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The New Directive 2015/412/EU and '*compelling grounds*': requirements for the justification of national measures

Martin Holle - Giulia Carlotta Salvatori

1.- Introduction

The European Union has recently adopted new rules with respect to the approval of genetically modified organisms for cultivation, which have entered into effect on April 2, 2015[1]. Directive 2015/412/EU gives a greater level of discretion to Member States regarding the cultivation of genetically modified plants on their territory. While under Directive 2001/18/EC Member States had to refer to the safeguard clause in Article 23 of the said Directive or to the emergency measures laid down in Article 34 of Regulation (EC) No. 1829/2003 to justify a restriction of such cultivation, the new framework now allows to limit or prohibit the cultivation of GMO plants based on so-called «compelling grounds», provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory[2].
The possible justifications of national measures thus were extended beyond the new or additional information on health and environmental grounds that could be invoked prior to the amendment. While this certainly is in the interest of those Member States that wanted a broader range of arguments to be considered in the authorization process for the cultivation of GMO plants, the concept of 'compelling grounds' raises some interesting legal questions.
Firstly, it is necessary to define the scope of the specific grounds listed under lit. a) to g) of Article 26b, par. 3 (inf. 3.).
Secondly, it must be determined what level of evidence a Member State must present in order to justify a restriction (inf. 4.).
Finally, it must be assessed, based on the jurisprudence of the European Court of Justice, what level of discretion is attributed to the Member States when they decide to regulate cultivation and to what degree they can invoke grounds that go beyond the list in Article 26b (inf. 5).
Before we embark on this analysis, it is necessary though to have a closer look at the changes that were introduced by Directive 2015/412/EU.

2.- The new Directive 2015/412/EU

The new Directive 2015/412/EU is part of the EU framework designed to regulate the commercialization of genetically modified organisms[3].
As defined in the law, a GMO is an organism – with the exception of human beings – in which the genetic material has been altered in a way that does not occur in naturally by mating and/or natural recombination[4].

([1]) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 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 territory, at the link http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0412&from=IT. This document has been adopted having regard to Article 114 of the TFEU, which concerns the approximation of the Member States' laws.
([2]) Article 26b, paragraph 3, of Directive 2001/18/EC, as amended by Directive 2015/412/EU.
([3]) E. Sirsi, *Su ogm e agricoltura. Una lettura alla luce della prospettiva di riforma della disciplina della coltivazione degli ogm nell'UE e dello sviluppo di tecniche alternative di modificazione genetica*, in *Agric., Istituz., Merc.*, 2013, 87 ss.; F. Rossi dal Pozzo, *Ogm, via libera del Parlamento europeo alla possibilita per gli Stati membri di vietarne o limitarne la coltivazione*, in *Eurojus*.it, 20 gennaio 2015, 1 ss.; Id. *Profili recenti in tema di organismi geneticamente modificati nel settore agroalimentare fra procedure di comitato e tutela giurisdizionale*, in *Dir. Comm. Internaz.*, 2014, 339 ss.; V. Ranaldi, *Novità sugli OGM: prosegue il confronto tra Stati membri ed Unione europea*, in *Ord. int. e dir. umani*, 2014, 643 ss.; M. Lee, *GMOs in the Internal Market: New Legislation on National Flexibility*, in *The Modern Law Review*, 2016, Vol. 79, Issue 2, 317 ss.
([4]) This is the definition given by the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The GMO can be considered as the direct and immediate consequence of the innovative applied biotechnology, as said by F. Rossi dal Pozzo, *Profili comunitari ed internazionali della disciplina degli organismi geneticamente modificati*, Milano, 2005, 9. See also

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In order to manage any potential risks that may be associated with the use of this man-made technology, the European legislation sets out a general prohibition for the deliberate release of such organisms as well as foods and feed derived from them, but allows for an authorization if the absence of risks to human or animal health and the environment can be proven for a specific GMO[5]. While Directive 2001/18/EU concerns the deliberate release into the environment and the commercialization of GMOs[6], Regulation (EC) No. 1829/2003 deals with genetically modified food and feed[7]. Under both regimes, so far the authorization meant that the GMO or the products derived from it could freely move into the territory of every Member State.

This principle was now abandoned with Directive 2015/412/EU, which allows Member States to ban or restrict the cultivation of GMOs in their territory, even if such cultivation has been approved at the level of the European Union in accordance with Part C of Directive 2001/18/EU or with Regulation (EC) No 1829/2003.[8] Every Member States thus has now more flexibility to decide whether it wishes to cultivate GMOs in its territory.

In this way, a difference is created between the placing on the market or import of GMOs on one side, and their cultivation on the other. The first aspect is regulated uniformly by the legislation of the European Union, in order to facilitate the functioning of the Internal Market. The second one is a competence shared between the Member States and the Community, according to Article 4 par. 2 TFEU. Consequently, they can both legislate and adopt legally binding acts in the field of cultivation of GMOs. The days of this dichotomy may be numbered, though.

In its Communication COM (2015) 176 final the European Commission concluded that the current legal framework should also be amended for the authorization of genetically modified food and feed, in line with the approach agreed in the Directive 2015/412/EU[9]. The respective legislative proposal intends to allow Member States to decide if a GM food or feed that has been authorized on EU-level will also be allowed on their internal markets or not[10]. To do this, Member States could adopt 'opt-

S.D. Murphy, *Biotechnology and International Law*, in *Harvard International Law Journal*, 2001, 47; B. Sheridan, *EU Biotecnology, Law and Practice*, Bembridge, Palladian Law Publishing Ltd., 2001, 3; L. Costato, *Diritto nazionale, diritto comunitario e organismi biologicamente modificati*, in *Studium Iuris*, 1997, 1268; D. Liakopoulos, *Il dibattito europeo relativamente ai problemi emergenti in merito al libero commercio degli organismi geneticamente modificati (OGM)*, in *Riv. di dir. dell'econ., dei trasp. e dell'amb.*, 2006; J.P. Anger, P. Kintz, *Les OGM: une révolution technologique qui inquiète et qui passionne*, in *Annales de Toxicologie Analytique*, 2010, 22(1), 19 ss.

(5) See Article 2, par. 8, of Directive 2001/18/EC. See also, *ex multis*, L. Bodiguel, M. Cardwell, *The Regulation of GeneticallyModified Organisms: Comparative Approaches*, Oxford, 2010; M. Lee, *EU Regulation of GMOs, Law Decision Making for a New Technology,* Cheltenham, 2008; P. Borghi, *Gli OGM, le nuove congiunzioni astrali e il fuoco sotto la cenere*, in *Agric., Istituz., Merc.*, 2009, 1 ss.; E. Sirsi, *GM food and feed*, in L. Costato, F. Albisinni, *European and Global Food Law*, Padova, II ed. 2016, 425 ss.

(6) P. Rey Garcia, *Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs: an Overview and the Main Provisions for Placing on the Market*, in *JEEPL*, 2006, 1, 3.

(7) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. See also M. Valletta, *Biotecnologia, agricoltura e sicurezza alimentare: il nuovo regolamento sui cibi e mangimi geneticamente modificati ed il processo di sistematizzazione del quadro giuridico comunitario*, in *Dir. pubbl. comp. ed eur.*, 2003, 3, 1471; G. Amadei, *L'innovazione transgenica in agricoltura: vantaggio economici*, in *Riv. dir. agr.*, 1998, 1, 357; B. van der Meulen, *EU Food Law Handbook*, Wageningen Academic Publishers, 2014, 276 ss.; M. Rosso Grossman, *Protecting Health, Environment and Agriculture: Authorisation of Genetically Modified Crops and Food in the United States and the European Union*, in *Deakin Law Review*, 2009, Vol. 14, No. 2, 257.

(8) V. Paganizza, *La Direttiva (UE) 2015/412 dell'11 marzo 2015 e la possibilità pe gli Stati membri di limitare o vietare la coltivazione di OGM sul loro territorio*, in this *Rivista*, www.rivistadirittoalimentare.it n. 1-2015, 80 ss.; S. Visani, *Modelli normativi a confronto: regolamentazione degli Ogm tra UE ed USA. Giurisprudenza in materia di brevettabilità degli organismi viventi*, in this *Rivista*, www.rivistadirittoalimentare.it n. 3-2015, 62 s.; S. lee, *The Member States' Long and Winding Road to Partial Regulatory Autonomy in Cultivating Genetically Modified Crops in the EU*, in *EJRR*, 2013, 2, 143 ss.; M. Weimer, *What Price Flexibility? The Recent Commission Proposal to Allow for National 'Opt-Outs' on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform post-Lisbon*, in EFFL, 2011, 4, 232 ss.

(9) COM (2015) 176 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, reviewing the decision-making process on genetically modified organisms (GMOs).

(10) COM (2015) 177 final, Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, at the link http://ec.europa.eu/food/plant/docs/plant_gmo_authorisation_proposal_regulation_en.pdf.

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out' measures to restrict or prohibit the use, in all or part of their territory. However, the proposal was rejected by the European Parliament in first reading in October 2015 because of concerns about negative effects of such unilateral national measures on the free movement of goods and the functioning of the Internal Market[11]. The European Commission, though, declared that it is not willing to drop the proposal and is presently consulting the Member States on possible options to proceed.
With its new approach the European Union aims to facilitate the central EU-wide approval process by allowing Member States to exercise a larger level of discretion in determining the acceptable level of GMO use. The benefit for the European Commission in this is twofold. Shifting back the final decision to the Member States may help to resolve the frequent deadlocks experienced in the European authorization procedures that were triggered by strong opposition in a number of countries. At the same time, the risk of non-compliance with WTO rules that had to be equally shared by the whole EU in the past will now rest with those Member States that implement restrictions.
Despite their regained powers, Member States are not entirely free when it comes to the adoption of restrictions, as they still must respect the principle of free movement of goods in the Internal Market and the decisions taken in the harmonized sectors of the EU. This includes those aspects of a GMO authorization that were already assessed in the central European authorization procedure, in particular risks for human and animal health together with not territory-specific environmental risks. As a result, Member States can only adopt national restrictions or prohibitions based on grounds distinct from those taken into consideration in the phase of the EU risk-assessment[12].
First, the Member State must provide that the measures adopted in order to restrict or prohibit the cultivation of GMOs in its territory are in conformity with Union Law, reasoned, proportional and non-discriminatory.
National restrictions may be adopted on grounds relating to environmental or agricultural policy objectives, or other non-scientific compelling grounds, such as town and country planning, land use, socioeconomic impacts, avoidance of GMOs presence in other products and public policy.
Since the term 'compelling grounds' is contained both in the new Directive 2015/412/EU and in the new Proposal, it is important to analyze it, trying to understand what it refers to and how the measures adopted by every Member State should be justified.

3.- What are 'compelling grounds'?

Reading Article 26b of the Directive 2015/412/EU, we can make a first remark.
The list of the letters a) to g) in par. 3 is not exhaustive because according to Article 26, par. 3, the measures adopted by a Member State to ban or prohibit the cultivation of GMOs in its territory must be based on compelling grounds «such as those related to», indicating that the letters a) to g) are only some examples of what a compelling ground may be.
While a Member State can adopt national cultivation restrictions or prohibitions based on different grounds, it must always ensure that such measures comply with all requirements in Article 26b, par. 3, of the new Directive.
The first 'compelling ground', mentioned in letter a) is «environmental policy». Typically, the environmental aspects have already been taken into account during the central, European authorization procedure for the cultivation or placing on the market of GMOs. To avoid any interference with the competences granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) 1829/2003 on European level, the new Directive only permits to the Member States the reference to environmental policy objectives that relate to impacts which are distinct from and complementary to the assessment of risks to health

([11]) See the Report of the European Parliament on the Proposal, at the link http://www.europarl.europa.eu/sides/getDoc.do?pubRef=//EP//NONSGML+REPORT+A8-2015-0305+0+DOC+PDF+V0//EN.
([12]) As results from the Recital number 13.

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and the environment which had already been assessed in the context of the initial authorization procedure.

Consequently, every Member State, before banning or prohibiting the GMOs cultivation in its territory, must evaluate the scope and rationale of the European authorization decision. Environmental aspects that had already been considered there cannot be taken into account again as a compelling ground concerning the environmental policy. They are 'forfeited'.

Some examples of new environmental policy objectives that could be invoked are mentioned in Directive 2015/412/EU itself: the maintenance and development of agricultural practices that offer a better potential to reconcile production with ecosystem sustainability or the maintenance of local biodiversity.

The term 'biological diversity' or 'biodiversity' has been an important term in the literature of both biology and ecology[13]. It has emerged recently as a leading goal of scientists, environmentalists, and policymakers[14]. From a biological point of view, it is the diversity that exists in the biological world, the variety of life on Earth and the natural patterns it forms[15].

From a juridical point of view, the Convention on Biodiversity, signed at the 1992 Rio Earth Summit, is dedicated to promoting sustainable development[16]. It recognizes that biological diversity is about more than plants, animals, microorganism and their ecosystems; it is about people and their need for food security, fresh air and water, and a clean and healthy environment in which to live. The objectives of the Convention are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources[17].

Other international documents on biodiversity are the Protocol of Cartagena on Biosafety that concerns the different aspects of the transboundary movement of living modified organisms and the Nagoya Protocol on Access and Benefit Sharing[18].

Speaking of cultivation of GMOs, it is important to analyze its impact on agricultural biodiversity[19]. Agricultural biodiversity includes all components of biological diversity of relevance to food and agriculture, and all components of biological diversity that constitute the agro-ecosystem, and that are necessary to sustain key function on the agro-ecosystem, its structure and process.

Changes to this ecosystem due to technological progress are not new. At the end of the Seventies, with the so-called 'green revolution', there was a transformation in agricultural practices. New chemical fertilizers and synthetic herbicides and pesticides were invented and had a strong impact on the way the land was cultivated. Not much later, the use of genetically modified organisms in agriculture started.

Clearly all these elements can have an important impact on the biodiversity, e.g. on the number of plant and animal species that can be found in a certain habitat.

The letters b) and c) of the new Directive name «*town and country planning*» and «*land use*» as 'compelling grounds'. We know that the GMOs cul-

(13) See N. de Sadeleer, *Ec Law and Biodiversity*, in *JEEPL*, 2007, 3, 168; S. Amato, *La biodiversità è un valore?*, in L. Marini, A. Bompiani, *Agricoltura transgenica, convenzionale e biologica: verso una coesistenza possibile?*, Milano, 2007, 99.

(14) D. Farrier, *Conserving Biodiversity on Private Land: Incentives for Management or Compensation for Lost Expenctations?*, in *Harvard Environmental Law Review*, 1995, 19, 303 ss.; B.C. Karkkainen, *Biodiversity and Land, in Cornell Law Review*, 1997-1998, Vol. 83, Issue 1, 2.

(15) M. Scott, D.D. Goble, F.W. Davis, *The Endangered Species Act at Thirty, II, Conserving Biodiversity in Human-Dominated Landscapes*, Washington, 2006, 53. See also G. Franco, *Rischio ambientale e principio di precauzione nella direttiva sugli Ogm*, in *Ambiente*, 2010, 951 ss.

(16) I.M. Porras, *The Rio Declaration: a New Basis for International Cooperation*, in *Review of European Community & International Environmental Law*, 1992, 245 ss.; G.C. Garaguso, S. Marchisio (a cura di), *Rio 1992: vertice per la Terra*, Milano, 1993, 230 ss.

(17) A. Smagadi, *Analysis of the Objectives of the Convention of Biological Diversity: Their Interrelation and Implementation Guidance for Access and Benefit Sharing*, in 31 *Columbia Journal of Environmental Law* 243, 2006.

(18) Aa. Vv., *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN, Gland, Switzerland - Cambridge, UK, 2004, 1 ss.

(19) L. Paoloni, *Diritto degli agricoltori e tutela della biodiversità*, Torino, 2005.

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tivation has an impact on these two aspects.
Even if GM crops will contribute to forest conservation by allowing marginal land to be cultivated, preventing further deforestation for conversion to cropland, some experiences have indicated that GM crop cultivation can also accelerate land use change[20].
Moreover, the GMO-based agriculture is characterized by holdings (or farm businesses) that are bigger and larger than the ones that we can find in the conventional agriculture. In fact, GM crops are often planted in monoculture formats, thus having an impact also on agricultural biodiversity, while the traditional agricultural practices offer a better potential to reconcile production with ecosystem sustainability.
Secondly, to avoid genetic contamination between the GMOs and other products – especially the organic and conventional ones – the farmers should adopt so called 'segregation measures'. In particular, distance regulations and isolation distances between the fields must be respected in order to protect non-GM agriculture from impact by GM cropping. Consequently, these "buffer" areas cannot be used anymore, neither can they be cultivated nor be built upon.
Thirdly, the trade policy of GMO-based agriculture can have a tendency to create large scale structures, since GM plants and crops should be cultivated on bigger fields in order to capitalize on the superior properties of the plants. However, farms and businesses of modest size characterize the organic and conventional agriculture that is common in many areas of the European Union. If these structures were converted into GMO-based agriculture, farmers would need to scale-up the size of their agricultural cropland and would have to employ heavy machinery. As a consequence, the infrastructure – for examples the streets – would have to be adjusted accordingly.
We can also notice that the opportunity to get new transgenic 'individuals', able to resist adverse climatic conditions, can create a transfer of the cultivation from the traditional areas of cultivation or breeding to new places. This might create problems relating to the conservation of the rural territory. The transfer could be for a legitimate reason, such as increasing the degree of food-self-sufficiency in a country. However, it can also occur to reduce the cost of production. In the latter case, this could result in unemployment and rural exodus in the abandoned lands as well as a disruption of the link between production technique and place of production.
Finally, an example of changes in land use due to cultivation of GM plants is the phenomenon of land grab to secure sufficiently large areas of arable land to maximize the efficiency of GMO-based agriculture[21].
Another potential 'compelling ground', according to letter d) of the Directive 2015/412/EU, can originate in the «*socio-economic impacts*» of the release of GMO into the environment.
There is not a clear and agreed definition on what such 'socio-economic impacts' are. They can be defined as the set of the intertwined social and economic consequences resulting from the changes arising from the introduction of GMOs into the environment[22].
The term is undefined to a high degree. It comprises a large range of economic, social and ethic aspects, such as effects on food, feed and commodity prices, sustainability issues, the risk of the extinction of traditional varieties, the corporate control of seeds and property rights on land, effects on income and employment, effects on farms and farming communities, requirements for education, information,

([20]) See H.R. Grau, M. Aide, *Globalization and Land-Use Transition in Latin America*, in Ecology and Society, 2008, 13 (2): 16, online version at the link www.ecologyandsociety.org/vol13/iss2/art16. See also the Ecosystem and Human Well-being, a Report of the Millennium Ecosystem Assessment, at the link http://www.millenniumassessment.org/documents/document.356.aspx.pdf. Moreover, see the phenomenon of the land grab, *infra*.
([21]) See, *ex multis*, S.M. Borras Jr., J.C. Franco, C. Kay, M. Spoor, *Land Grabbing in Latin America and the Caribbean*, in *The Journal of Peasant Studies*, 2012, Vol. 39, Issue 3-4, 845 ss.; N. Cuffaro, D. Hallam, '*Land Grabbing' in Developing Countries: Foreign Investors, Regulation and Codes of Conduct, 2011*, 1 ss.; L. Cotula, S. Vermeulen, R. Leonard, J. Keeley, *Land Grabbing or development opportunity? Agricultural investment and international land deals in Africa*, IIED/FAO/IFAD, London-Rome, 2009; S. Liberti, *Land Grabbing. Come il mercato delle terre crea il nuovo colonialismo*, Roma, 2011, 63.
([22]) B. Sadler, M. McCabe, *Environmental Impact Assessment Training Resource Manual*, Geneva, 2002, 561.

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vocational and continuing training, effects on health, safety and dignity of farm families and laborers, social acceptance and well-being, operating costs and competitiveness or the impact on investment and access to finance.

We can try to split all these socio-economic impacts into two different groups. On one side, we can find tangible and mainly quantitatively measured effects; on the other hand, there are the intangible and qualitatively measured implications, such as cultural and psychological changes and related impacts[23].

To determine better what the term 'socio-economic impacts' means, we can refer to the Report from the Commission to the European Parliament and the Council on socio-economic implications on GMOs cultivation[24]. The Commission notes that the socio-economic dimension of GMOs cultivation varies among the Member States and the stakeholders. Moreover, there is a difference between Member States having experience in GMOs cultivation and the other Member States. In fact, the first ones have referred to ex post studies performed on their territory, while the second ones have referred to literature and experience from third countries[25].

We can find information on the socio-economic impacts of GMO cultivation in Europe also in other documents, e.g. the Recommendation on guidelines for the development of national coexistence measures, adopted on 13 July 2010[26]. The Commission recognizes that the potential loss of income for producers of organic products is not necessary limited to the cases where the labelling threshold set at 0.9% in the EU legislation is exceeded[27]. In certain cases, the presence of traces of GMOs in particular food crops – even at a level below 0.9% – may cause economic damages to operators, who would wish to market them as not containing GMOs.

In particular, if a product is organic, the admixture of GMOs has specific implications for the farmers. Because of the higher price of the production in the market, stricter segregation efforts to avoid GMOs presence must be adopted[28].

The FAO has also been active in publishing analyses of the socio-economic impacts of transgenic crops in developing countries[29].

([23]) For example, quality of life, freedom of research, social changes and so on.

([24]) COM (2011) final, Report from the Commission to the European Parliament and the Council on socio-economic implications of GMOs cultivation based on Member States contributions, as requested by the Conclusions of the Environment Council of December 2008. We can read in the report that: «Therefore the Commission launched a consultation on Member States on the socio-economic implications of GMO cultivation via a questionnaire». It was articulated around the following headlines: a) economic and social implications; b) agronomic sustainability; c) environmental impact; d) other implications». See also G. Brookes, P. Barfoot, *Global Impact and Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use*, in *AgBioForum*, 2006, 139 ss.; K. Ludlov, S.J. Smith, J. Falck-Zepeda, *Socio-Economic Considerations in Biotechnology Regulation*, Springer, 2014.

([25]) We can read in the report that: «According to the contributions, only 7 Member States have past or present experience in cultivating pest resistant (Bt) maize MON 810 for commercial purposes. RO cultivated Herbicide Tolerant (HT) soybean before joining the EU and the cultivation of GM potato Amflora has started in 3 Member States». Moreover: «The scientific literature and studies referred to by contributors were mostly focused on economic impacts of GMO cultivation on the in-farm level. It is noticeable that respondents usually backed their estimations of the likely impacts of GM crops cultivation with extrapolations of literature and experience from third countries, with the exception of respondents from Member States having experience in GMO cultivation, who also referred to ex post studies performed on their own territory». The Commission report the results on the Bt maize and on the HT soybean. For what concern the other socio-economic impacts «on the rest of the seed-to-shelves chain and the wider society (e.g. transport, insurances, food industry, testing laboratories, employment/work patterns, administrative activities, consumers' choice) were also largely commented in contributions of both cultivating and non-cultivating Member States. However, the views expressed are scarcely scientifically and statistically documented».

([26]) Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (2010/C 200/01).

([27]) In point 1.1. of the Recommendation, we can read that «this could cause a loss of income, due to a lower market price of the GM crop or difficulties in selling it. Moreover, farmers might incur if they have to adopt monitoring systems and measures to minimize the admixture of GM to non-GM crops».

([28]) In addition, these segregation measures can be more difficult and costly in some geographic areas, due to local constraints and characteristics.

([29]) The International Plant Protection Convention; the International Treaty on Plant Genetic Resources for Food and Agriculture. See also T. Raney, *Economic impact of transgenic crops in developing countries. Current Opinion in Biotechnology*, 2006, Vol. 17, Issue 2, 1 ss.; E. Evenson, T. Raney, *The Political Economy of Genetically Modified Foods, Cheltenham*, UK and Northampton, MA, US, 2007.

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Based on these documents and on analyses made by scholars in this field, we can notice that the socio-economic impacts of GMOs comprehend:

- Farm level impacts for GM crop adopters[30]: farmers can have different socio-economic motivations for adopting or not GMOs. On one side, the cultivation of GMOs can generate benefits, such as profit and yield increases, more flexibility on time management and more efficiency due to the use of technologies. On the other hand, it comes at an extra cost, e.g. because of higher expenses for seeds, herbicides or pesticides prices as well as rental of machinery;
- Co-existence aspects between GM and non GM-farms[31]: as described in the Recommendation of July 2010 of the European Commission, conventional farms can get contaminated with GM material. As a consequence, coexistence and segregations systems might have to be adopted (ex ante measures, such as mandatory segregation, traceability, minimum GM tolerance level, and ex post measures, such as compensation funds, insurance schemes, and market place liability). The different coexistence options influence GM and non-GM farm-level costs in different ways. Moreover, we have to take into consideration that social factors, such as the level of trust on neighbors, can influence farm-level costs too;
- Consumers' acceptance and welfare changes associated to the availability of GM food[32]. If many consumers have a negative attitude towards GMOs, this limits the potential for welfare gains that might be achieved by the use of such technologies.
- Trade impacts[33]: At the moment, countries have different regulations and labelling provisions on GMOs (for example, the European Union on one side, and the United States of America on the other side), this affects international trade. The differences can have a significant impact on the competitiveness of the countries´ agricultural sector.
- Interdependency of GMO technology and policy[34]: as we know, the adoption or rejection of GMO authorizations is not solely based on scientific considerations, but also on political ones. Economic policy considerations like the support of domestic farmers or national agro-chemical companies may play as well a role in the decision making process as cultural aspects like preserving a certain lifestyle.

The letter e) of the Directive 2015/412/EU mentions «*avoidance of GMO presence in other products*

(30) A. Hilbeck, T. Lebrecht, R. Vogel, J.A. Heinemann, R. Binimelis, *Farmer's choice of seeds in four countries under different levels of GM crop adoption*, in *Environmental Sciences Europe*, 2013, 25:12.

(31) E. Gray, T. Ancev, R. Drynan, *Coexistence of GM and non-GM crops with endogenously determined separation*, in *Ecological Economics*, 2011, 2386 ss.; R. Groeneveld, J. Wesseler, P. Berentsen, *Dominos in the dairy: an analysis of transgenic maize in Dutch dairy farming*, in *Ecological Economics*, 2013, 86, 107 ss.; J. Falck-Zepeda, *Coexistence, genetically modified biotechnologies and bio-safety: implications for developing countries*, in *American Journal of Agricultural Economics*, 2006, 88, 1200 ss.; M. Giuffrida, *I 'modi' di coltivare, ovvero la tutela della libertà di scelta dell'imprenditore agricolo fra diritto nazionale e diritto comunitario*, in *Regole dell'agricoltura – Regole del cibo. Produzione agricola, sicurezza alimentare e tutela del consumatore*, a cura di M. Goldoni - E. Sirsi, Pisa, 2005.

(32) P. Aerni, J. Scholderer, D. Ermen, *How will Swiss consumers decide if they had freedom of choice? Evidence from a field study with organic, conventional and GM corn bread*, in *Food Policy*, 2011, 36, 830 ss.; M. Costa-Font, J.M. Gil, *Consumer Acceptance of Genetically Modified Food (GM) in Spain: A Structural Equation Approach, in Risk Management*, 2008, 10, n. 3, 194-20; P. Ganiere, W.S. Chern, D. Hahn, *A Continuum of Consumer Attitudes Toward Genetically Modified Foods in the United States*, in *Journal of Agricultural and Resource Economics*, 2006, 31, n. 1, 129-149; G.P. GruÈre, C.A. Carter, Y.H. Farzin, *What Labelling Policy for Consumer Choice? The case of Genetically Modified Food in Canada and Europe*, in *The Canadian Journal of Economics*, 2008, 41, n. 4, 1472 ss.; W. Hu, F. Zhong, Y. Ding, *Actual Media Reports on GM Foods and Chinese Consumers' Willingness to Pay for GM Soybean Oil*, in *Journal of Agricultural and Resource Economics*, 2006, 31, n. 2, 376 ss.; C. Mora, D. Menozzi, *Conoscenza e atteggiamento dei consumatori verso gli alimenti derivanti o contenenti organismi geneticamente modificati*, in *Riv. dir. alim*, 2008, 1; C.P. Lewis, J.N. Newell, C.M. Herron, H. Nawabu, *Tanzanian farmers' knowledge and attitudes to GM biotechnology and the potential use of GM crops to provide improved levels of food security. A Qualitative Study*, in *BMC Public Health*, 2010, 10, 407 ss.

(33) M. Tothova, J. Oehmke, *Whom to join? The small country dilemma in adopting GM crops in a fragmented trade environment*, in *Quarterly journal of international agriculture*, 2005, 44, 291ss.

(34) J. Swinnen, T. Vandemoortele, *Policy gridlock or future change? The political economy dynamics of EU biotechnology regulation*, in *AgBioForum*, 2010, 13, 291 ss.

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without prejudice to Article 26a» as a 'compelling ground'. This expression clearly refers to the problem of the genetic contamination caused to agricultural production by the presence of GMOs in the surrounding fields[35].

This type of contamination originates from the coexistence of different productions. In fact, we live in a moment in which there are both traditional crops and GM plants. Moreover, in the same fields, different crops are often implemented over time. The phenomenon of genetic contamination is caused by the transmigration of the pollen of GM plants grown in an area to the neighboring areas[36].

In most cases, this transmigration takes place by natural causes. The plants tend to cross-pollinate because of the wind and the distribution by insects that favors the shift of the pollen from the donor plant to the recipient one.

For this reason, conventional and organic crops grown in the proximity of GM crops can have a more or less high percentage of genetically modified DNA as a result of genetic contamination. This leads to economic and even legal issues. Although cross-pollination is a natural phenomenon and thus inevitable, when the pollen is transgenic, it is an 'invasive introduction' (in Italian «immissione invasiva»), on nearby conventional crops. It can cause damages to the farmers, in terms of choice and access to the market. Their production, in fact, is not GM-free anymore.

Secondly, genetic contamination can be caused by the successive presence of different crops on the same field (GM and non-GM).

A third cause of genetic contamination could be a negligent way of working of farmers. The grower of both GM plants and conventional ones must follow forms of segregation of these different crops, e.g. during storage or transport.

Moreover, farmers must adopt measures to prevent the use of impure seeds.

From a legal point of view the Directive 2001/18/EC does not specifically address genetic contamination[37]. The only provision that can be invoked is Article 26a of the Directive. The objective of this article is to avoid contamination of GMOs in conventional or organic products[38]. To achieve this, it allows Member States to take all appropriate measures to avoid the presence of GMOs in other products.

To what degree this provision establishes an obligation for a Member State to act in every single case of a contamination is an open question. Due to the lack of specificity of Article 26a it is unlikely that it should establish a legal basis for an action by an aggrieved party against either the polluter or the authorities for lack of enforcement. It only obliges the Member States to provide an effective legal framework in which the damaged party can seek redress.

The first case in such a matter that reached the European Court was about pollen from GM plants in honey that was supposed to be marketed as conventional food[39]. It illustrates very nicely the complex legal issues that can arise if GM reach a neighboring field. The Court had to decide whether pollen can still be considered an "organism" within the meaning of Article 2 par. 4 of Regulation (EC) No. 1829/2003 if it isn´t able to reproduce itself anymore and has lost its ability to fertilize a female blossom (which it answered in the negative) and if it could be regarded as an "ingredient" of a food

(35) E. Sirsi, *L'impiego in agricoltura di organismi geneticamente modificati e la coesistenza con le coltivazioni non geneticamente modificate*, in L. Costato, A. Germanò, E. Rook Basile, *Trattato di diritto agrario*, II, Milano, 2011, 293; I. Canfora, *Ogm e agricoltura biologica, in Agricol., istituz. e mercati*, 2006, 419 ss. See also L. Bodiguel, *La coesistenza delle colture: lo Stato ai comandi?*, in this *Rivista* www.rivistadirittoalimentare.it n.4-2009. The term 'genetic pollution' was used by Jeremy Rifkin, in 1998 in his book 'The Biotech Century', as remembered by S. Sirohi, P. Mago, I. Gunwal, L. Singh, *Genetic pollution and biodiversity*, in *International Journal of Recent Scientific Research*, vol. 5, issue 6, June, 2014, 1152.

(36) A. Germanò, *Sulla coesistenza tra coltivazioni transgeniche e coltivazioni convenzionali: profili giuridici*, in *Riv. dir. agr.*, 2005, I, 396 s.

(37) E. Sirsi, *Sulla coesistenza*, cit., 397.

(38) I. Canfora, *Ogm*, cit., 420; E. Sirsi, *Quando la contaminazione da Ogm è 'tecnicamente inevitabile': riflessioni in vista dell'adozione di 'misure di coesistenza' nella Regioni italiane*, in *Agric., istituz. e mercati*, 2009, 33 ss.; E. Sirsi, *L'impiego*, cit., 292 s.; E. Sirsi, *Rilievi metodologici per lo studio del problema della 'coesistenza' tra colture transgeniche, convenzionali e biologiche*, in M. Goldoni, E. Sirsi (a cura di), *Regole*, cit., 194.

(39) ECJ, case C-442/09 – Bablok et. al.

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(which it erroneously affirmed, causing the Commission to correct this mistake by an amendment of the Directive 2001/110/EC on honey).
In order to address the growing number of issues with coexistence the European Commission issued Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional or organic farming[40]. The Recommendation confirms the right of European farmers to cultivate GM plants, because «no form of agriculture be it conventional, organic and agriculture using genetically modified organism (GMOs) should be excluded in the European Union». However, at the same time it addresses the potential economic loss and impact of the admixture of GM to non-GM crops. Member States should take the most appropriate management measures available to minimize such admixture, based on a case-by-case approach[41]. The type of instruments adopted may have an impact on the application of national liability rules in the event of economic damage resulting from admixture. Member States therefore should examine their civil liability laws to find out if the existing national laws are sufficient or not in this regard[42].
The Recommendation was updated in 2010[43], when the European Commission introduced the possibility to create local or national GM-free zones[44]. Under certain economic and natural conditions, the Recommendation gives Member States the possibility to exclude GMO cultivation from large areas of their territory to avoid the unintended presence of GMOs in conventional and organic crops. They must demonstrate however that for those areas other measures are not enough to achieve sufficient levels of purity. Moreover, the restriction measures should be proportionate to the objective pursued.
With Directive 2015/412/EU the level of national discretion in this regard was further expanded, as every Member State can now decide to limit or prohibit in its territory the cultivation of GMOs to avoid the GMO presence in other products.
In letter f) of Article 26b, par. 3, of the Directive «*agricultural policy objectives*» are also regarded as a potential 'compelling ground'. It further specifies that grounds relating to agricultural policy objectives may include the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material purity.
To understand more deeply the meaning of this provision, we have to remember that the European Union has a Common Agricultural Policy, the so-called CAP. Since 1990, the farm sector's cooperative scheme has undergone several reforms to adapt to the dynamism of political, economic and social realities. Since 1999, the CAP has been through successive reforms that have increased market orientation for agriculture, improving the integration of environmental requirements and giving support for rural development across the EU.
The CAP was recently reformed again. On 16 December 2013 the Council of EU Agricultural Ministers formally adopted four Basic Regulations for the reformed CAP concerning rural development, horizontal issues, direct payments and market measures[45]
The objectives of the first regulation – Regulation (EU) No. 1305/2013 – are to foster the competitiveness of agriculture, to ensure the sustainable mana-

(40) M. Valletta, *La disciplina delle biotecnologie agroalimentari. Il modello europeo nel contesto globale*, Milano, 2005, 264 ss.; G. Brookes, P. Barfoot, *Coesistenza tra colture arabili Gm e non Gm: il contesto Gm e quello biologico nell'Ue*, in *Riv. dir. agr.*, 2004, I, 103.
(41) Since the conditions under which European farmers work are very different, the Commission expresses itself in favor of an approach that would leave it up to Member States to develop and implement national strategies and measures for coexistence. These should be created in cooperation with all relevant stakeholders and in a transparent manner. They must take into account the regional and local constraints and situations, as well as the specific nature of the crop concerned. There is also an indication of a specific tool: every Member State is free to adopt various types of instruments, from voluntary agreements, to non-legal binding provisions and the highest standards.
(42) Consequently, farmers, seeds suppliers, and other operators should be fully informed about the liability criteria that apply in their country in case of damage due to genetic contamination.
(43) Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200, p. 1.
(44) Recital 5 and point 2.4 of the annex to the Recommendation.
(45) E.M. Appiano, *Le riforme del 2013 alla OCM vino*, in *Contr. e impr./Europa*, 2014, 451 ss.

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gement of natural resources and climate action and to achieve a balanced territorial development of rural economies and communities, including the creation and maintenance of employment[46].
These objectives and all the measures prescribed in Title III of this Regulation can be a starting point to justify the prohibition or ban cultivation of GMOs, using the compelling ground described in letter f) of Directive 2015/412/EU.
The last of the 'compelling grounds' that is included in Article 26b letter g) of the new Directive is «*public policy*».
We notice that while every compelling ground could be invoked individually or in combination, this ground must always be invoked in combination with another compelling ground. The reason for this might be that public policy is a very broad and generic concept.
The regulator does not give examples of what might be considered under this ground. Generally speaking, it can be defined as a system of laws, regulatory measures, courses of action and funding priorities concerning a given topic promulgated by a governmental entity or its representatives. The European Court of Justice has also interpreted it as to do with protecting the machinery of government, and in this way, it can justify measures against dangers of civil disturbances[47].
If a Member State wants to invoke this compelling ground, it has to demonstrate that the cultivation of GM crops involves a serious threat to fundamental interests of the Member State's society.
Article 26b, par. 3, as seen before, has a non-exhaustive character: therefore Member States can base their measure on other 'compelling grounds'.
On one side, the Directive 2015/412 EU gives an example, speaking of «other legitimate factors including those relating to cultural traditions»: according to the Commission, this could include preservation of societal tradition in term of traditional farming methods and preservation of cultural heritage linked to territorial production processes with particular characteristics[48].
On the other side, the Commission has also proposed «social policy objectives»: prohibitive or restricted measures could be adopted to seek keeping certain type of rural development in given areas to maintain the current level of occupation.
Moreover, the Commission suggested another ground: «public morals», including religious, philosophical and ethical concerns: however, it has not been included in the Directive 2015/412/EU.

4.- Conditions for the application of 'compelling grounds'

Firstly, as written in the Directive, the restriction or ban adopted by a Member State in its territory should refer to the cultivation and not to the free circulation and import of genetically modified seed and planting propagating materials, or in products and of the products of their harvest.
Moreover, the restriction or ban of a GMO´s cultivation, apart from being based on one or more compelling grounds, has to:

a) Be *in conformity with the Union Law*: this could be considered a reminder that even if every Member State has now more flexibility in its competence to restrict the cultivation of GMOs, it is still bound by its legal obligation under the EU law. The Directive says that restriction or prohibition of a GMO´s cultivation must be in conformity with the Treaties, in particular with Article 34 and 36 TFEU, will say that opt-out measures must comply with the guarantee of free movement of goods.
The first article forbids quantitative restrictions on imports and measures having a similar effect.

(46) Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 december 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005. See the considerando number 3.
(47) See ECJ, Case C-231/83 - *Cullet vs. Centre Leclerc*, in M. Geelhoed, *A Growing Impasse: the Future of the EU's GMO Regime, in Edinburgh School of Law Research Paper* n. 2014/46, Europa Working Paper n. 2014/08, 2014.
(48) Commission SEC (2011) 184 final, Complementary considerations on legal issues on GMO cultivation raised in the opinion of the legal service of the Council of the European Union of 5 November 2010 and of the legal service of the European Parliament of 17 November 2010 (Indicative List of Grounds for Member States to restrict or prohibit GMO cultivation).

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Consequently, in order to justify its measure, the Member State has to demonstrate that it is justified by the exceptions to the principle of free movement of goods, referred to in Article 36 TFEU[49], or by the requirements established by the EU Courts' case law[50]. The latter shows that a large range of both social and ethical objectives has been relied on successfully by Member States[51];

b) be *reasoned*: national measures cannot constitute arbitrary discrimination or restriction on trade between Member States;

c) be *proportional*: this means that the ban or restriction must be in accordance with the principle of proportionality[52]. In the EU law, this legal principle regulates the exercise of powers by the European Union. Under its rule, the action of the EU must be limited to what is necessary to achieve the objects of the Treaties: the content and the form of the action must be in balance with the aim pursued. The first legislative manifestation of proportionality can be considered Article 5 of the Treaty on the European Union and the criteria for applying this principle are set out in the Protocol no. 2 on the application of the principles of subsidiarity and proportionality annexed to the Treaties. It has been imposed as a requirement on trade restrictive measures by the EU Courts[53].

According to this principle, the measures adopted by the EU institutions or by the Member States should not exceed the limits of what is necessary and appropriate in order to attain the legitimate objectives pursued by the legislation in question. The application of this principle refers to the relationship between the means and the end: it means that the restrictive measure chosen is suitable or appropriate in order to achieve the invoked objective. Moreover, the chosen measure must be necessary in order to achieve the proposed goal: in other words, the goal cannot be attained in a less restrictive manner; however, if more than one option is available, the adopted measure must be the least trade-restrictive.

Applying this principle to a case where a Member State has adopted a restrictive measure against cultivation of GMOs, the Member State must demonstrate, for example, that the central, European risk assessment procedure hasn't taken into consideration, in a proportional manner, the need to protect the diversity of agricultural production;

d) be *non-discriminatory*: the prohibition or restriction adopted should be in conformity with the principle of non-discrimination between national and non-national products. It is contained in Article 34 TFEU, according to which: «Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States». This provision does not regulate a particular activity, but in general, it prohibits national measures discriminating based on the origin or nationality of a product.

It can be considered as a standard that the Member States must follow in making rules. Consequently, it has a dual function: on one side, it has a negative function, since it invalidates every discriminatory national rule; on the other side, it has a positive function, prohibiting the adoption of a national rule that discriminates on grounds such as nationality and origin;

([49]) This article states that: «The provisions of Article 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archeological value; or the protection of industrial and commercial property».

([50]) ECJ, case C-8/74, *Procureur du Roi/Benoit and Gustave Dassonville*, par. 5: all measures enacted by Member States, which are «capable of hindering, directly or indirectly, actually or potentially» the trade in the European Union must be considered as having an equivalent effect to quantitative restrictions. See also ECJ, case C-142/05, *Åklagaren/Percy Mickelsson and Joakim Roos*; ECJ, case 120/78, *Rewe-Zentral AG/Bundesmonopolverwaltung fur Branntwein* (Cassis de Dijon); ECJ, case 302/86 *Commission/Denmark* (Danish Bottles); ECJ, case C-110/05, *Commission/Italian Republic*, par. 62; ECJ, case 124/81, *Commission/United Kingdom of Great Britain and Northern Ireland*, par. 35; ECJ, case C-320/03, *Commission/Republic of Austria*, par. 71; ECJ, case C-141/07, Commission/Federal Republic of Germany, par. 47.

([51]) See M. Lee, *Eu Environmental law, Governance and Decision-Making*, Oxford, 2014, 239 ss.

([52]) R. von Schomberg, *The Precautionary Principle: Its Use Within Hard and Soft Law*, in EJRR, 2012, 2, 150; M. Poto, *The Principle of Proportionality in a Comparative Perspective*, in *German Law Journal*, vol. 08, n. 09, 835 ss.

([53]) See ECJ, case C-4/75, *Rewe Zentralfinanz eGmbH/Landwirtschaftskammer*. See also M. lee, *EU Environmental law*, cit., 242.

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e) be *in conformity with the WTO law*: the national restrictions or prohibitions of GMOs´ cultivation have to be in conformity with the Treaties, in particular Article 216 of the TFEU. It refers to the agreements concluded by the European Union, which are legally binding for the institutions of the EU and the EU Member States.
This includes WTO agreements. Consequently, when a Member State adopt an opt-out measure concerning the cultivation of GMOs, it must also adhere to WTO laws.
Finally, we have to underline some practical aspects. The demand to ban or restrict the cultivation of GMOs should be a written one. It must be accompanied by a written justification.
The Member States could not just claim that the compelling ground is present without giving a well-founded rationale for it. As said by the Commission, the sole invocation of one or several of these justifications in abstract terms will not be sufficient to meet the scrutiny of the Court of Justice of the European Union.
Consequently, Member States have to prove in a plausible manner that compelling grounds exist, the measure adopted is in conformity with the Union law and with the principles of proportionality and non-discrimination.
Moreover, where relevant, the Member State must support the measure by scientific data, showing the appropriateness and proportionality of the restrictive measure adopted.
However, a Member State cannot be asked to prove positively that no other conceivable measures could achieve the objective to be attained under the same conditions.

5.- Member States discretion and judicial review

In general, the European Court of Justice grants a wide space of discretion to the European institutions in fields where they must undertake complex assessments that entail political, economic and social choices[54]. This principle equally applies to national measures[55] and was particularly acknowledged by the Court for the area of agricultural policy pursuant to Articles 40 to 43 TFEU[56]. The limits of this discretion are determined by the interests the European institutions or the Member States pursue on one side and the fundamental rights of the individuals and private organizations affected by the measures taken on the other[57]. In the assessment of the legality of a measure, the Court considers particularly the area concerned, the nature of the right at issue guaranteed by the Charter of Fundamental Rights of the European Union, the nature and seriousness of the interference and the object pursued by the interference[58]. Additional benchmarks are the general legal principles of good administration and proportionality[59], with the latter also being explicitly codified in Article 5 TFEU.
A legal expression of broad discretion attributed to European institutions are the so-called “other legitimate factors”, a commonly used construct in European food law which can be found in a number of provisions like Article 7 par. 1 of Regulation (EC) No 1829/2003, Article 17 par. 1 of Regulation (EC) No. 1924/2006 on Nutrition and Health Claims or - most recently - in Article 12 par. 1 lit. d) of Regulation (EU) 2015/2283 on Novel Foods. They typically appear as complementary aspects to be taken into account next to the scientific asses-

(54) ECJ, case C-547/14, *The Queen/Secretary of State for Health*, par. 166; case C-601/11 P, *France/Commission*, par. 142; case C-491/01, *British American Tobacco*, par. 123; case C-236/01, *Monsanto Agricoltura Italia et al*., par. 135.
(55) Cf. ECJ, case C-573/12, *Ålands Vindkraft AB/Energimyndigheten*; case C-77/02, Steinicke, par. 61, and case C-144/04, *Mangold*, par. 63, in the field of social and employment policy; opinions of Advocate General Kokott in case C-254/08, *Futura Immobiliare et. al./Comune di Casoria*, par. 55 et seq. and cases C-378/08, C-379/08 and C-380/08, *Raffinerie Mediterranee SpA (ERG) et al./Ministero dello Sviluppo Economico* et. al., par. 106.
(56) ECJ, case C-301/04, *Spain/Council*, par. 96 et seq.; case C-331/88, Fédesa et al., par. 14; case C-265/87, Schräder HS Kraftfutter, par. 22.
(57) ECJ, case C- 292/97, *Karlsson et al*., par. 45.
(58) ECJ, case C-293/12 and C-594/12, *Digital Rights Ireland*, par. 47.
(59) ECJ, case C-189/01, *Jippes/Minister van Landbouw, Natuurbeheer en Visserij*, par. 81; joined cases C-133/93, C-300/93 and C-362/93, *Crispoltoni et al*., par. 41; case C-331/88, *The Queen/Ministry of Agriculture, Fisheries and Food*, ex parte FEDESA et al., par. 13.

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sments made for the authorization of the placing on the market of a specific food or of a nutrition or health claim. Their purpose is to introduce wider policy considerations into the decision-making process. Some examples of such aspects are given in Recital 19 of Regulation (EC) No 178/2002 and include societal, economic, traditional, ethical and environmental factors. This list bears a striking resemblance to the "compelling grounds" mentioned in Article 26b par. 3 of the revised Directive 2001/18/EC, which also include socio-economic impacts as well as environmental and agricultural policy objectives. These "compelling grounds" thus can be regarded as a kind of extension to the list of "other legitimate factors".

When invoking a "compelling ground" or "legitimate factor" as a justification for a measure, the European institutions and the Member States must aim to minimize the financial and administrative burdens for authorities, economic operators and citizens that are created by the measure[60].

Due to the political nature of the decisions that are to be taken on the basis of "other legitimate factors" or "compelling grounds" respectively, the European Court of Justice exerts judicial self-restraint when it comes to the legal assessment of such measures. According to settled case-law the Court in such cases limits its review to the verification that the measure at issue is not "vitiated by any manifest error or misuse of powers", and that the institution concerned has not "manifestly exceeded the limits of its discretionary power"[61]. The institution that took the measure must further demonstrate that objective reasons for it exist that aren´t manifestly inappropriate and must provide the Court with sufficient information to assess those grounds[62]. It must disclose clearly and without ambiguity the reasoning it has followed so that the Court is enabled to exercise its power of review[63]. However, as the judicial review will not only consider the wording of such a statement of reason but also its overall context and the totality of legal rules applicable to the case, not all relevant facts or points of law must be explicitly mentioned[64].

6.- Conclusion

After analyzing the New Directive 2015/412/EU – concerning the possibility of every Member State of the European Union to ban or restrict the cultivation of genetically modified organisms in its territory – the meaning of 'compelling grounds' and how the proof of the 'compelling grounds' themselves can be given, we can make a number of additional remarks in conclusion. The GMOs were, during the last decades, object of an important debate that has involved representatives of different fields, from the science to the law. The new Directive 2015/412/EU and the new Proposal of the European Commission for an amendment of Regulation (EC) No. 1829/2003[65] show a continued attention of both Member States and European Institutions to the theme of GMOs.

Reading the two documents, we can notice two opposite interests: on one hand, the protection of health and of the environment, on the other hand the development of the international market and competition. The balance between them is not easy to achieve and some authors hold that the Commission seems to be biased towards the principle of freedom of economic initiative[66]. Those interests may conflict with other issues – for example, the social, economic, cultural or urban profile of a coun-

([60]) Article 5 par. 2 of Protocol No. 2 on the Application of the Principles of Subsidiarity and Proportionality; ECJ, case C-547/14, *Philip Morris et. al*, par. 186.
([61]) ECJ, case C-601/11 P, *France/Commission*, par. 142; case C-545/11, Agrargenossenschaft Neuzelle, par. 43; case C-221/09, AJD Tuna, par. 80; case C-236/01, *Monsanto Agricoltura Italia* et al., par. 135.
([62]) ECJ, case C-545/11, *Agrargenossenschaft Neuzelle*, par. 44 et seq.; case C-127/07, *Arcelor Atlantique et Lorraine et al*., par. 48 and 58.
([63]) ECJ, joined cases C-341/06 P and C-342/06 P, *Chronopost*, par. 88.
([64]) ECJ, joined cases C-341/06 P and C-342/06 P, *Chronopost*, par. 88; case C-501/00, *Spain/Commission*, par. 73; Case C-367/95 P, *Commission/Sytraval*, par. 63.
([65]) COM(2015) 177 final.
([66]) V. Ranaldi, *Novità sugli OGM*, cit., 1042 ss.

try –. This is what the 'compelling grounds' in Article 26 par. 3 aim to address.
Handing back decision powers to the Member States is a significant change of tack in the Commission´s approach towards food regulation. It remains to be seen, whether we will see similar developments of re-nationalization in other areas of food law. First signs on the horizon are the apparent lack of resistance of the European Commission against attempts of Member States to introduce complementing national rules on origin labelling in the context of Art. 26 of Regulation (EC) No. 1169/2011 on food information.
The Commission´s 'new approach' on GMOs shows a high degree of flexibility towards the Member States, even if this does not mean a complete change of the system. Still, a central authorization procedure is maintained on European level with an assessment that covers environmental and health aspects. Member States can deviate from this default setting only by invoking specific local, regional or national peculiarities that justify restrictions to the cultivation of GMOs, as illustrated by the list of 'compelling grounds'[67].
While this concept was supported by the other EU institutions for the purpose of cultivation, the European Parliament opposed a similar rule for the use of GMO in food and feed by rejecting the Commission´s prposoal to amend Regulation (EC) No. 1829/2003 accordingly[68]. This shows that a re-nationalization of rules on GMO use is easier to accept for the European institutions if they´re linked to the use of the land than it is if they concern the free circulation of goods in the Internal Market. Thus, it remains to be seen whether any new proposal presented by the Commission on this subject will still contain a full "opt-out" provision for Member States.
Nevertheless, the new regime on GMO cultivation results in a significant recovery of national sovereignty: positive sovereignty for the Member States that want to permit the GMOs cultivation on their territory and negative sovereignty for those who want to prohibit or restrict it.
In this way, the European Commission managed to escape its 'sandwich position', in which it was trapped between its obligations resulting from its position as a guardian of the Internal Market and the international free trade on one hand, and the pressure coming from the national or sub-national level to introduce GM-free zones on the other.
The new legal regulatory framework could present several problems when national or local choices are influenced by other factors than those that are considered legitimate according to the list of 'compelling grounds'. To prevent national protectionism and unjustified barriers to trade it is therefore crucial that national restrictions will be scrutinized by the European Commission for compliance with the requirements of Article 26b. Only convincing evidence should stand the test. This will lend credibility to those initiatives that truly pursue the protection of traditional practices, food cultures, functioning social structures and a high level of quality.
Anyway, the rich cultural heritage of food is too valuable to be abused for the gain of unfair commercial advantages.

ABSTRACT

Directive 2015/412/EU provides the Member States with a greater level of control on the cultivation of GMO plants on their territory. The new rules allow for limitations or a complete prohibition of such cultivation on the basis of so-called „compelling grounds", such as environmental and agricultural policy objectives, land use, avoidance of cross-contamination with conventional products or socio-economic impacts. As the list is not exhaustive, it is important to define under which conditions the compelling grounds can be invoked. In particular, any restriction based on such grounds must be compliant with EU and WTO law, reasoned, non-discriminatory and proportionate. Only if these requirements are met, unjustified barriers to trade and protectionism can be prevented and legitimate grounds like traditional production practices or food culture and heritage can prevail.

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