Biosafety of the Convention on biological diversity. Section 3. The present Protocol shall not affect mode some to the sovereignty of States over their territorial sea established in accordance with international law, sovereign rights or jurisdiction of States over their exclusive economic zones and their continental in accordance with the international law of shelves, or the exercise by ships and aircraft of all States of the rights and freedoms of navigation established in international law and collected in the relevant international instruments. Section 4. No provision of this Protocol shall be interpreted in a sense that restricts the right of a party to adopt stricter measures to protect the conservation and sustainable use of biological diversity than those set out in the Protocol, provided that such measures are compatible with the objective and the provisions of this Protocol and comply with the other obligations of that party under international law.

³ MARTOS CALABRÚS, M.A.: "La problemática de la seguridad en los movimientos transfronterizos de OMV: Protocolo de Bioseguridad". En el libro coord. por HERRERA CAMPOS, R Y CAZORLA GONZÁLEZ, M.J.: "Agricultura transgénica y medio ambiente. Perspectiva legal". Ed. Reus. Madrid. 2009. Págs.: 24 y ss. La profesora Martos consideró conveniente utilizar la nomenclatura de Organismo Vivo Modificado al referirse al Protocolo de Bioseguridad y de Organismo Modificado Genéticamente con carácter general, siendo este último el término que la autora utilizará en el presente trabajo.

to show, in the content of article 16, risk management from a global perspective, and making it clear that Member States are the ones that will establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions associated with the use, handling and transboundary movement of living modified organisms. I.e., that shows a protocol signed by many States, who signed it in order to establish a legal framework that would serve as a shield against the release and marketing of GMOs and whose impact can entail a twofold risk in two protected subject-matters: environment and human health.

I. LEGAL FRAMEWORK FOR GM AGRICULTURE: COEXISTENCE OF CROPS IN THE EU.

In the late 20th century, European society considered a risk the fact of releasing genetically modified organisms and products coming from GM crops. Risk assessed as being unnecessary since they understood it as a danger to the environment and human health. The truth is that Europe under the precautionary principle, stressed the idea of taking effective preventive measures for those cases in which the lack of data or scientific uncertainties, give as a result a reasonable doubt about the possibility of causing harm; in 1999, and based on this principle a moratorium was placed on transgenic foods⁴.

For this reason, in 2003 the US reported the European Union⁵ to the World Trade Organization (WTO) calling into question the legality of moratorium. Europe was accused of slowing down technological development of genetic engineering in the fields, and was forced to lift the moratorium on April 19th, 2004. However, and this is our criticism, these years were not taken into advantage, missing the opportunity to address a risks and harm legislation related to human health, environmental contamination or damage to other crops, producing the EU Commission just a recommendation⁶, weak since its beginning, adopted on the guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, focusing in particular, on transparency and information disclosure as well as in inner cooperation in the production process, in which an equitable balance between the interests of farmers of all production types may result.

This recommendation comes from two perspectives on which it is built:

⁴ CAZORLA GONZÁLEZ, M.J.: " Aspectos jurídicos del proyecto de coexistencia entre cultivos. Revista de derecho agrario y alimentario, ISSN 0213-2915, Año nº 21, Nº 46-47, 2005, págs. 83-114. I.A.A.V.V.(A. Ramos, I. G. Laguna, M.L. Martín de Lucía, David Hernández Moreno, M. Pérez-López, M.P. Míguez): "Alimentos transgénicos: perspectivas actuales y futuras". Revista de tecnología e higiene de los alimentos, Nº Extra 1, 2008, págs. 115 y ss.

⁵ Directive 2001/18 CE of the European Parliament and of the Council of 12 March 2001 on the intentional release into the environment of genetically modified organisms and for the Council - statement by the Commission directive 90/220/CEE repealing it. ° L 106 official journal 17/04/2001.

⁶ Recommendation from the Commission of 23 July 2003 on guidelines for the preparation of strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic agriculture notified under document number C (2003) 2624. Diario oficial Nº. L 189 of 29/07/2003 p. 0036-0047.

Firstly, that in the European Union should not be excluded any form of agriculture, whether it is conventional, organic or based on GMOs uses. This fits all Member States political, economic⁷ and social ideas which come to approach the legal principles of equality and equity⁸ that they all share. Although it is surprising that it turns up shortly after the United States reported the European Union, and after some Member States such as Austria submitted a complaint to the European Court in order to preserve a free region from possible GMOs⁹ contaminations.

Secondly, the ability to maintain different agricultural production systems is the right of farmers to freely choose the type of crop and it is a prerequisite for providing a high degree of consumer choice. Although we believe this is not fulfilled in the labelling rules when in the 1830/2003 Regulation, it is allowed that labelling of products whose composition has a percentage up of 0.9 contained in an ingredient of the foodstuff but serving no technological function, and being its presence unavoidable in the finished product, the transgenic specification does not have to be mentioned on its label.

From the 2003 Community recommendation, we highlight the subsequent Vienna Conference which took place on April 4th - 6th, 2006. In this forum the European Union preferred not to adopt a firm stance on coexistence and leave farmers free to choose between traditional, organic or GM farming. Its argument was based on two aspects: firstly, the territorial diversity of individual Member States and, secondly, the inconsistent results from the very few trials carried out so far. I.e., as uttered in the

⁷ BERDOT, C.: "Quiebra y dependencia: el coste social de los alimentos transgénicos". Anuario económico geopolítico mundial, N°. 25, 2009, págs. 112 a116.

⁸ CANO MARTÍNES DE VELASCO, J.I.: "[La equidad en el Derecho privado](#)". Bosch Editor. 2009.

⁹ Court of JUSTICE of the European Communities (third Chamber). Case Austria and others v Commission of the European communities. Judgment of 13 September 2007. TJCE2007/231. The Republic of Austria adds that the scientific developments constitute an essential element of article 95 EC, paragraph 5, and that, even within the framework of the appreciation of the requirement relating to the existence of a specific problem of the Member State, the Court of first instance should not escape the question of the coexistence of genetically modified crops and natural crops, the inadequacy of assessments of risks and the application of the precautionary principle. According to the Republic of Austria, the Commission did not conduct a comprehensive scientific analysis of risks, nor took into account the right to be heard, and finally breached the obligation to provide justification. Second, the appellants criticise paragraph 67 of the contested judgment, to the extent in which is based the absence in this case of a specific problem in the sense of article 95 EC, paragraph 5, that is had not demonstrated the presence of GMOs in the territory of the Land Oberösterreich. In his opinion, the contested judgment comes into contradiction with the obligation based on a high level of protection by adopting, in accordance with that article 95 EC, measures in the field of health, safety, protection of the environment and consumer protection.

Austria, according to the Court, had not provided sufficient evidence to call into question the basis of these assessments already that had been limited to emphasize the small size of farms and the importance of organic farming in Land Oberösterreich. In particular, he added that the appellants had not provided data that invalidated the conclusions of EFSA, according to which the Republic of Austria has not demonstrated that the territory of the Land Oberösterreich has exceptional or unique ecosystems that required an assessment of risks to those carried out for Austria as a whole or to other similar regions of Europe. According to the Court of first instance, the considerations made by the appellants, by their general nature, could not override the specific comments contained in the contested Decision.

Opinion of 6 December 2006. LCEur2007/399. There are other documents: opinion of 28 June 2005 LCEur 2005/1346 and the report on the implementation of national measures to ensure the coexistence of genetically modified, conventional and organic agriculture crops (COM1042006 of 9 March LCEur 2006/2448).

December 2006¹⁰ recommendations, the market is thus left to find its own dynamics, aided by the choice of consumers, who remain free to choose whether or not to purchase GM products.

In this context, How does Spain respond? Naturally, according to its factual situation. At this point we should remember that it is different to any other European Union Member States, because Spain is still the only European Union Member State which cultivates GMOs on a large scale. In 2014, about 136,000 hectares of GMO corn were cultivated in our fields. In addition to this, several experimental trials for new outdoor varieties were carried out. Thus, Spain is the leading country in growing and researching into new transgenic plant varieties¹¹ within the European Union.

In particular, the sixth recommendation that the EU Commission established in July 2003, says: Farm structures and farming systems, and the economic and natural conditions under which farmers in the European Union operate, are extremely diverse, and efficient and cost-effective measures for coexistence vary greatly between the different parts of the European Union. And the first recommendation indicates that¹², no form of agriculture, be it conventional, organic or agriculture using genetically modified organisms (GMOs), should be excluded in the European Union. I.e. the sixth consideration of the 2003 recommendation, recognizes the diversity of States throughout their regions¹³, as when speaking of areas, in our view, is thinking about

¹⁰ Dictamen of 6 December 2006. LCEur 2007/399. There are other documents: opinion of 28 June 2005 LCEur 2005/1346 and the report on the implementation of national measures to ensure the coexistence of genetically modified, conventional and organic agriculture crops (COM 104/2006 of 9 March LCEur 2006/2448).

¹¹ <http://iumalpicabernuy.blogspot.com/2010/04/la-coexistencia-de-cultivos.html>. Informal estimates Castilla - La Mancha is the third region of Spain in surface dedicated to the cultivation of transgenic plants, mainly corn, with experimental plantations, of which there are hardly any data and whose records are kept mostly secret, Porzuna (Ciudad Real), Malpica de Tajo (Toledo) and the staff of the Provincial farm, in Albacete.

¹² Map of experimental trials with GM in Spain 2010: <http://maps.google.es/maps/ms?source=embed&hl=es&geocode=&ie=UTF8&hq=&hnear=Nuez+de+Ebro,+Zaragoza,+Arag%C3%B3n&msa=0&msid=110511989309199444785.000485db095bfe2f56bd5&ll=39.944458,-3.751831&spn=6.345132,8.983384>. And the exact location of the plots in which has been applied for experiments in the air free with GM in 2010, and the companies that carry them: http://www.tierra.org/spip/IMG/pdf/Localizacion_ensayos_2010.pdf

¹³ As regards the third plea, alleging infringement of Article 95(5) EC, the Court held, at paragraphs 65 to 67 of the judgment under appeal:

In the contested decision, the Commission rejected the arguments of the Republic of Austria by which it sought to demonstrate that there was a specific problem within the meaning of Article 95(5) EC, on the ground that it was clear from the notification that the small size of farms, far from being specific to the Land Oberösterreich, was a common characteristic, to be found in all the Member States. The Commission also adopted the conclusions of EFSA, in particular those according to which, first, “the scientific evidence presented contained no new or uniquely local scientific information on the environmental or human health impacts of existing or future GM crops or animals” and, second, “no scientific evidence was presented which showed that this area of Austria had unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or for other similar areas of Europe” (recitals 70 and 71 of the contested decision).

It must be stated that the applicants have failed to provide convincing evidence such as to cast doubt on the merits of those assessments as to the existence of a specific problem, but have confined themselves to drawing attention to the small size of farms and the importance of organic production in the Land Oberösterreich.

Judgment of the Court (Third Chamber), 13 September 2007. Joined Cases C-439/05 P and C-454/05 P Land Oberösterreich and Republic of Austria.

environmentally protected areas, in regions that have declared their willingness to be GM-free zones using for this purpose their own freedom of choice, and also it may refer to the different resources each region has, hence there have been several statements and the creation of the European network of GMO-free regions in 2003. Both recitals are set out under the principle of proportionality, and they just refer to labelling but not to growing. However, it was also said that such measures, to be in accordance with proportionality should avoid any unnecessary burden for farmers, seed producers, cooperatives and other actors associated with any production type, and should take into account the regional and local constraints and situations, as well as the specific nature of the crop concerned.

If we relate both, we have on one hand, the recognition of diversity within economic interests that lie in different European regions which usually corresponds with their own regional policies; and on the other hand, the principle of freedom of choice they all share: States, regions, companies, farmers and consumers.

Our questions to these recitals and approaches are: Where are the measures to be taken in order to achieve that coexistence in contaminated productions do not suffer a decrease in the profitability of the affected farmer? How is it going to be guaranteed the right to freedom of choice for those who desire a GMO-free land? Which preventive and conflict-solving measures are going to be established among adjacent regions with different interests? How is Europe going to protect its citizens, consumers and producers?

What is, as yet, not addressed is the answer to these questions, being unresolved in 2015, although the existence of clear intentions to do so over the past few years. However, negotiations have failed within the EU, and the recent Directive 2015 is the continuation of the European Parliament legislative resolution of 13 January 2015, on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory¹⁴.

II. EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION OF 13 JANUARY 2015 TO AMEND THE DIRECTIVE 2001/18CE.

In particular, the applicants have not put forward evidence to rebut EFSA's conclusions that the Republic of Austria failed to establish that the territory of the Land Oberösterreich contained unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or in other similar areas of Europe. When requested at the hearing to comment on the scale of the problem posed by GMOs in the Land Oberösterreich, the applicants were not able to state whether the presence of such organisms had even been recorded. The Land Oberösterreich stated that the adoption of the notified measure was prompted by the fear of having to face the presence of GMOs because of the announced expiry of an agreement pursuant to which the Member States had temporarily committed themselves no longer to issue consents for those organisms. Such considerations, by their general nature, are not capable of invalidating the concrete findings set out in the contested decision.'

¹⁴ Directive 2001/18 governs the deliberate release into the environment of genetically modified organisms (GMOs) and the placing on the market of GMOs as or in products. In Spain Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente. BOE núm. 100 de 26 de Abril de 2003

In accordance with article 2.2 of the Treaty on the Functioning of the European Union (TFEU), Member States have the possibility to adopt legally binding acts by which the cultivation of GMOs can be prohibited or restricted in their territory once GMOs are lawfully permitted in the European market. However, the common authorization procedure and, in particular, the evaluation process carried out mainly by the European Food Safety Authority (the 'Authority'), should not be held back by this type of flexibility.

In this context, the negotiating capacity of Member States do not always give appropriate results to market needs and international policies, because after years of deferred debates, it tends to fail, and the European Parliament has missed the possibility to reach a consensual agreement, so that the new Directive about genetically modified crops has not provided one solution for all. Under this alleged rule, the 2001/18 EC Directive is amended. This proposal has unveiled as the result of an "agreement" between the Council, Parliament and the Commission. The agreement is based on the difficulty of reaching a unified agreement (difficulty closer to impossibility) in the diverse context of genetically modified varieties among European States and even between regions within Member States.

Therefore, the Directive proposal has been to return competences from the EU to the Member States so as to decide their own policy about genetically modified organisms or genetically modified food. The States will be the ones to decide whether they want to allow this type of crop - or ban them - and what varieties and under what conditions they will operate in their territories. The Parliament establishes zones with neighboring countries that prevent cross-border pollution between the States, and when the time comes to finalize this text, we will have to check whether or not it includes, for those States among which Spain is part, the obligation to adopt measures to protect conventional and organic farming from GM contamination.

In this way the answer of the future directive brings us back to the article 16 of the Protocol on Biosafety 2003, where The Parties were called to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions. Once again, maintaining an unresolved issue. What we had, will be likely to be back: Keep working as a guarantee under the precautionary principle for those countries that have been opposing to GMOs crop in their territory, and that over many years have avoided its cultivation in their States, vetoing its entry. We refer to Germany, Austria, Bulgaria, Greece, Hungary, Italy, Luxembourg and Poland.

On the other hand, it ensures the power of States as the French, who has spent years immersed in a conflict between the legislative and judicial power as a result of a moratorium on this type of crop.

Far from resolving all questions unanimously, the EU misses another opportunity and steps back in 2015 to what was set in the Commission recommendation July 13th, 2010. This recommendation serves as a guidance to all Member States for the development of coexistence measures, even within internal border zones, highlighting the need to cooperate with each other so as to implement appropriate measures at

borders between Member States, avoiding unintended consequences of transboundary pollution.

The guarantee to freely choose the culture has to handle with the guarantee that such GM production does not lead to the unintended presence of GMOs in other products, while respecting the principle of subsidiarity, special attention should be paid to the prevention of possible cross-border pollution from a Member State in which the crop is allowed, to a neighbouring State in which it is forbidden, unless the Member States concerned agree that it is not necessary due to specific geographical circumstances.

But except “surprises”, and it is what we question, it seems that it won’t resolve, at a community level, demands from regions located in countries, like Spain, which legislates on the cultivation of GMOs, but that has regions such as the Autonomous Community of the Basque Country, which belongs to the European Network of GMO-Free Regions. Therefore, the resolution of 2015 announces that most of the restrictions or prohibitions adopted pursuant to this directive are applied at the stage of authorization or renewal, addressing the authority given to Member States for taking all appropriate measures to prohibit or restrict the cultivation of GMO or of a GMO group, defined by their principal characteristics or crop variety, throughout its territory or part of it, based on different and complementary reasons from those evaluated under the harmonized standards of the EU. I.e., It maintains the same interpretive criteria of Directive 2001/18CE and Regulation (EC) No. 1829/2003: Contributing to the functioning of the internal market, but legitimizing Member States to allege different reasons that are their own: can be related to the objectives of the environmental or agricultural policy or be other compelling grounds, such as town and country planning, land use, socioeconomic implications, the coexistence and public order. And all of them may be claimed individually or jointly, according to the particular circumstances of the Member State, region or area in which such measures might be implemented.

At this point, we are shown that the resolution of the European Parliament of 13 February 2015, is the result of a more extensive negotiation and it has to be related to the negotiation for the free trade agreement between the EU and The United States, called TTIP (Transatlantic Trade and Investment Partnership); agreement on the application of sanitary and phytosanitary measures, in line with the criteria applied in the United States. Among major risks, it is the negotiation of the chapter "regulatory cooperation" and the end of the "precautionary principle" on which is based - in theory - EU food safety standards.

Finally, if the most controversial issue of the TTIP negotiation was included: the Investor-State Dispute Settlement (ISDS), the American agribusiness multinationals would have the possibility to denounce the EU governments that decide to ban GM crops on their territory and they could also demand compensations of million-dollar indemnity payments for the so-called, loss of anticipated profits, as Ecologists in Action warn.

III. DIRECTIVE 2015/412, AS REGARDS THE POSSIBILITY FOR THE MEMBER STATES TO RESTRICT OR PROHIBIT THE CULTIVATION OF GENETICALLY MODIFIED ORGANISMS (GMOS) IN THEIR TERRITORY.

From April 2, 2015 and up to October 3, 2015, Member States may require the geographical scope of a notification or application lodged to be adjusted, or of an authorization granted under this directive or under Regulation (EC) no 1829/2003, before April 2, 2015. The Commission shall, without delay, submit the Member State's request to the notifier or the applicant, as well as to the other Member States¹⁵. This way, it is respected not only the States right but also the right of regions, though generating different positions in countries like Spain where the Autonomous Community of the Basque Country declared as transgenic-free has borders with the Autonomous Community of Aragon which cultivates them. Spain as a State, has the power either to prohibit or to restrain GMOs cultivation in all or part of its territory, but that's to the EU, because internally the Autonomous Regions have extensive delegated competence for current agriculture, therefore, before April 3, 2019, it will have to draw up an internal report with agreements not only based on cultivation, trade, marketing and utilization, but also on the actual remediation of environmental damages that crops may produce.

On the other hand, and out of the transitional measures the authorization of a particular GMO or during the renewal of the written authorization or the authorization decision, follows the system of respect and freedom to the Member States, who may request that he fits the geographical scope of application of the written authorization or the authorization decision to the territory of the Member State¹⁶.

¹⁵ Article 2. No later than 3 April 2019, the Commission shall present a report to the European Parliament and to the Council regarding the use made by Member States of this Directive including the effectiveness of the provisions enabling Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory and the smooth functioning of the internal market. That report may be accompanied by any legislative proposals the Commission considers appropriate.

By the same date as referred to in the first paragraph, the Commission shall also report to the European Parliament and to the Council on the actual remediation of environmental damages that might occur due to the cultivation of GMOs, on the basis of information made available to the Commission pursuant to Articles 20 and 31 of Directive 2001/18/EC and Articles 9 and 21 of Regulation (EC) No 1829/2003.

¹⁶ Remember JUDGMENT OF THE COURT (Fourth Chamber), 6 September 2012. In Case C-36/11. REFERENCE for a preliminary ruling under Article 267 TFEU from the Consiglio di Stato (Italy), made by decision of 14 January 2011, received at the Court on 24 January 2011, in the proceedings. Pioneer Hi Bred Italia Srl.

- Article 34 of Directive 2001/18 fixes its date of transposition as 17 October 2002 at the latest. Article 36 repeals, as from 17 October 2001, Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15) and provides that references to that directive are to be understood as references to Directive 2001/18 pursuant to a correlation table annexed thereto.

- In accordance with recitals 18 and 28 in the preamble to Directive 2001/18, and, previously, to Directive 90/220, the directive establishes harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment and a Community authorisation procedure for the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism(s) into the environment.

- Recitals 50 to 52 in the preamble to that directive state:

- The existing consents granted under [Directive 90/220] have to be renewed in order to avoid disparities between consents granted under that Directive and those pursuant to this Directive and in order to take full account of the conditions of consent under [Directive 90/220].

- Such renewal requires a transitional period during which existing consents granted under [Directive 90/220] remain unaffected.

- When consent is renewed, it should be possible to revise all the conditions of the original consent, including those related to monitoring and the time limitation of the consent.'

- As regards GMOs placed on the market as or in products, Articles 13 to 24 of Directive 2001/18 govern, in essence, the assessment and consent procedure for new products, renewal of the consent for

But this is further complicated when in article 26.6 ter of the directive differentiates the effects of a geographical scope readjustment from the written authorization and from the GMO approval decision, as set in paragraph 5, (we highlight) two assumptions:

- a) For a GMO authorized under this Directive, the competent authority which has issued the written consent shall amend the geographical scope of the consent accordingly and inform the authorization holder, the Commission and the Member States once this is complete.
- b) For a GMO which has been authorized under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorization accordingly, without applying the procedure set out in article 35(2) of that Regulation. The Commission shall inform the authorization holder and the Member States accordingly.

In both cases it will be amended as set out in the request. The question is, How will countries and regions demanding permission for new crops, solve, under this directive, what has not been solved before by the application of previous legislation? If we add the remedying of environmental damage, the result is controversial, freedom for some to the detriment of others, and apparent harmonization in the light of the failed negotiations.

We must not forget that the authorizations have suffered revocations by the European Court, which has criticized, in particular, the Community Executive for authorizing the genetically modified potato "*Amflora*" through the violation of procedures, the denial of reports to relevant committees and the veto over a public debate by the EU Council of Ministers on this controversial measure.

The judgment is the result of the disputed authorization submitted by the Government of Hungary, with the support of the Governments of France, Austria, Poland and Luxembourg.

The EU Court of Justice¹⁷ has criticized the European Commission for authorizing potato cultivation without submitting to the relevant technical committees

existing products, monitoring of authorised products, their labelling and a safeguard clause enabling the adoption by the Member States of restrictive measures where there is a risk to human health or the environment.

- With regard, in particular, to renewal, before 17 October 2006, of consents granted before 17 October 2002 under Directive 90/220, the procedure is governed by Article 17 of Directive 2001/18, entitled 'Renewal of consent'. In accordance with Article 17(9), a notifier who has submitted before 17 October 2006 a notification for the renewal of a consent made may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the renewal requested.

¹⁷ Judgment of the General Court (first Chamber, extended composition) of 13 December 2013.

Hungary v European Commission. Approximation of laws - deliberate release into the environment of GMO - marketing authorisation procedure - environment scientific opinions from EFSA - comitology - regulatory - substantial defects of form - procedure ex officio examination. Case T-24010. European case-law identifier: ECLI: Eu:t: 2013:645.

the proposal accompanied by scientific minority opinions, opposed to the authorization and to the consolidated report of the European Food Safety Authority (EFSA). The judgment also criticizes that the European Commission did not present the proposal, as it was required to do to the EU Council of Ministers for its debate and approval, instead, it chose to authorize it at its own risk.

At the final, the law and directive not affecting the GMO issue is between two legal principles: the principle of freedom and the principle of Justice.

The principle of freedom is coordinated and comes into harmony with the market and in consequence with economic interests; and the principle of Justice is more related in this case with caution, which follows is social values and solidarity that allow European constitutions and our institutions. So which elect to one or another principle will depend on what our society choose.

What if we want to highlight is that coexistence between different cultures is an exclusively, agronomic and economic problem which does not refer to food security, since only authorised genetically modified crops will be marketed.
