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The EU legislation on "GMOs" between nonsense and protectionism: An ongoing Schumpeterian chain of public choices

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ABSTRACT[1]. The EU regulation of agricultural biotechnology is botched and convoluted: the pseudo-concept of "Genetically Modified Organisms" has no coherent semantic or scientific content.

The reasons of the paradox by which the cultivation of "GMOs" is substantially banned in Europe, while enormous quantities of recombinant-DNA cereals and legumes are imported to be used as feedstuff, are explained.

The Directive 2015/412, giving Member states the choice to refuse the cultivation of genetically engineered crops at a national or local level, paves the way for a mosaic-like, Harlequinesque form of protectionism: nothing resembling a well-regulated free market. In the meantime, importation of "GMO" feed goes on at full speed all over Europe.

A proposal by the Commission to adjust the rules on importation according to those for cultivation has been rejected by the Parliament.

This dynamics may be seen as an ongoing "Schumpeterian" chain of public choices: the calculus of consent drives politicians more than a science-based approach to law-making.

The EU should restart from scratch with the right concept, i.e. the careful examination of the pros and cons, the costs and benefits of each new agricultural product ("GMO" or otherwise), freely cultivated and/or imported, assessed case by case, at last acknowledging that the biotech processes used to create new varieties are of no practical or legal relevance. In doing so, the EU would pursue its stated "better regulation" approach, cancelling any sectoral and sectarian regulation.

KEYWORDS. biotechnology regulation, European Union, free market, GMO, protectionism, Schumpeter

INTRODUCTION: EUROPEAN NEO-LYSENKOISM

The name of Trofim Lysenko (Liu, 2004), which means nothing to the general public, is unfortunately very well-known to scientists; the Ukrainian agronomist had a leading role in drawing up Soviet agricultural and food policy in the period between 1940 and 1960: on the back of some significant success in increasing the yields of various crops (wheat, peas, millet), with Stalin's approval and against what had

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become the established scientific consensus, which saw the emergence of the fecund combination of Mendelian genetics and Darwinism, Lysenko imposed an outdated vision of biology, and in particular of agriculture and of the techniques to improve cultivated varieties. By doing so, with the support of the State, the official and all-pervasive affirmation of a wrong-headed philosophy and policy led to the destruction of the blooming Russian school in the field of genetics (also by silencing opposing scientists in a «classic» Stalinist purge) and, as a consequence, to a series of falling harvests and general deterioration in the vital agricultural sector.

The historic parallel between Lysenkoism and the EU agricultural biotech regulation of the last quarter century seems to us as fitting as it is stunning: as we are going to explain, by refusing a rational approach to the matter, Europe's political decision-makers have for too many years been obstructing progress in one of the most promising scientific fields, also denying a real freedom of choice both to producers and consumers.

What is the only real difference between Lysenkoism and the current European situation? The former led to negative agricultural outcomes, which in a poor country such as the Soviet Union in the middle of the 20th century had a disastrous impact on the basic wellbeing of millions of families. Several decades later, rich Europe is losing ground in agricultural research and production: yet, given its purchasing power, whatever food or feed it cannot produce it simply imports (European Communities, 2013; Savage, 2013).

A Pointless Attempt to Define the Nonsensical "GMO" Pseudo-Category

The EU's legislation on agricultural biotechnologies is difficult to understand: the confusion lies above all in the original definitions. Directive 2001/18/EC basically confirmed the analogous law issued ten years before (see European Communities Council, 1990): for these founding texts, which regulate "the deliberate release into the environment[2] of genetically modified organisms," 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 naturally by mating and/or natural recombination" (European Union, 2001, Art. 2)[3]. So it would seem to be that: targeted cross-breeding, operated by plant growers, farmers and breeders, of individuals belonging to sexually compatible animal and vegetal species (so-called artificial selection) is considered "normal;" from which it could be deduced that any product which is the outcome of "unnatural" methods, such as many laboratory techniques (including direct intervention on the DNA) and especially chemical or physical mutagenesis, is a "GMO." Not so simple. Some detailed specifications are defined, and for them we must turn to an annex to the Directive: "Techniques [. . .] which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules [. . .]:

(1) in vitro fertilisation,
(2) natural processes such as: conjugation, transduction, transformation,
(3) polyploidy induction." (European Union, 2001, Annex I A, 27)

To find a reference to mutagenesis, we must turn to yet another annex which says: "Techniques/methods of genetic modification yielding organisms to be excluded from the Directive [. . .] are:

(1) mutagenesis,
(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods." (European Union, 2001, Annex I B to Art. 3, 28)

This convoluted and disorganized text is the basis for the contorted and contradictory regulation. At the start of the Directive, the general definition insisted on the "unnaturalness" of "GMOs:" yet, it looks difficult to talk of "naturalness" for, say, *in vitro* fertilisation or polyploidy induction. This last

[2]I.e. crop cultivation, animal farming, use of microorganisms outside labs.

[3]The official glossary of the EU is limited to this basic definition (http://europa.eu/legislation_summaries/glossary/genetically_modified_organisms_en.htm), i.e. without including the exceptions that we will now describe, which overturn its meaning: in this way, the reader of the glossary is seriously misled.

effect - the doubling of chromosomes, which can create new desired traits in a cultivar - can be obtained with several methods, physical or chemical: except for the fact that the lawmaker concedes it "on condition that they do not involve the use of recombinant nucleic acid molecules." The result is exactly the same, but certain techniques are allowed and others not. No rationale can be found.

This approach has generated paradoxes: the same cultivars which express the same trait, for example tolerance of rapeseed to weed-killers or rebalanced starch content in potatoes, are subject to radically different authorization procedures, depending on whether they are created using one method rather than another: token analysis for "non-GMOs," almost never-ending for "GMOs".[4]

In addition, it should be noted that, with complete disregard for reality (and for the principle of non-contradiction), it is claimed *by law* that numerous genetic modification techniques "are not considered to result in genetic modification."

The real reason for these arbitrary conceptual and semantic contortions seems to be the following: while struggling to keep "GMOs" at bay, EU lawmakers had to «save» a myriad of existing agricultural products (several thousand cultivars) and derivatives (from pasta to beer) which, if the numerous exceptions to the initial definition were not stated, would find themselves in the position of being "GMOs." All these efforts are aimed at identifying a (pseudo) category of products to be regulated separately, subjected to a particular treatment, i.e., more red tape, tests and analyses.

The EU's Double Standard on "GMOs:" Cultivation Forbidden, Importation Indispensable

The method of systematic obstructionism has worked. Indeed, since 1998 the EU has approved the cultivation of just one recombinant DNA variety, Bt corn MON810 (European Commission, 2013), which has not stopped various countries constantly blocking it with legalistic quibbles and bureaucratic hurdles, or even banning it - an illegal action. For example, the EU Court of Justice condemned France twice: 1. Court of Justice, case C-419/03 of 15 July 2004, Commission of the European Communities against French Republic, OJ C 275 of 15 November 2003, where the Court of Justice held that France had infringed Community law by failing to transpose Directive 2001/18/EC. 2. Court of Justice, case C-121/07 of 9 December 2008, Commission of the European Communities v French Republic, OJ C 95, 28 April 2007, in which France was condemned for failing to comply with the previous judgment. (See Mereu, 2011.)

Various national governments have imposed this constant opposition by appealing to the only legal instrument apparently available, the "safeguard clause" (European Union, 2001, Art. 23, 21–22. See the Appendix to this article), by which a Member State can refuse "a GMO" when there are well-grounded reasons, scientifically proven by adequate studies, regarding the negative impact of the product on the environment and/or on human health. The European Food Safety Authority is responsible for assessing the grounds put forward by governments; it has regularly declared as invalid dossiers which this or that country has

[4]An example of such bizarre situation is the case of the Amflora potato (http://en.wikipedia.org/wiki/Amflora). It was genetically engineered in order to inhibit the production of one of the two kinds of starch which are typically present in the tuber and which, in order to favour the production of paper (yes, a large share of potatoes are not eaten), is traditionally eliminated using a costly process: the inactivation of a certain gene solves the problem at source. The push and shove between the European Commission, the ministers of various recalcitrant European states, and the challenges of "anti-GMO" organisations concerning the authorization of the new cultivar lasted fifteen years until the producer, BASF, gave up marketing the product in Europe, only to see insult added to injury: another German company managed to produce the same desired phenotypic trait through a "non-GMO" method of mutagenesis, and immediately started the mass production of its "Super potato" without any particular bureaucratic burden (www.potatopro.com/news/2009/emsland-st%C3%A4rke-processed-100-tonnes-amylopectin-potatoes-fall). No reaction from activists. Clearly, the mutagenized potato is politically correct, the "GMO" one is not.

presented (EFSA, 2009 The ban on Bt maize by the German and French governments is discussed in Ricroch, Bergé and Kuntz, 2010), because no negative data have emerged. This flaw is revealed by the Commission itself: "The fact that Member States have currently [2010] no margin of appreciation on cultivation of authorized GMOs has led in several cases some Member States to vote on the basis of non-scientific grounds. Some of them have also invoked the available safeguard clauses, or used the special notification procedures of the Treaty under the internal market, as ways to prohibit the cultivation of GMOs at national level" (European Commission, 2010b, 3). And: "No Member State which had adopted a so-called "safeguard clause" had ever been in a position to put forward new evidence." (European Commission, 2015a).

The EFSA's outcomes were to be expected: "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies" (European Commission, 2010a, 16). In other words, "GE [genetic engineering] bio safety research in Europe over the past 25 y has cost more than 300 million EUR and can be summarized in one sentence: GE is no more dangerous than crop modification by any other method." (Masip et al., 2013, 322) However, since the opinion of the EFSA, even if it is required by law, does not green light products when unjustified requests to block them are rejected (unlike the situation, for example, with similar American agencies), in many cases the «safeguarding» countries have preferred to risk an infraction procedure - which in any case the European Commission, for political and diplomatic reasons, is very slow and reluctant to implement - rather than give "GMOs" their due go-ahead.

Therefore, a clear double standard is evident in EU "GMO" politics: on the one hand, the persistent refusal to allow the *cultivation* of DNA-recombinant crops and vegetables has been ongoing for many years; on the other, there is a regular, huge stream of *importation*[5], above all "GMO" soybeans and corn as animal feed, accounting for several million tons annually: "Whilst less than 0.1% of the global acreage of GM crops is cultivated in Europe, more than 70% of EU animal protein feed requirements are imported as GM crop products" (Baulcombe et al., 2014, 5). European farmers are not allowed to grow these crops, even if they are identical to cultivars shipped from across the Atlantic; apparently contrary to all logic, numerous products are safe to eat, but if imported from across the Atlantic, not cultivated in Europe.

The paradox by which the cultivation of "GMOs" is substantially banned in Europe, while enormous quantities of DNA-recombinant cereals and legumes are imported to be used as feedstuff can be explained by various political and economic incentives.

It is forbidden to *cultivate* "GM" crops:

- In order not to harm the old-fangled products of EU farmers: "profitability in markets where GM varieties have not been introduced, such as in Europe, becomes threatened by competition from lower priced GM imports. It is, therefore, logical for farmers in such a position to oppose approval of GM varieties if there is a prospect for maintaining some product differentiation and continuing to sell the conventional product at the previous, higher price." (Graff, Hochman and Zilberman, 2014, 13–14) In other words, "when faced with greater competition, the optimal response of farmers in countries with a comparative disadvantage in GM adoption may be to lobby for more-stringent GM standards" (Anderson, Damania and Jackson, 2004, Abstract).
- To gain the political and electoral consensus of "organic" food producers and

[5]It should be remembered that the cultivation of "GMOs" and the use/importation of them (or their derivatives, or products which contain them as ingredients) are two very different questions which are regulated by distinct legislative instruments, Directive 2001/18 and Regulation 1829/2003 respectively.

retailers: "suppression of GE agriculture in the EU is widely recognized as ideological rather than scientific, driven to a large extent by the organic food industry in an effort to protect organic food premiums at the expense of overall competitiveness" (Masip et al., 2013, p. 313)[6].

- To spare public money: "European governments have to pay less agricultural subsidies to the extent that their own farmers are able to sell their own produce at high prices." (Allen, 2009)
- To satisfy the "anti-GMO" brigade, which is very lively in Brussels and in many EU nations; for some conservative anti-biotech groups, though, continuing activity can be envisaged, since the relentless "opposition to GE and support for stiff regulation against it is financially rewarding" (Zilberman, Graff, Hochman and Kaplan, 2015, 218).
- To adapt policy to the preferences of consumers (Swinnen and Vandemoortele, 2011), who are suspicious of "GMOs" due to an inflated perception of their supposed risks.
- Last but not least, to protect the interests of the traditional herbicide/pesticide chemical industry: "European governments may be less supportive of the technology as long as it results in reduced exports of pesticides." (Zilberman, Graff, Hochman and Kaplan, 2015, 215) Such industry has been quietly taking advantage for two and a half decades of the "anti-GMO" movement's incessant propaganda: "given that activist groups were already highly motivated for their own reasons, all the incumbent industry needed to do to achieve a desired result was to abstain from intervening and to leave the activists unchallenged in forming the public's opinions and risk perceptions of biotechnology." (Graff, Hochman and Zilberman, 2014, 683–684) This can be seen as a neat example of the infamous "bootleggers and baptists" effect. (.Yandle, 1983, Miller and Conko, 2003)[7]

In the meantime, it is necessary to *import* "GMO" feed to allow animal breeders to work.

The costs of such schizophrenic[8] rules are shown by a particularly bizarre example: "Extraordinarily, in Romania before they joined the EU, GM soybeans were extensively grown and exported to Europe. Since they joined the EU, Romania is now forbidden to grow GM soy as it is not authorized for cultivation in Europe. Instead, the EU pays farmers in Brazil, Argentina and US to grow GM soy, and provides subsidies to Romania from regional funds." (Baulcombe et al., 2014, 35)

Europeans must in any case hope that there are no significant drops in the availability of "GMO" animal feed for import, or there would be very serious economic problems, as the European Commission itself warns! (European Commission, 2007)

Therefore, the "GMO" paradox is only apparent: "EU taxpayers spend considerable sums both nationally and Europe-wide on plant science and technology that could result via GM in EU crops with better performance and reduced environmental impact. However, excessive regulation is preventing EU taxpayers from benefiting from their own investment - why?" (Jones, 2011, 1824) The former interpretation, from the point of view of political-electoral interests, may help perplexed rationalists to understand.

Harlequinesque Protectionism in the EU

The long-running stall on new authorisations for recombinant DNA crops to be cultivated, which concerns all countries of the EU, is due to the fact that, under European decision-making mechanisms, the unyielding opposition of some states has denied the freedom to cultivate

[6]We would not call such motivations "ideological", rather "economic"!

[7]A possible objection to this last point of our analysis is that it can be considered too speculative: in fact, the traditional chemical industries did not play a proactive role in the "GMO" opposition.

[8]More than one commentator used this strong adjective: see e.g. Mereu 2011

"GMOs" in other countries which tend to be more open to new cultivars (for example the United Kingdom[9]). To try to overcome the ongoing generalized block, in 2010 the Commission offered a compromise to the EU governments: without prejudice to the centralized scientific evaluation of the environmental and health safety of any product by the EFSA (European Commission, 2010b, 2.2.3, 6), each Member State would remain free to ban their cultivation (not their import for transformation or for consumption, human or animal) on its territory (or part of it) for socio-economic reasons (EPEC, 2011, 100–104) or on the grounds of agricultural policy, or similar motivations. In short, every state could activate an opt-out option for any unwelcome "GMO" authorized for cultivation in the EU.

A particularly problematic issue emerges from the inevitable verbiage used: the restrictive measures which individual states decide to adopt must be "consistent with the international obligations of the EU, and in particular with the ones established under the World Trade Organisation (WTO)" (European Commission, 2010b, 3.2, 7). In fact, there is a precedent for trade disputes on "GMOs:" in the years around the turn of the millennium, the block on the commercialization in the EU of agricultural products, appealing to the alleged inherent riskiness of "GMOs," triggered recourse to the WTO by three countries (Argentina, Canada and the USA) which claimed that their exports were unjustly discriminated against. The EU lost the dispute (WTO, 2006; excellent summary of the case: Bernauer and Aerni, 2008) and authorized the *import* of quite a few DNA-recombinant crops and vegetables, but did not see fit to end the prohibition on *cultivating* them[10] - a sort of *de facto* compromise. A new law which gives Member States explicit permission to prohibit their farmers from cultivating "GMOs" could fuel the transatlantic conflict again: "A WTO panel would likely not consider socio-economic concerns as an acceptable justification for the imposition of trade barriers" (Kerr, Smyth, Phillips and Phillipson, 2014). "[I]ndividual EU member states with their own sui generis approach to banning of cultivation on socio-economic grounds are quite likely to face bilateral legal challenges from other countries within the framework of the WTO" (Morris and Spillane, 2010, 365; for a thorough analysis, see Punt and Wesseler, 2015).

The 2010 Commission proposal looks like a nice attempt to pass the buck («Dear Member States, each of you will decide whether to reject authorized GMOs, the Commission is fed up with the deadlock. . .»); yet it appears as a clever and justified move to place responsibilities on single countries. As the old adage goes, thinking the worst of someone may be a sin, but it is often spot on; thus, we'll maliciously imagine an unacknowledgeable motivation, as if the Commission were leaving unsaid: «. . .then, if some WTO member sees itself damaged and goes onto the attack, affirming that free trade rules have been violated, those who adopted such restrictions on "GMOs" will face possible retaliations on their own, without the EU executive acting again as a cushion, caught between the devil and the deep blue sea!».

Anyway, European politicians recently decided to bring an end to the long-standing negative situation, also highlighted in a major official study regarding the efficiency and effectiveness of Directive 2001/18: "from the time [the GMO directive] came into force [2001] until March 2010 the EU did not adopt a single decision, positive or negative, on an application to cultivate a GMO. [. . .] Applications cycle within the system, are stalled, inch forward and then cycle again at the next stage of the process. Dissatisfaction and frustration is widespread in all quarters." (EPEC, 2011, 73)

So, in March 2015 the EU Parliament approved a new short directive, which modifies the directive of 2001 in regard to "GMOs to be

[9]Following the Brexit, the scenario in the UK may change.

[10]The EU official list of authorized "GMOs" is not so short: 58 items have been imported for years, plus 19 cleared on 24th April 2015 (http://europa.eu/rapid/press-release_IP-15-4843_en.htm), and some 40 requests are still pending (5 March 2016); but for all the cultivars – except maize MON810 – use (importation) is allowed for "Marketing of food and feed and derived products", "with the exception of cultivation": http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

used for cultivation purposes throughout the Union as seeds or other plant-propagating material ('GMOs for cultivation')" (European Union, 2015, Preamble, 1). The individual countries of the EU need "to decide whether or not they wish to cultivate GMOs on their territory [...]. The grant of that possibility to Member States is likely [...] to ensure freedom of choice of consumers, farmers and operators" (European Union, 2015, Preamble, 8). This type of clarification looks self-contradictory: saying that legalizing the prohibition on cultivating varieties which are recognized as healthy would increase the freedom of choice is a sort of *excusatio non petita*.

The text of the directive more than once stresses that the general European authorisation of every "GMO," based on the assessment of the absence of risks to health and the environment, which is delegated to the EFSA, must not be undermined by the new opportunities offered to individual states: "the common authorisation procedure, in particular the evaluation process conducted primarily by the European Food Safety Authority [...] should not be adversely affected by such flexibility" (European Union, 2015, Preamble, 6; see also Preamble, 8 and 14, and Art. 26b, point 3). The grounds that the Member States may put forward must be different.

And so the formula, which was hypothesized as early as 2010, has been confirmed which allows the banning, on a national or local basis, of "GMOs" that have been approved at European level: measures can be adopted "related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy" (European Union, 2015, Preamble, 13. See also Art. 26b, point 3). Yet, town and country planning, which is a legitimate and necessary political action, has nothing to do with "GMOs;" in fact, if the planning schemes foresee that a certain area is going to be cultivated, the permission to grow cereals or legumes or any other crop has no link with the origin of the varieties that farmers will use. In other words: if planners decide that here we'll have huge fields of maize, or small plots of different vegetables, or vast orchards, why should these decisions prohibit the use of, say, mutagenized cultivars, or *in vitro* multiplied clones, or... "GMOs"? Here's an attempt to rationalize an illiberal diktat.

Notwithstanding its incoherence, Directive 2015/412 is an important change. We have already set out the fact that the opposition to the cultivation of "GMOs" by many Member States has appealed, on several occasions, to specious health and environmental justifications which were a fig leaf for completely different (ideological and economic) motivations that could not be admitted as such: we predict that this approach will be abandoned because it is no longer necessary for the purposes which it helped pursue. In fact, by having broad freedom to (pseudo)justify the ban on cultivating unwanted vegetal produce without any longer having to appeal to (pseudo)grounds of alleged intrinsic problems, the "anti-GMO" states will end up sending the EFSA inconsistent dossiers, always duly returned to sender, setting out improbable scientific grounds for hypothetical risks: as early as 2010, commenting the Commission proposal, some authors foresaw a "[potential] reduction in the frequency of Member States implementing health and environmental safeguard clauses on approved GM crops." (Morris and Spillane, 2010, 367). Those alleged motivations were only pretexts, but they served to continue with prohibitionist policies, at least gaining some time. But now the EU Parliament has ratified a partially more correct approach: as before, the EFSA assesses the risk of the new "GMOs" for health and the environment, and the decisions on the general authorisations will still be taken by committees which are not technical but political[11]; but the fierce «centralized» opposition to

[11]Standing Committee on Plants, Animals, Food and Feed, Section Genetically Modified Food and Feed and Environmental Risk http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/regulatory_committees_en.htm; Regulatory Committee 2001/18/EC http://ec.europa.eu/food/plant/standing_committees/rc_2001-18-ec/index_en.htm; Appeal Committee on Genetically Modified Food and Feed and Environmental Risk http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/gm_food_feed_env_risks_en.htm

new recombinant DNA cultivars should ease off significantly, because Member States which are opposed to GMOs, faced with the pressure from others which are in favor, will no longer be interested in trench warfare to block "GMOs" in the whole of the EU, since they will be able to do it comfortably at national level.

Such opinion is shared by certain scholars (Mühlböck and Tosun, 2015), but not by others. "Unity in the EU concerning the approval of GE crops for their various uses, is lacking. Research is required for finding possible mechanisms for breaking the gridlock so that those MSs [Member States] wishing to gain from using these innovations earlier, can do so" (Smart, Blum and Wesseler, 2015, 256). This statement, based on the authors' in-depth analysis of the voting behavior (2003–2015) on "GMO" authorizations in the EU, could have been written before the partial enfranchisement of the single Member States allowed by Directive 2015/412: in our opinion, its legal procedures represent a potential dissolution of the gridlock.

It is a testable hypothesis: time will tell.

It is therefore interesting to note that, with Directive 2015/412, European politicians have deactivated *de jure*, and probably soon *de facto*, a long-standing weapon of the "anti-GMO" brigade: the claim that the opposition to all genetically modified cultivars should be based on their alleged inherent, general danger.

The new directive then states that measures adopted by Member States "should not prevent biotechnology research from being carried out" (European Union, 2015, Preamble, 19): we really doubt that the testing of "GMOs" in the field will start up again in any meaningful way in those EU countries - such as Italy and Austria - where the block has been total; let's hope we will be proved wrong by the facts.

There is also a significant new element that stands out: ostracism can be selective, i.e., it can concern not the entire world of "GMOs," but it can allow the banning of certain crops or even of certain traits (European Union, 2015, Preamble, 13 and Art. 26b, point 3). Let's try to explain the reason for this novelty, which may seem very strange. Are you a politician in country A, where "organic" crops dominate, and you rely on the support and votes of this sector? You will be delighted with the new freedom to ban the whole group of similar "GMOs," even if they are equivalent to or better than organic produce, and also cheaper. Or are you a decision-maker in country B, where the old-fashioned herbicide and pesticide industry is strong (and perhaps legally bankrolls your party)? You can now find some legal excuse to ban corn and soya that are tolerant to weed killers or potatoes and tomatoes that resist mold, i.e., avoid some "GMOs" which reduce the use of products whose trade you wish to support. Ultimately, what do you care if, on the other side of Europe - or even in some bordering states - these vegetables, cereals, pulses or fruits can be grown? You have maintained the consent of your "organic" farmers or of your chemical industry, and you hope they will remember the fact at election time.

Therefore, the Old Continent will most probably become a patchwork of areas where cultivation of a range of similar or very different groups of "GMOs" are forbidden or not, even differing across national borders. For anyone who believes in well-regulated free economy, this Harlequinesque protectionism is certainly a half-empty glass; but we should not forget that up to now the glass had been almost dry - i.e., the prohibitionist ban was EU-wide. In any case, this outcome represents an undoubted split in the single European market, which was so painstakingly built up in the second half of the 20th century.

Leading British scientists, consultants to their government, have long been promoting this opt-out formula of decision-making freedom for the individual states: "to safeguard in part against the losses and damage to European agriculture that follow from the failure to adopt GM crops, we propose that approval for commercial cultivation of new GM crops is made at a national level, as happens at present with pharmaceuticals" (Baulcombe et al., 2014, 4). So this new legal framework creates an independence for EU Member States, which is apparently limited but in reality is broad.[12]

[12]For the list of the countries which have already decided to opt out, see http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm

From the formal viewpoint, the Member States which wish to exclude in their territory, or in part of it, the cultivation of a GMO which is in the process of being authorized (or is the only one already authorized, MON810 Bt corn), will communicate this intention to the Commission, which forward it to the company that is requesting, or has already received, the authorization; the company can decide to exclude the recalcitrant state from the geographical area for which approval is being requested: but in any case, after having waited for a maximum of 75 days for "non-binding comments" from the Commission, the Member State can legislate however it likes (European Union, 2015, Art. 26b, point 4). If in the future it wants to reintegrate previously excluded territory back into the area authorized for cultivation, it only has to communicate it (European Union, 2015, Preamble, 21 and Art. 26b, point 5).

Directive 2015/412 contains no reference to harmonization with the WTO rules: the 2003–2006 dispute has been settled with Argentina and Canada, not yet with the USA (WTO, 2010). As we have already explained, new challenges may be expected by EU states from other WTO members, although the target has shifted: "the ban would most likely constitute a complaint under the TBT [Technical Barriers to Trade] agreement, rather than the SPS [Sanitary and Phytosanitary Measures] agreement" (Punt and Wesseler, 2015, 167).

The Sword of Damocles is still hanging.

The Double Standard is Confirmed[13]

Recently, the European Commission would have liked to complement the reform, amending Regulation 1829/2003 (European Union, 2003): "The Commission therefore proposes to extend the solution agreed in Directive (EU) 2015/412 by the European Parliament and by the Council on GMO cultivation to GM food and feed" (European Commission, 2015b). It is a sort of parallelism: on the one hand, Directive 2015/412 has given Member States the possibility to prohibit, totally or partially, the *cultivation* of "GMOs" on their territories for non-scientific reasons; on the other, a new amended Regulation would give the same power to limit or ban the "use" (*importation*) of "GMOs" to be consumed as food or feed.

This proposal seems coherent: it is far removed from what scientific and legal reason would like to see, i.e., the abolition of all special regimes for so-called "GMOs," whether cultivated or imported, but it is a step which has its own sense of logic: Directive 2015/412 granted individual States the possibility to ban cultivation of recombinant DNA plants; so it would seem appropriate to bring the rules on importing recombinant DNA foods and feeds into line, using the same criterion.

There was, however, a problem: EU parliamentarians immediately showed their fierce, cross-party opposition to the envisaged reform of the current rules for the use of "GMOs" as food or feed (European Parliament, 2015a). EU parliamentary groups named as the rapporteur of their counter-proposal the Chair of the Environment Committee, Giovanni La Via, entrusting him directly with returning the Commission's idea to the sender. At first sight, this seems slightly surprising. So far, almost all politicians have thundered against the cultivation of "GMOs" in the EU, glossing over the fact that Member States import millions of tons of the stuff as animal feed: so why not adopt, on the quiet, a new Regulation that would leave things as they stand? In fact, while many States are using Directive 2015/412 to reiterate the prohibition on cultivation, they could simply avoid to request the opt-out for the import of genetically engineered animal feed.

But it is not quite so simple: it would be very embarrassing for politicians to have to decide *explicitly* whether to grant or ban the import of "GMO" foodstuffs: if they were to authorize it, they would make clear the manifest contradiction in their behavior and undergo the outrage of "anti-GMOers;" if they were to ban it, they would be faced by the catastrophic situation of soon being without soya and corn for European cows and pigs.

[13]This chapter is a summary of Tagliabue (2016c).

Thus, it seems that there is no desire to amend Regulation 1829/2003 (European Union, 2003) simply to leave the status quo intact: "GMO" foods, which are theoretically allowed in the EU, are not to be found on shop shelves as a consequence of the choice made by retailers, who are well aware of the deterrent effect created by obligatory labeling; duly labeled and available "GMO" feed is imported in industrial quantities, because farmers could not care less about the propaganda and have to provide their livestock with good feed.

How therefore can the multi-party rejection of the Commission's proposal be defended? EU parliamentarians justify the rebuttal by highlighting above all the risk of segmenting the EU's single market: if some Member States were to ban the import of "GMOs" while others did not, the argument goes, there would be some very harmful divisions. Yet, one may point out that the single market has already been violated by the directive which allows for the "patchwork" prohibition on cultivating "GMOs."

The European Parliament voted the rejection of the Commission's proposal on 28th October 2015 (European Parliament, 2015b): the Commission must take back its proposal and everything will go on as if nothing had happened.

However, one question remains: why did the Commission, with its proposal to review the rules on importing "GMOs," want to stir things up? What was the logic behind creating problems for the Parliament by inviting it to adopt positions that would certainly be clearer, but which would at the same time highlight the MEPs' contradictions?

Maybe the Commission, which has stated it has no "plan B," i.e., it is unable to present any alternative reform of Regulation 1829/2003 (European Union, 2003), has from the start been tending toward getting the proposal rejected: that way it would highlight the immobilism of Parliament and would have good grounds to arrange faster authorization of the numerous future "GMOs" on which the EFSA will, in all likelihood, express a positive opinion in terms of health and environmental impact.

Contrasting Approaches

So, highly democratic Europe has for many years been indulging in an illiberal form of law-making: the steadfast, continuing "anti-GMO" policy is a clear form of state dirigisme; now it is no longer imposed on all the Member States by the will of some (minoritarianism, i.e., political blackmail) or many (a tyranny of the majority), but this is only the lesser of two evils.[14]

Unfortunately, we must agree with the cutting judgment delivered by a seasoned expert on regulation, who managed to sum up too many years of confused EU agri-biotech law in unusually crude but refreshingly direct language: "Europe has screwed up, royally" (Cantley, 2012, 46).

For a better understanding of these ongoing entanglements, let's distinguish: 1. the scientific side, plus the semantic and legal morass of "GMO" and surroundings, 2. the limbo where the so-called New Breeding Techniques are still stuck, and 3. the political-economic side, i.e., the persistent *vulnus* to the free market.

The Scientific Consensus as a Base for Good Policy

The principle by which the correct criterion is to regulate the product, regardless of the process - and therefore avoid writing the regulation of "GMOs" on the basis of their recombinant DNA origin - was warmly recommended also in Europe right from the start by the most important scientific bodies; it is sufficient here to note the position of the European Molecular Biology Organization: "EMBO strongly believes that there is no scientific justification for additional, special legislation regulating recombinant DNA research *per se*. Any rules or legislation should only apply to the safety of products according to their properties, rather than according to the methods used to generate them" (1 October 1988, 40th meeting of the Council of the EMBO, cit. in Cantley, 1995, 560). But not even

[14]For the EU voting mechanisms, see www.consilium.europa.eu/en/council-eu/voting-system/qualified-majority/

two subsequent letters (see Cantley, 1995, 560–561) in 1989 and 1990 to the decision-makers of the then European Community on the part of sixteen European Nobel prize winners for medicine or chemistry, who were concerned for the future of research and development in the sector of recombinant DNA, managed to convince European politicians to abandon the path of prohibitionist approach for "GMOs."

As the vast majority of scientists recommend, the norms - not only in Europe, but at all geographical levels - should be rewritten, thus uprooting the nonsensical "anti-GMO" fence, re-harmonizing the due analysis and careful supervision, applying the rules, with the necessary strict criteria, impartially on each and every product ("GMO" or otherwise), once created, *a posteriori*, not *a priori* with respect to the biotechnological processes used. This position was reconfirmed for the umpteenth time in a detailed report by the leading scientific council in the EU (the European Academies Science Advisory Council): "A future regulatory framework should be product rather than process based so that it is consistent and applies to the novelty of the characteristics of new plant varieties" (EASAC, 2013, 32).

For the EU, in particular, even an official report which assesses the implementation of the regulation on "GMOs," and which does not spare criticism of the serious flaws with which it has long been tarnished, notes, albeit timidly, how the confusing situation is destined to continue, "especially if the focus is on the techniques used rather than the characteristics of the final products and the traits they express. There is a case for considering the principles that should define the scope of the legislation in the future" (EPEC, 2011, p. 74).

A rational and science-based technical-legal framework is already available: the Stanford Model (more precisely: Stanford University Project on Regulation of Agricultural Introductions) dates back to almost twenty years ago (Barton et al., 1997; see also Miller, 2009) and has been very recently updated (Conko et al., 2016): it is the result of the participatory work of a number of scientists from several countries. The guidelines for careful, well-calibrated risk assessment of new cultivars are explained; to ascertain the pros and cons of each new plant, the different biotech methods are considered irrelevant: the "GMO" pseudo-concept is not even mentioned. As for field tests, sensible questions are provided, regarding the ecological impact (to what extent is the plant potentially invasive?) and the health issues (what exams need to be done to evaluate possible allergenicity or toxicity?). The creators of these guidelines emphasize that it is not a mere theoretical hypothesis, but it draws inspiration from similar experiences which are already well tested in the real world: "One great advantage is that it is analogous to existing regulatory regimes, such as those for quarantine regulations for plant or animal pests, and also to the US government's approach to handling dangerous pathogens or other microorganisms in the laboratory. In other words, the approach is not fundamentally new and has worked well in practice for decades" (Miller, 2009, 633).

The New Breeding Techniques in a Limbo

The persistent rejection of any "GMO-like" agri-food biotechnology would perpetuate the hindering of innovation. There is an entire, blooming field of promising agri-biotech methods which has been flourishing in recent years: collectively called "New (Plant) Breeding Techniques," briefly NBTs (sometimes NPBTs), these achievements are posing a stronger challenge to the shaky "GMO" pseudo-concept, especially in Europe (Sprink, Eriksson, Schiemann and Hartung, 2016). The subject has been engaging the EU Commission and an appointed committee of experts since 2008: the detailed story of a wrong question ("Are these techniques producing GMOs?") which cannot have a clear answer - and even if such answer could be given, it would be meaningless - has been told elsewhere (Tagliabue, 2016a). The question is wrong, for two strong reasons: 1. as we have already noted, defining "GMOs" is an exercise in futility, because there is no clear border, but a blurry watershed; and - most important! - 2. the pros and cons of any agri-food novelty cannot be linked *in advance* to one or another biotech method used by

breeders: that's why we have lists of unsatisfactory "GMOs," as well as a number of new cultivars from "traditional" breeding methods which have been reportedly discarded (see Haslberger, 2003, 739 and 740; Kuiper et al., 2001, 516; see also http://cls.casa.colostate.edu/transgeniccrops/defunct.html).

Anyway, the embarrassment in deciding on such a thorny issue has delayed any decision by the EU Commission: as of the end of 2016, the Final report of the Working Group on New Breeding Techniques, released in April 2012, has not been officially presented yet, and the status of NBTs is still in limbo. In the meantime, such Report, long discussed and not yet published, is already outdated: the very recent explosion of the CRISPR-Cas revolutionary gene-editing approach - which is much broader in scope than the application to new cultivars, but is certainly the *newest* breeding technique, opening extraordinary landscapes (see Hall, 2016) - is obviously absent from the Report. While the "GMOity" of CRISPR products is just a too expected stance of the usual agricultural biotech opponents[15], the hope of many scientists is that a gesture of courage from the Commission - as well as by other regulatory agencies all over the world - will legally exempt the NBTs from entering the "GMO" red tape thicket, applying the only science-based criterion for the assessment of new cultivars - the already explained "product, not process" approach. (Carroll, Van Eenennaam, Taylor, Seger, and Voytas, 2016). A few countries have already chosen to exclude the NBTs from the "GMO" smothering umbrella (see Schuttelaar & Partners, 2015).

So, the EU Commission will have to assess the long overdue legal status of the New Breeding Techniques: a decision that could possibly allow a step outside the quagmire is to avoid regulating them as "GMO" methods, as far as, once this or that technique has been applied, no "foreign DNA" is present in the final products. Such a position is encouraged by some experts (Huang et al., 2016; Nature, 2016; EASAC, 2015), and even a clever performance in hair-splitting has proposed to set the limit of exogenous DNA at less than 20 base pairs (NBT Platform, 2013, 2.6. The insertion of small nucleotide sequences).

It would be a botched compromise, starting from an unscientific stance: the same concept of "foreign" or "donor" DNA is weird, since the protein or trait which is expressed in a phenotype must be considered on its own merits and demerits, without assigning a peculiar relevance to the origin on the DNA sequences (the genes) that "dictate" the outcome. But such an accommodation will at least disembarrass a good part of the agri-biotech novelties from an otherwise never-ending regulatory nightmare.

Denying the Free Market for Political Opportunism: The "Schumpeterian" Realpolitik

The ongoing "GMO" troubled situation shows a mistreatment of both the ideal and practical realization of a well-regulated free market in agriculture, both inside the EU and with respect to Europe's trade relationships with the rest of the world.

The mosaic-like "anti-GMO" protectionism denies many economic players a real freedom to act or to move in new directions: seed companies cannot legitimately market their newest products in the "opting-out" Member States; farmers who would like to shift to enhanced cultivars may be forbidden to use them; consumers cannot reap the full benefits of improved products, in terms of both nutritional value and fairer prices; traditional agri-food chemical producers are not motivated to change - quite the opposite.

Why did EU office-holders refuse to embrace a science-based approach in the "GMO" continuing policy decisions? Rational observers must be very perplexed, if they are not aware that public choices are often dictated by a different kind of logic: politicians will always proclaim their approach to be inspired by the optimal search for common good, but a much less idealistic reading was proposed decades ago

[15] www.theecologist.org/News/news_analysis/2986839/gm_20_geneediting_produces_gmos_that_must_be_regulated_as_gmos.html

by Joseph Schumpeter, when he argued that, in a democracy, any political or administrative action is a mere corollary of the opportunistic estimates which every law-maker adopts: "The democratic method produces legislation and administration as by-products of the struggle for political office" (Schumpeter, 1942, p. 286). It is impossible to escape the clear impression that such a disposition is applicable in our case, and maybe most "normal" politics falls into the narrow definition highlighted by the great economic-political thinker.[16]

Another quotation may reinforce the understanding of the mind-set which leads to such patently unscientific policy decisions: "Politically speaking, the man is still in the nursery who has not absorbed, so as never to forget, the saying attributed to one of the most successful politicians that ever lived: «What businessmen do not understand is that exactly as they are dealing in oil so I am dealing in votes." (Schumpeter, 1942, p. 286) Crude but truthful realism, which explains and exposes policy outcomes substantially dictated by a calculus of consent: most probably, in our case EU politicians reckoned that following the "anti-GMO" wave would have cost them less than the possible outrage deriving from encouraging recombinant DNA crop cultivation. It is called political expediency, and it is too often the main rule of the game.

We could also call it a Machiavellian approach: if the end is to conquer and/or maintain and/or widen power, and in democracy this means anticipating the probable reaction of public opinion (read: voters) and/or legitimately collecting funds from economic lobbies, it is easy to link a means to an end: avoiding the fury of the "anti-GMO" brigade, as well as protecting some industries from competition, was worth reiterated decisions which set science aside, while at the same time those affected by the consequences (consumers, farmers interested in better seeds) were not expected to protest too much. They did not.

As for the main dynamics which drove the European lawmakers toward imposing the "anti-GMO" straitjacket, the best explanation is given by an author who for decades has been following the developments of the "anti-GMO" movement and the creation of the strictest regulations in the world: politicians "were in many countries acutely conscious in the late 1980s that the major political parties were losing ground to the Green movements; and to recapture these votes, were anxious to demonstrate their own "Green" credentials. A severely restrictive approach to the highly publicized new gene technology appeared to be a painless and popular way of doing so" (Cantley, 1995, p. 670).

That happened almost three decades ago. There is no sign that such Schumpeterian-Machiavellian approach is going to change, as far as "GMO" regulation in the EU is concerned.[17]

What about the Future?

For the thorny "GMO" issue, it is difficult to see a rational development in the short term, i.e., the recognition by EU lawmakers that agricultural biotech regulation has to be open for real to scientific inputs and to a consistent development of free trade.

A pessimistic (realistic) note. Hysteresis - a persistent effect of a temporary stimulus - is a concept that, as applied to political-economic and social dynamics, in our case strongly contributes to explaining the inertia of the continuing "anti-GMO" attitude in the EU (Swinnen and Vandemoortele, 2011).

An optimistic (utopian?) note. At the end of 2015, the "three institutions" of the EU (the European Parliament, the Council and the Commission) published the text of a proposed "interinstitutional agreement on better regulation" (European Commission, 2015c) whose

[16]For a particular case of Schumpeterian "anti-GMO" policy decision in the EU, see Tagliabue (2016b).

[17]One may wonder why the politicians' approach regarding agri-food biotechnology was so different in the Americas. This analysis is beyond the scope of this paper, but it is clear that diverse socio-economic incentives were at work: see Zilberman et al. (2013).

primary aims are "delivering high quality legislation, ensuring that Union legislation [. . .] is as simple and as clear as possible, avoids over-regulation and administrative burdens for administrations, businesses and citizens, and especially for small and medium-sized enterprises" (European Commission, 2015c, 2). Ambitious objectives. To pursue such results in the area of green biotechnologies, the EU should recognize an historical blunder, acknowledging the benefits of rDNA innovation (Smyth, Kerr and Phillips, 2015) and therefore, applying its stated "obligation to legislate only where and to the extent it is necessary" (European Commission, 2015c, 3), should scrap any sectoral and sectarian regulation on so-called "GMOs." Plain and (not) simple.

The absurd and counterproductive "GMO" imbroglio should have never seen the light of day: we must never give up on exposing its noxious consequences. Hoping to bury it, eventually.

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

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Appendix: Use of the safeguard clause concerning the cultivation of GMOs

List received from Europe Direct Contact Centre [Case ID: 1084061 / 3394679] on 7 October 2015

Member State	Product	Date of notification	EFSA opinions or statements (publication)	Further clarifications
Austria	MON 810 maize	June 1999	10 December 2008	The proposed decision (COM(2009) 56 final, 10.2.2009) requesting Austria to lift its ban on cultivation was rejected by the Council on 2 March 2009.
Hungary	MON 810 maize	January 2005	25 July 2005 (updated on 6 July 2006)	The proposed decision (COM(2006) 713 final, 23.11.2006) requesting Hungary to lift its ban was rejected by the Council on 20 February 2007.
			11 July 2008	A further proposed decision (COM(2009) 12 final, 21.1.2009) requesting Hungary to lift its ban was rejected by the Council on 2 March 2009. This ban is no longer in force but was replaced by a new ban (cf below).
		April 2013	None	
Luxembourg	MON 810 maize	March 2009	None	This ban is no longer in force but was replaced by a new ban (cf below).
		June 2012	24 September 2013	
Germany	MON 810 maize	April 2009	None	
Bulgaria	MON 810 maize	April 2011	None	This ban is no longer in force but was replaced by a new ban (cf below).
		April 2014	16 December 2014	
France	MON 810 maize	February 2008	31 October 2008	Ban annulled by the French Conseil d'Etat.
		February 2012	21 May 2012	Ban annulled by the French Conseil d'Etat.
		February 2014	1 August 2014	
Italy	MON 810 maize	July 2012	24 September 2013	Ban prolonged by 18 months early in 2015 (cf below)
		February 2015	None	
Greece	MON 810 maize	March 2006	17 November 2006	This ban is no longer in force but was replaced by a new ban (cf below)
			11 July 2008 (*on new elements submitted in September 2007*)	
		November 2011	11 September 2012	This ban is no longer in force but was replaced by a new ban (cf below)
		November 2013	10 June 2014	
Greece	Amflora potato	July 2012	None	Authorization annulled by the General Court on 13 December 2013 (case T-240/10). These bans have thus become devoid of purpose.
Austria	Amflora potato	June 2010	28 March 2012	
Hungary	Amflora potato	July 2010	19 December 2012	The Greek ban expired this year and was not renewed.
Luxembourg	Amflora potato	June 2010	20 September 2012	
Poland	Amflora potato	January 2013	None	
Austria	T25 maize	May 2000	10 December 2008	The proposed decision (COM(2009) 51 final, 10.2.2009) requesting Austria to lift its ban was rejected by the Council on 2 March 2009. In 2013 the authorization holder withdrew its application for renewal of the authorization for cultivation. This ban has thus become devoid of purpose, since this maize is no longer authorized for cultivation