Review

Feature Review

Paradoxical EU agricultural policies on genetically engineered crops

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European Union (EU) agricultural policy has been developed in the pursuit of laudable goals such as a competitive economy and regulatory harmony across the union. However, what has emerged is a fragmented, contradictory, and unworkable legislative framework that threatens economic disaster. In this review, we present case studies highlighting differences in the regulations applied to foods grown in EU countries and identical imported products, which show that the EU is undermining its own competitiveness in the agricultural sector, damaging both the EU and its humanitarian activities in the developing world. We recommend the adoption of rational, science-based principles for the harmonization of agricultural policies to prevent economic decline and lower standards of living across the continent.

Importance of agriculture in the EU

Agriculture is one of the most important pillars of social and economic development in the EU, and Europe remains one of the world's largest traders in agricultural products (Figure 1) (http://ec.europa.eu/agriculture/publi/map/01_12_en.pdf). However, a substantial genetic gain in yield potential and stress resistance is required to ensure that sustainable agricultural practices can be developed to meet the demands of a growing population in Europe and in the many agriculture-dependent developing countries (http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf) [1].

EU agricultural policy is proposed by the European Commission, approved by agriculture ministers in EU member states, and ratified by the European Council and Parliament. The stated objectives are to support farm incomes, encourage the production of high-quality goods led by domestic and export market demands, promote environmentally sustainable practices, and increase the competitiveness of European agriculture (http://ec.europa.eu/agriculture/cap-overview/2012_en.pdf). However, the common agricultural policy (CAP) of the EU has provoked intense criticism because it reduces competitiveness, productivity, and sustainability, and ultimately invites economic and social instability (http://www.agriregionieuropa.univpm.it/materiale/2011/Erjavec_OptionsForTheCAP_16_2_2011.pdf). Although they aim to promote environmentally sustainable agricultural practices, nutritious food, and inexpensive medicines, EU policies hamper the development of key technologies to achieve those objectives.

There are three major paradoxes in current EU agricultural policy that not only affect agriculture directly but also have knock-on effects on the environment, on human health, on the wider economy, and on food security in developing countries. First, the Lisbon Strategy aims to create an EU knowledge-based bioeconomy (KBBE) and recognizes the potential of genetically engineered (GE) crops to deliver it [2], but EU policy on the cultivation of GE crops has created an environment in which the aims of the Lisbon Strategy can never be achieved. The policy sets a framework for coexistence measures ensuring sufficient segregation between GE and conventional crops, thus offering choice to farmers and consumers [3,4], but also encourages the haphazard implementation of these measures without coordination or a rational scientific basis, including plans to allow member states and their regions an unconditional opt-out. This has imposed a *de facto* moratorium on GE maize (*Zea mays*) and soybean (*Glycine max*) crops in Europe, even though these same GE products are imported because there is insufficient capacity to grow these crops using conventional agricultural practices [5].

The second paradox is the CAP, which aims to ensure a stable supply of high-quality food for the EU population at fair prices while providing farmers with a reasonable standard of living and preserving rural heritage [6]. However, most of the subsidies available under the CAP are used to benefit large producers rather than family farms (http://www.attac-netzwerk.de/fileadmin/user_upload/AGs/Agrarnetz/EU-Agrarpolitik/marita_eusubsidies.pdf), and the dumping of CAP-subsidized EU products disrupts agriculture in developing countries (http://www.cedia.eu/en/policy/2011/swiss_paper_cap_policy_2011.pdf). The third paradox is the contrast between policy aims and outcomes.

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Keywords: genetically engineered crops; EU agricultural policies; CAP; pesticides; food security.

1360-1385/$ – see front matter
 http://dx.doi.org/10.1016/j.tplants.2013.03.004

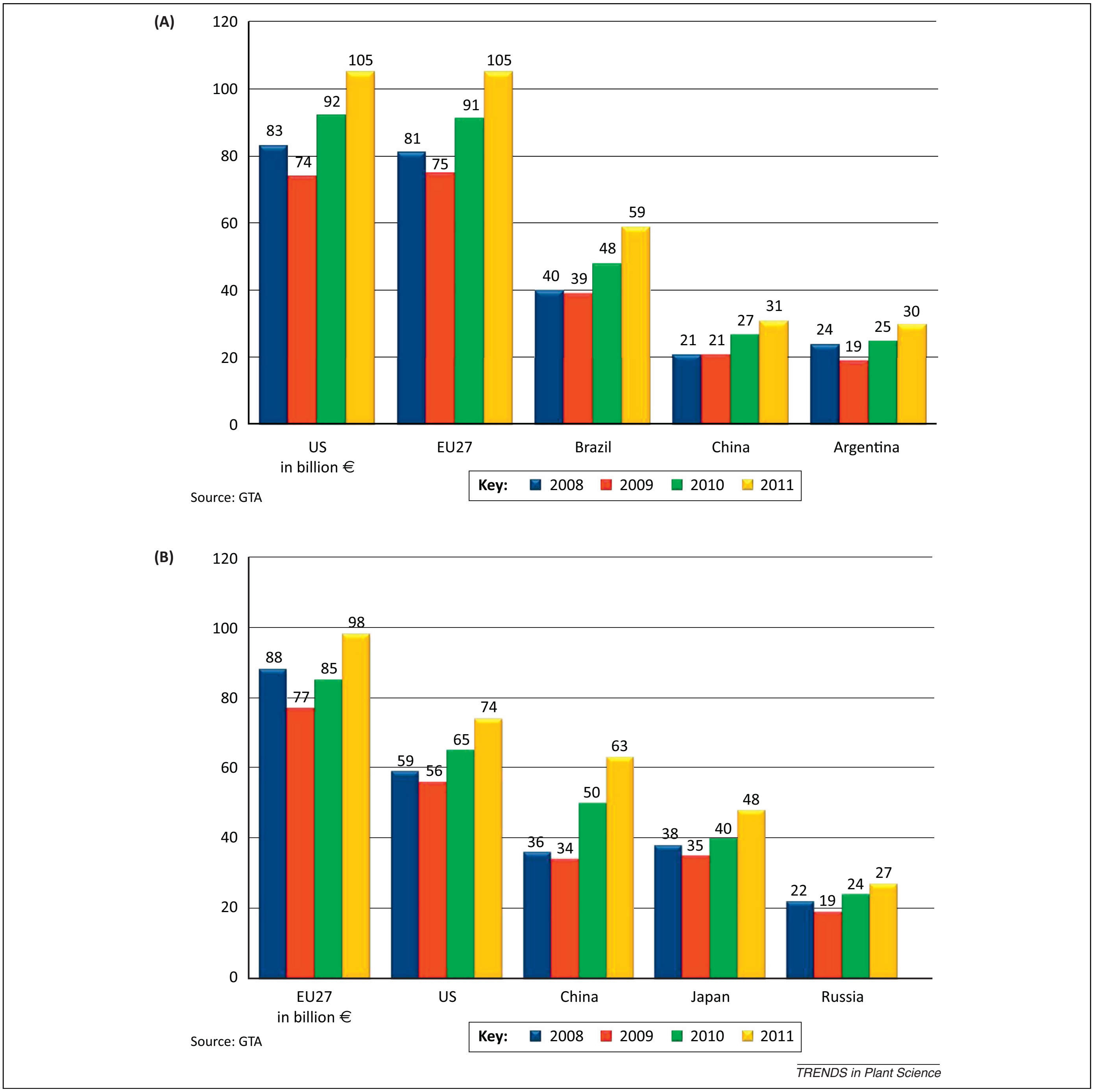


Figure 1. The world's top five **(A)** exporters and **(B)** importers of agricultural products (reproduced from http://ec.europa.eu/agriculture/trade-analysis/map/05-2012_en.pdf). (A) EU exports fell in 2009 but increased in 2010 and 2011 to record levels. (B) The EU is currently the largest importer in the world, although the USA and China have increased imports since 2009.

For example, the EU has banned many pesticides, but approves the import of food products treated with banned chemicals (http://europa.eu/legislation_summaries/food_safety/plant_health_checks/l21289_en.htm; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1976:340:0026:0031:EN:PDF).

This review focuses on the role of GE agriculture, how its deployment in Europe is necessary to achieve the stated goals of EU agricultural policy, and how continued resistance is placing short-term political and economic interests above the long-term goals of environmentally sustainable agriculture, food safety, and human health (Table 1). The 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 [3]. This policy is actively working against the EU's own goals, driving research, development and innovation abroad, and granting commercial and economic benefits to other countries that then sell the products back to EU member states [5]. The EU is thus becoming increasingly uncompetitive and isolated in the international markets, which thrive on innovation and technological development in agriculture [7,8].

Table 1. Paradoxes among agricultural and health policies of the EU

Policy	Intention	Reality	Consequences	Solution
Knowledge-based economy				
KBBE	To promote European competitiveness based on excellent science and technology using industry as a base to deliver innovations.	The development of innovations in GE agriculture is blocked, SMEs are failing and major industry is moving overseas.	EU agriculture will not benefit from innovations and its competitiveness will be reduced.	Promote high-quality agricultural biotechnology, in both the public and private sectors by streamlining the regulatory pathway for GE crops.
Agricultural policy				
CAP	Increase agricultural productivity and ensure a good standard of living for the agricultural community, stabilize markets, and ensure fair prices for consumers.	Promotes the overproduction of noncompetitive commodities, inequality in the distribution of subsidies, and the artificial competitiveness of EU produce. Isolates the EU from world market fluctuations.	A substantial portion of the EU budget is wasted. Large producers gain subsidies at the expense of small farmers. Products are dumped on developing country markets damaging local infrastructure. The adoption of competitive technologies such as GE crops is obstructed.	Increase competitiveness by adopting agricultural innovations such as GE crops. Combine a reduction in subsidies with policies that prevent dumping. Reduce the overproduction of crops.
Trade policy				
Treaty on the Functioning of the EU Article 207 EC	Balance agricultural import and export to meet the demands of home and export markets in the most economically beneficial manner.	EU imports animal feed (mainly soybean and maize) because it cannot meet home demand. More than 80% comes from GE producers, with 39 GE crops authorized for import but only 2 (1 food crop) for cultivation. Member states do not allow their own farmers to grow GE crops even if they are identical to imported varieties. Imports must meet EU thresholds for adventitious presence.	EU farmers cannot use new technologies such as GE to increase competitiveness. Imported foods are impounded if they fail EU thresholds, creating trade barriers, economic damage to importers and exporters, and the perception of the EU as an economic risk for exporters. Decline in overall trade with the rest of the world.	Rationalize and harmonize EU policy on the cultivation and import of GE crops.
Coexistence measures				
Recommendation 2003/556/EC	Coexistence measures should be transparent, science-based, and proportionate and should embrace cross-border cooperation, equal stakeholder involvement, and coherent liability rules to provide farmers with freedom of choice.	Coexistence measures are purely an economic issue. They are neither proportionate nor science-based and discriminate against farmers seeking the choices the measures are meant to promote. They place farmers at risk of litigation and effectively ban GE agriculture in large areas of the EU.	Suppression of GE agriculture, which will damage the EU economy and global scientific standing. Increases the public's negative perception of GE crops. Reduces freedom of choice.	Harmonization of coexistence measures throughout the EU with a strict evidence-based threshold for minimum distances.
Recommendation 2010/C 200/01	Autonomy for member states to manage the cultivation of GE crops unilaterally, develop their own coexistence regulations, and overturn EFSA recommendations without presenting new evidence, ostensibly to prevent EU-wide bans caused by a minority of uncooperative member states.	The lack of EU-wide regulations means that member states can impose arbitrary minimum isolation distances that have no scientific basis and make approval decisions for political rather than scientific reasons.	The creation of GE free zones in Europe, pandering to extremist views, and further damage to the public's perception of GE agriculture.	Strict adoption of EU-wide science-based rules for the adoption of GE crops backed up by legal sanctions against countries that do not comply.

Trends in Plant Science June 2013, Vol. 18, No. 6

Table 1 (*Continued*)

Policy	Intention	Reality	Consequences	Solution
Environmental policy				
Regulation (EC) 1698/2005 and Regulation (EC) 1257/1999	Improve the competitiveness of the agricultural and forestry sector, improve the environment and the countryside, and improve the quality of life in rural areas by encouraging diversification of the rural economy by increasing agricultural subsidies.	Subsidies, grants, and export refunds do not provide enough to keep EU farmers competitive. Market-driven agriculture is reducing crop diversity, promoting deforestation, and reducing long-term sustainability.	Loss of competitiveness in the rural farming sector and rural economy generally.	Decentralize rural economy measures and allow farmers to use cost-saving technologies that can enhance productivity and profitability in a more sustained manner.
Regulation 396/2005/EC	Set maximum residue levels (MRLs) for pesticides used in the EU to eliminate trade barriers and increase market transparency.	Allows the import of foreign products treated with pesticides banned in the EU. Different MRLs for home-grown and imported products.	Farmers must reduce the use of pesticides but must compete with imports of crops treated with the same chemicals. Restriction to a small number of essential pesticides means that resistance becomes more likely. The MRLs set by the EU are a trade barrier for developing countries.	Harmonize MRLs based on scientific evidence and allow the cultivation of GE crops that are competitive without the need for pesticides.
Regulation 1107/2009/EC	Promote environmentally sustainable practices by banning many pesticides and encouraging the use of integrated pest management and nonchemical alternatives.	Exception for 'essential pesticides' that cannot be replaced means that farmers focus on a small number of products but overall use does not change.	Increases the risk that pests and pathogens will evolve resistant populations against the limited number of permitted chemicals. More effective chemicals cannot be used thus overall pesticide levels in the environment increase.	Allow the use of pesticides on a case-by-case basis where minimum harm is achieved. Allow the cultivation of GE crops that reduce pesticide usage.
Health and safety policy				
Regulation 165/2010/EEC	Ensure the protection of public health and, where appropriate, set maximum levels for certain contaminants.	Stringent levels for mycotoxins compared with the rest of the world.	Generates a trade barrier with countries unable to meet EU limits. Benefits the high-quality export market for which the EU pays a premium, whereas lower quality commodities are used for domestic markets in developing countries.	Harmonize levels based on scientific evidence. Allow the cultivation of Bt crops that reduce mycotoxin levels.
EU policy on nutrition	Protect consumer health while guaranteeing smooth operation of the single market by ensuring that food hygiene control standards are established and met, reducing the risk of contamination.	EU agriculture policy blocks the development of cost-effective technologies that increase the quality and quantity of food grown in Europe, and the production of more accessible pharmaceuticals for the EU and developing countries.	Budget required for the treatment of food-related diseases and to meet the costs of increased disability-adjusted life years.	Allow the cultivation of crops bred for increased nutrition and pharmaceutical production.
Directive 2001/83/EC (also Regulation EC 726/2004 and EC 1394/2007)	Directive 2001/83/EC requires individual approvals for the manufacture of health products in the EU. The other policy instruments established the EMA and set up rules to ensure the free movement of biotechnology-derived drugs within the EU.	The authorization and marketing of novel pharmaceutical products from plants is regulated jointly by the EMA and the EFSA.	The development of novel and inexpensive pharmaceutical products is hindered by regulatory complexity, meaning that both developed and developing countries need to pay more than necessary for essential drugs.	Unification of the regulations so that there is a single process for the approval of medicines derived from plants.

The CAP no longer fits

The policy instruments encompassed by the CAP were intended to provide farmers with a reasonable standard of living while preserving rural heritage and ensuring a stable supply of high-quality and fairly priced food within the EU [6]. However, the objectives have changed over the years, and now most of the subsidies go to large food-processing and trading companies along with the wealthiest farmers, protecting the larger industry players from the economic impact of competition with imports [9] (http://ec.europa.eu/agriculture/publi/app-briefs/01_en.pdf), whereas small farms are largely ignored unless they fall within the scope of rural development programs (http://www.cedia.eu/en/policy/2011/swiss_paper_cap_policy_2011.pdf) or they are linked to the organic farming industry and become automatically eligible for payments because of their perceived environmental benefit (http://www.soilassociation.org/news/newsstory/articleid/2690/soil-association-welcomes-cap-reform-announcements; http://europa.eu/rapid/press-release_IP-11-1181_en.htm?locale=en). Another major criticism is that direct payments and export refunds promote the practice of dumping (i.e., exporting at prices below the cost of production), which allows artificially competitive EU commodities to displace home-grown products in developing countries [10]. Similar criticism has been leveled at US Farm Bills [11,12].

Maintaining the CAP in its current state means that the EU will continue to waste a large proportion of its budget supporting uncompetitive producers and processers, while poorer farmers remain in poverty and agriculture in developing countries is suppressed. GE agriculture would offer a competitive advantage to food producers and processers based on the adoption of new technology rather than artificial subsidies. Some claim that reducing or abolishing subsidies will not have the predicted positive impact on prices and the welfare of small farmers [13]. Instead, they propose a combination of reduced subsidies and policies that place limits on export dumping, global commodity overproduction in key crops, and the market power of agribusiness conglomerates [14].

KBBE – support in principle, obstruction in practice

The Lisbon Strategy was launched in 2000 by the European Council to increase the productivity and competitiveness of the EU by aspiring to create '...the most dynamic and competitive knowledge-based economy in the world...' (http://www.europarl.europa.eu/summits/lis1_en.htm). Knowledge is considered a valuable resource for economic growth and social welfare, highlighting the importance of investment in research and development [2]. Biotechnology and the life sciences were identified as essential components of this strategy with the establishment of the KBBE, which accounts for €1.5–2 trillion of the EU gross domestic product (Table 2) (http://www.bio-economy.net/reports/files/KBBE_2020_BE_presidency.pdf).

A bioeconomy comprises all the industries that produce, manage, or exploit biological resources. Because crops are the major source of biomass used by humans, the EU has recognized the potential of agricultural biotechnology as a means to increase the yield and quality of economically relevant crops [15]. But despite official acknowledgement of the potential benefits, and generous funding of precompetitive research in this area, little has been done to promote translational research and the commercialization of agricultural technology so that the benefits are realized at the farm and consumer levels. Indeed, the EU's politicians and policymakers have actively obstructed the adoption of GE agriculture through the establishment of complex and inconsistent regulations that strongly discourage farmers from considering the technology.

Table 2. EU bioeconomy

Sector	Annual turnover (billions of euro)	Employment (thousands)	EU population (%)
Food	965	4400	0.880
Agriculture	381	12 000	2.400
Paper and pulp	375	1800	0.360
Forestry and wood	269	3000	0.600
Fisheries and aquaculture	32	500	0.1 00
Biobased industries			
Biochemicals and plastics	50[a]	150[a]	0.030[b]
Enzymes	0.8[a]	5[a]	0.001[b]
Biofuels	6[c]	150	0.030
Total	2078	22 005	4.400

[a]Estimate 2009.

[b]http://www.bio-economy.net/reports/files/KBBE_2020_BE_presidency.pdf.

[c]Estimate based on the production of 2.2 million tons of bioethanol and 7.7 million tons of biodiesel at average EU market price.

EU legislation for the approval of GE crops (Directive 2008/27/EC and Regulation EC 1829/2003) is the most restrictive in the world. Regulatory compliance for a new crop can cost up to €11 million and requires a dedicated legal team working for many years [16]. For example, the Amflora potato took 15 years to develop, 13 of which were required for regulatory approval. Such onerous regulation blocks the approval pathway to all but the most committed and well-funded companies, preventing the realization of innovation generated by public sector institutions and small-to-medium enterprises (SMEs) unless they agree to collaborate with major industry players [17,18].

Perhaps more importantly, the final decision for approval is political rather than scientific. As part of the regulatory process, a scientific opinion on safety must be sought from the European Food Safety Authority (EFSA), the official and expert scientific body charged with the task of safety evaluation in the EU. This opinion is based on the views of expert panels that consider the available scientific evidence. However, the opinions of the EFSA are routinely ignored by many member states and the EU has recently approved a plan to allow member states an opt-out for the cultivation of approved GE crops with no requirement for scientific justification or evidence of risk (http://www.europabio.org/sites/default/files/europabio_-_ernst_young_report___what_europe_has_to_offer_biotechnology_companies.pdf; http://www.europarl.europa.eu/news/en/headlines/content/20110627FCS22686/8/html/GMOs-Parliament-backs-national-right-to-cultivation-bans). Although the ostensible reason for the proposal is to allow member states to adopt GE agriculture on an individual basis rather than relying on voting in the European Parliament, the European

Commission, and ultimately the Council of Ministers, the opt-out may only serve to legalize the formerly illegal (although widely practiced) strategy of declaring GE-free zones within the EU, thus damaging not only the EU economy but also its global scientific standing and opposing the basis of the Common Market [5].

The lack of GE agriculture in the EU is an overall symptom of the promising but poorly executed Lisbon Strategy. By failing to uphold the rights of farmers to adopt GE crops, the EU is moving rapidly away from the KBBE model, actively discouraging innovation and investment in the sector, stifling the growth of SMEs, driving research and development abroad, and therefore handing the EU's competitive advantage to the industry in North and South America and Asia (http://www.basf.com/group/corporate/en/function/conversions:/publish/content/news-and-media-relations/news-releases/downloads/2012/P109e-PlantBiotechnology.pdf).

Farmers – choice in principle but not in practice

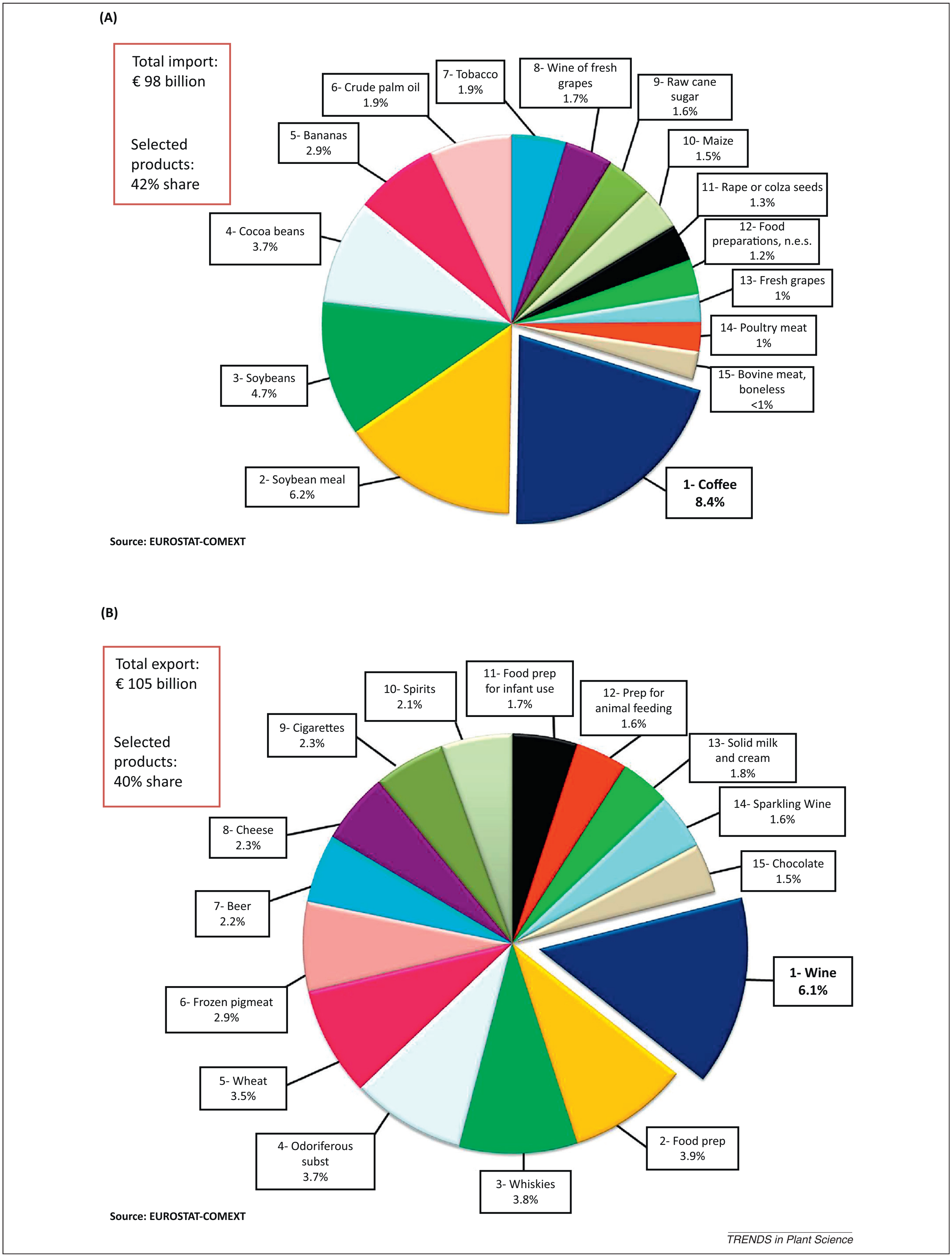
EU policy officially supports the coexistence of GE and conventional agriculture, and lays down coexistence regulations by allowing member states to establish minimum distances between fields of GE and conventional crops to prevent admixture. Coexistence refers to the ability of farmers to make a practical choice among conventional, organic and GE crops, in compliance with legal obligations for labeling and/or purity standards as defined in European Commission legislation. The European Commission has published detailed and pragmatic recommendations for the development of coexistence regulations for implementation at national or regional levels, based on a tolerance threshold for adventitious presence above which a conventional crop must be labeled as containing GE material (http://ec.europa.eu/agriculture/publi/reports/coexistence2/index_en.htm). Despite the absence of any science-based public health or environmental safety justifications, the regulations were developed in response to lobbying by self-regulating organic industry groups which claimed that adventitious presence could reduce the value of a conventional or organic crop, particularly the latter, which is often sold at a premium. This implicitly acknowledges that coexistence measures are concerned with the economic impact and not the health or environmental safety of the product, given that no GE crops can be grown without a positive safety evaluation from the EFSA [19,20] (http://www.gmcc13.org/files/proceedings_gmcc05.pdf).

The adventitious presence thresholds in the EU are the strictest in the world. There is a two-tier tolerance policy (EC 1830/2003) with a 0.9% adventitious presence limit applied to approved products and zero tolerance applied to unapproved products, replacing the temporary 0.5% second-tier limit previously approved by the EFSA. There are clear scientific principles that can be used to establish acceptable minimum distances between GE and conventional crops and other mitigation strategies to achieve these thresholds, and these principles are explained in Recommendations 2003/556/EC and 2010/C 200/01 to allow the development of national coexistence strategies and best practices. The major changes in Recommendation 2010/C 200/01 provide individual member states with greater flexibility and responsibility for their own coexistence policies, aiming to speed up pending authorizations by removing the ability of those member states to veto approvals throughout the EU. However, the practical effect of these recommendations has been to allow member states to impose arbitrarily large minimum distances between conventional and GE crops so that GE agriculture is effectively prevented unless farmers agree to surround their crops with large areas of uncultivated land or risk litigation from surrounding farms [5,21]. As a consequence, only 100 000 ha of GE crops was grown in the EU in 2012

Table 3. Paradoxes among coexistence measures of the EU[a]

Principle	Intention	Consequence
Transparency	National strategies and best practices for coexistence should be developed in a transparent manner.	Coexistence requirements are confusing and those implementing them are unaccountable [3,4].
Cross-border cooperation	Member states should ensure cross-border cooperation with neighboring countries to guarantee the effective functioning of coexistence measures in border areas.	There is no cooperation because member states act independently and national governments are responsible for coexistence policies. Each member state establishes a legislative framework on a crop-by-crop basis [3,4].
Stakeholder involvement	National strategies and best practices for coexistence should be developed in cooperation with all relevant stakeholders.	GE farmers are sidelined. Farmers who choose to grow GE crops have to invest extra money to comply with the excessive coexistence measures [21,23].
Based on scientific evidence	Management measures for coexistence should reflect the best available scientific evidence on the probability and sources of admixture between GE and non-GE crops.	The thresholds for adventitious presence are far stricter than for conventional crops and the isolation distances enforced to achieve such thresholds are arbitrary, excessive, and are politically motivated rather than reflecting scientific reality [3].
Proportionality	Measures to avoid the unintended presence of genetically modified organisms (GMOs) in other crops and vice versa should be proportionate to the intended objective (protection of the particular needs of conventional, organic, and GE farmers).	Measures are neither regionally nor economically proportionate [23]. Proportionality is still linked to economic loss even if not necessarily to the labeling thresholds [3].
Liability	The policy instruments adopted may have an impact on national liability rules in the event of economic damage resulting from admixture.	Strict liability regulations mean that GE farmers are always responsible for any admixture and risk fines or litigation from surrounding farms [3,4,21,23].

[a]http://ec.europa.eu/agriculture/publi/reports/coexistence2/index_en.htm.



(See figure legend on the bottom of the next page.)

(http://www.isaaa.org/resources/publications/briefs/43/). In Luxembourg, for example, it is necessary to leave 800 m between GE and non-GE maize plots and 3 km between GE and non-GE rapeseed (*Brassica napus*) plots. Similarly in Latvia, it is necessary to leave 4 km between GE and non-GE rapeseed and 6 km if the non-GE rapeseed is organic [4]. These national coexistence strategies do not comply with most of the key coexistence principles established by the European Commission, as summarized in Table 3.

Exaggerated coexistence measures are often justified in the name of safety even though the principal reason is to achieve established tolerance thresholds, but this nevertheless damages the perception of GE crops because most consumers only note the nature of the regulations, not the underlying justification. Coexistence measures are therefore being used as a convenient and politically expedient proxy for EU policymakers to prohibit GE agriculture, limiting the extent of GE agriculture in Europe to less than 115 000 ha in 2011 and approximately 100 000 ha in 2012 compared to 160 million ha in the rest of the world [3,4].

Most EU farmers are indirectly denied the choice of growing GE crops and must therefore continue to use unsustainable and uncompetitive farming practices, making them unwitting coconspirators to maintain the CAP. A recent study showed that coexistence measures that actually ensured the coexistence of GE and non-GE crops rather than preventing GE agriculture would alter the attitude of farmers towards the adoption of GE technology [22]. GE crops would reduce production costs by reducing pesticide use, labor, and fuel consumption, resulting in significant economic benefits (http://ec.europa.eu/food/plant/gmo/reports_studies/docs/economic_performance_report_en.pdf). However, the ability of member states to impose their own rules means that farmers choosing to adopt GE crops in nonsupportive member states lose any economic advantages the technology might bring through the costs of compliance, negotiations with surrounding farms, and insurance to cover litigation in the event of admixture [23]. The obligations placed on farmers growing conventional or organic crops are much less restrictive than those growing GE crops [23–25].

Safe to eat, but only if imported

As discussed above, food derived from approved GE crops has been deemed safe for human consumption by the EFSA. Approval must also be granted by the equivalent body in the USA, which comprises experts from the US Department of Agriculture (USDA) and the Food and Drugs Administration (FDA). Notably, even in the highly litigious USA, there have been no lawsuits, no product recalls, no reported ill effects, and no other evidence of risk from a GE product intended for human consumption since the technology was first deployed commercially in 1996.

The perceived risks of GE food and feed to human health persist in the EU despite all the contrary evidence from the regulators and the lack of harm in countries that have embraced the technology. Further evidence comes paradoxically from the population of the EU itself, which regularly consumes GE food imported from other countries because the restrictions that apply to home-grown GE foods do not apply to imports. Indeed, the EU is largely dependent on GE products from abroad [25]. Approximately 80% of animal feed consumed in the EU is imported, of which more than half is GE produce imported from countries such as Brazil, the USA, and Argentina, which are the largest exporters of GE products [25] (http://www.europabio.org/sites/default/files/position/pocket_guide_gmcrops_policy.pdf). The EU is dependent on soybean meal from South America and dried distillers' grains of maize from the USA (Figure 2) [26]. In 2009, the 12.9 million tons of maize imported into the EU included 69% (8.9 million tons) and 17% (2.2 million tons) from Brazil and the USA, respectively [25].

EU policy on GE food imports is less restrictive than the regulations covering GE agriculture in the EU owing to its dependence on imports to maintain the livestock industry. This explains the big difference between the numbers of crops approved for import and cultivation (Figure 3; http://www.europabio.org/sites/default/files/report/approvals_of_gmos_in_eu_europabio_report.pdf). A total of 39 different GE crops were approved for import in 2011/2012: 24 varieties of maize, 7 of cotton (*Gossypium* spp.), 3 of rapeseed, 3 of soybean, and 1 variety of sugar beet (*Beta vulgaris*) (http://www.gmo-compass.org/). In contrast, only two products have been approved for cultivation, the pest-resistant maize variety MON810 and the Amflora potato variety, which is for industrial starch production rather than food use (http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Plants%20and%20Animals_Paris_EU-27_7-23-2010.pdf). Even so, cultivation of the Amflora potato was prohibited in Germany in September 2010 due to intermixture with another GE potato variety that has not yet been approved, during its cultivation in Sweden (http://www.gmo-compass.org/eng/news/536.iamflorai_potato_intermixing_sweden_ban_germany.html). These barriers eventually persuaded the developer BASF to move production abroad because '. . .there is still a lack of acceptance for this technology in many parts of Europe. . .' (http://www.basf.com/group/corporate/en/function/conversions:/publish/content/news-and-media-relations/news-releases/downloads/2012/P109e-PlantBiotechnology.pdf).

The member state opt-out discussed above only applies to cultivated GE crops because EU member states are not legally permitted to block the marketing of approved imported GE products. This means that EU markets are flooded with imported GE products that could just as easily be grown in the EU, and that member states such as Austria, Belgium, or Luxembourg with some of the most hostile policies towards GE crops need these imported products the most. The absurdity of this position is that a ban on cultivation often means that GE soybean, maize,

Figure 2. The main agricultural **(A)** imports and **(B)** exports in the EU (reproduced from http://ec.europa.eu/agriculture/trade-analysis/map/05-2012_en.pdf) (A) Coffee is the main agricultural product imported into the EU, followed by soybean meal and soybeans, which represent 11% of EU agricultural products, then maize. After these, the next agricultural product that is imported to Europe is maize, which is tenth in the list. (B) Approximately 64% of EU agricultural exports are finished products, whereas commodities and intermediate products represent 8% and 19%, respectively (average 2009–2011). The top EU export is wine (€6.1 billion) followed by prepared foods (€4 billion) and whiskies (€3.9 billion).

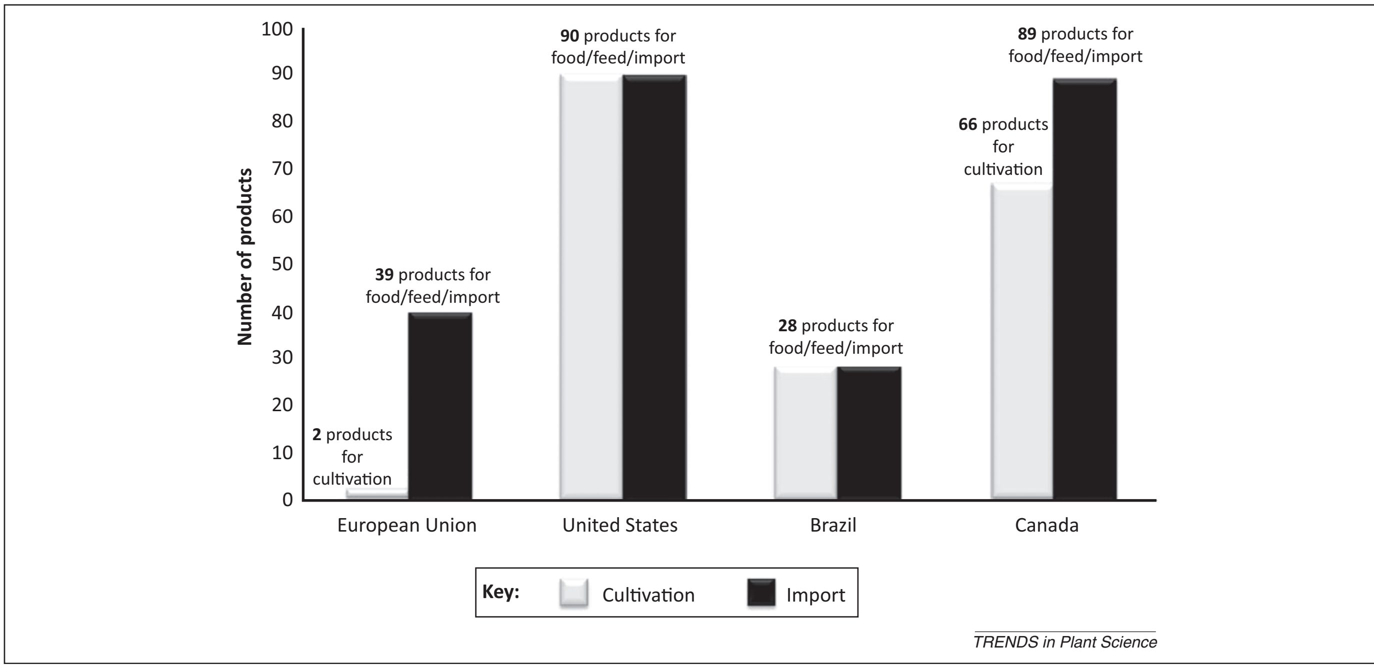


Figure 3. Number of approved genetically engineered (GE) products in the EU, USA, Brazil, and Canada (http://www.europabio.org/sites/default/files/report/approvals_of_gmos_in_eu_europabio_report.pdf). The EU has the lowest number of approved products for cultivation, MON810 and the Amflora potato. However, 39 products are approved for import, compared to the USA and Brazil, where 1 approval covers both import and cultivation.

or cotton is imported instead, which undermines claims that GE crops should not be grown because they are unsafe [5] (http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf).

Although less stringently regulated than cultivation, the import of GE products is nevertheless still heavily controlled, causing logistic and economic problems for exporters and EU importers alike, reducing the flow of commodities and threatening the stability of the livestock industry. The import approval process differs between countries, which causes delays and asynchronous authorizations in different parts of the world [26]. The zero tolerance for the adventitious presence of GE products that have not yet been approved for import into the EU results in shipments containing traces of GE material that are approved by the exporter being rejected at the point of import, with significant economic consequences for both the EU and the supplier, particularly if the supplier is a developing country [27]. Europe is increasingly being perceived as a risky export market, resulting in preferential trading between other countries, and EU importers bearing high prices and insurance premiums to offset risks undertaken by the supplier [25] (http://ftp.jrc.es/EURdoc/report_GMOpipeline_online_preprint.pdf). The situation described above may worsen with the increasing adoption of GE agriculture as a mainstream technology outside the EU, leading to deficits initially in the demand and supply chain for soybean meal and then in the feed industry more generally, with a knock-on effect on the livestock, poultry, and dairy industries and economic decline throughout the EU [8,27].

Sustainability – promoted in principle but discouraged in practice

Agricultural sustainability is a key program within the CAP and has a strong impact on market forces and the food supply chain (http://ec.europa.eu/agriculture/publi/app-briefs/01_en.pdf). Subsidies based on land use are provided to encourage environmentally responsible cultivation methods and reduce the use of chemicals and pesticides (http://aei.pitt.edu/559/1/1_Bandarra.pdf). However, the subsidies have instead resulted in the intensification of agriculture and a dramatic increase in the use of fertilizers and pesticides, thus increasing the rate of environmental damage (http://www.wwf.org.uk/filelibrary/pdf/ag_in_the_eu.pdf). The restriction of pesticide use has encouraged farmers to rely on a small number of permitted chemicals, risking the emergence of resistant pest populations and making agricultural sustainability difficult to achieve [28].

Integrated approaches can help to achieve sustainability, and biotechnology can play a crucial role in this process as seen in other parts of the world [29]. For example, the cultivation of insect-resistant GE crops has reduced the use of pesticides in India and China, improving the environment and the health of farmers [30]. GE papaya (*Carica papaya*) that is resistant to *Papaya ring spot virus* has improved disease management in Hawaii, resulting in a sustainable supply of papaya fruits for the domestic population [31]. Furthermore, the cultivation of herbicide-tolerant crops in the Western Hemisphere has promoted reduced/zero-tillage farming to reduce soil erosion and water contamination caused by agriculture [32].

Insect-resistant maize in Europe provides efficient pest control without pesticides, also limiting the impact of agriculture on nontarget organisms while increasing yields and the net economic benefits of farming. This has been realized in countries such as Spain, where GE crops are still encouraged, whereas other parts of the EU see no benefit because of the costs of compliance with national regulations [33]. Mycotoxin levels in GE maize are much lower than those in conventional maize, therefore reducing the risk of acute toxicity effects and long-term health issues [34]. The deployment of Bt maize has reduced pesticide use in Spain and has led to a significant reduction in mycotoxin levels, compared to conventional maize [35]. Growing Bt maize throughout the EU could achieve annual savings of up to 700 tons of pesticide active ingredient, adding to the current 443 000 tons saved globally by the cultivation of pest-resistant maize and cotton [36] (http://ec.europa.eu/food/food/biotechnology/reports_studies/docs/Europabio_contribution_II_en.pdf). Between 1996 and 2010, GE agriculture has reduced fuel use and increased carbon sequestration, thus reducing the carbon footprint of agriculture by 146 million tons [36].

Despite the economic and environmental benefits demonstrated in other regions, EU policies continue to block the adoption of approved GE crops [18,37,38]. Developing countries that formerly embraced GE agriculture as a means to improve the health and welfare of subsistence farmers are being discouraged because of the hurdles they encounter when exporting their produce to the EU. The reluctance of the EU to accept GE commodities has diminished the enthusiasm of developing countries to approve GE crops. This is the case in Egypt, where the likelihood of a ban on the import of GE potato into the EU has delayed the approval of this crop. Similarly in Thailand, the government has refused to approve the cultivation of GE crops because they fear losing export markets in Europe (http://agbioforum.org/v7n12/v7n12a12-kent.pdf).

Pesticides – banned but not forgotten

European Commission regulations EC/396/2005 and 1107/2009/EEC were introduced to harmonize the maximum residue levels (MRLs) for pesticides in food and feed and to reduce pesticide use in agriculture, particularly by prohibiting the use of certain chemicals deemed to be hazardous [39]. A special essential-use category was created to extend the use of pesticides that could not be replaced, giving manufacturers 5 years to make the product safe. However, if alternative products are still not available after that period then farmers will be able to continue using them for another 5 years (http://www.pan-europe.info/Resources/Links/Banned_in_the_EU.pdf; 1107/2009/EEC). The regulations create the impression that the EU is making efforts to reduce pesticide use in agriculture, but in reality they favor the use of a small number of chemicals thus greatly enhancing the risk that resistant pest populations will emerge. Meanwhile, imported food treated with banned products is still approved, thus EU citizens are still exposed to banned pesticide residues but through the import chain rather than those used and regulated in the EU. The EU MRLs for pesticides are exceeded in 6.9% of imported agricultural products but in only 1.5% of home-grown products (http://www.efsa.europa.eu/en/press-/news/111108.htm) because Regulation 396/2005 allows pesticide thresholds to be set at different levels for imported products, including the threshold for substances that are no longer authorized in the EU (http://europa.eu/legislation_summaries/food_safety/plant_health_checks/l21289_en.htm).

EU pesticide-use policies are intended to promote environmentally sustainable agriculture (i.e., farmers should protect their crops without using chemicals if possible or combine them with measures that reduce the amounts required). The net result is that EU farmers lose the ability to protect their crops effectively in many cases, and the lower yields need to be compensated by the import of food from outside the EU even though it has been treated with products that are banned in the EU. Because the MRLs for crops grown in EU countries are lower than those for imported crops, EU farmers are prevented from competing with farmers outside the EU because the regulations favor the market for imported foods.

Directive 2009/128/EC establishes a framework for community action to achieve the sustainable use of pesticides: 'Member States shall take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods'. In practice, however, this legislation does little to promote nonchemical methods. For example, *Diabrotica virgifera virgifera* is a maize pest that was accidentally introduced into Europe from the USA in the early 1990s, and it now causes substantial yield losses in Central Europe. GE crops provide effective protection against the pest in the USA and additional pesticides are not required. Directive 2009/128/EC advocates the use of such crops because they facilitate nonchemical control methods, and an expert study commissioned by the EU states that '...the main benefits of transgenic varieties are an increased protection of the root system, a decrease of volumes of insecticides being used by farmers in soil treatments, and an easy management for the farmers...'. Even so, EU farmers in affected areas and neighboring regions are obliged to use pesticides because the only GE maize variety authorized for cultivation in the EU is MON810, which is not resistant to *D. virgifera* (http://ec.europa.eu/food/plant/organisms/emergency/final_report_Diabrotica_study.pdf). There is a similar contradiction in Regulation 1107/2009. Insect pheromones and other semiochemicals are widely used in European orchards and vineyards to control insect pests by disrupting mating. However, the regulations for marketing plant protection products apply to all substances regardless of origin and properties, which means that the same lengthy and expensive approval process must be followed for a natural and ubiquitous volatile chemical emitted by female insects to attract males as that required for a highly toxic synthetic pesticide [40]. Dozens of active natural products that are potentially useful in agriculture and that are not harmful to humans or the environment cannot be marketed in the EU due to this legislation.

The MON810 maize variety has been grown in Spain for more than 14 years. During that time there have been no reports of health issues for consumers, resistant pest populations, or of impacts on nontarget organisms [34,41]. However, there has been a significant reduction in pesticide use for borer control as well as economic benefits for farmers (http://www.europabio.org/sites/default/files/position/europabio_socioeconomics_may_2011.pdf). Many other GE varieties with favorable EFSA opinions are mired in the regulatory process, awaiting clearance for commercial cultivation, while known harmful pesticides continue to be used.

Mycotoxin safety levels – moving the goalposts

Mycotoxins are secondary metabolites produced by certain filamentous fungi that infect crops and stored food such as cereals, nuts, spices, dried fruits, apple juice, and coffee [42]. If consumed, these compounds can be acutely toxic to humans (mycotoxicosis) and cause long-term carcinogenic effects [43]. The tolerance levels set for mycotoxins are highly controversial because they imply a compromise between human health and economic factors (http://agecon.ucdavis.edu/people/faculty/roberta-cook/docs/links/LCfood-safettrade03.pdf). In 1997, the EU harmonized the acceptable level of aflatoxin contamination in groundnuts (*Arachis hypogaea*) at 10 ppb for groundnuts intended for further processing and at 4 ppb for cereals intended for direct human consumption. This caused a sudden reduction in imports into some member states and the levels were strongly criticized by many members of the World Trade Organization (WTO) because the measures would create a trade barrier for countries economically dependent on exports to the EU. In response, the thresholds were increased in 1998 to 15 ppb in groundnuts intended for further processing (8 ppb for aflatoxin B1, which is the most toxic mycotoxin) and 4 ppb for foods intended for direct consumption (2 ppb for aflatoxin B1) [44].

The policy instrument used to set the maximum levels for aflatoxins in food is Regulation 165/2010/EC, which has doubled the tolerance threshold to 8 ppb but provides an exemption in that levels are expected to be '. . .as low as can reasonably be achieved. . .' This was justified on the advice of the Scientific Panel on Contaminants in the Food Chain (CONTAM), which stated that exceeding the maximum levels occasionally would have a low overall impact on health. Therefore, standards have been lowered in developed countries that have the technology to detect and thus avoid mycotoxins in food in a cost-effective manner, but have remained stringent for developing countries without these capabilities, blocking their export markets [45]. Furthermore, attempts to meet these demands mean that developing countries export their highest quality food, leaving the poverty stricken domestic population to consume mycotoxin-contaminated food that cannot be exported [46]. The restriction of the market in this manner also results in the EU paying more for higher quality foods [47].

However, GE agriculture could provide a solution to this challenge. For example, Bt maize is resistant to insect pests that cause damage and allow penetration by mycotoxin-producing fungi [48]. MON 810 is the only GE maize variety approved in the EU, but under the proposals for a member state opt-out it could soon disappear from much of the continent. However, to meet its stringent requirements for mycotoxin-free maize, the EU imports the MON 810 GE maize variety as well as other more advanced Bt varieties from other countries [5].

Road to nutrition

One of the major global health challenges is malnutrition. Approximately half the world's population (including 5% of the EU population) suffers from malnutrition, yet the biofortification of crops could provide a method to address this problem and could potentially save lives [49–51]. EU policies on food and nutrition are described in the European Commission White Paper on Food Safety (2000) (http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf). The fortification of processed food and agronomic biofortification using nutrient-rich fertilizers has overcome the lower endogenous levels of some nutrients in the UK and Finland [52,53]. However, the biofortification of crops with essential minerals and vitamins by genetic engineering can yield nutritious foods more rapidly and more sustainably by equipping plants with the means to synthesize, absorb, and accumulate nutrients at source [54–57]. The development of Golden Rice, a variety of rice (*Oryza sativa*) enriched with β-carotene [58], multivitamin corn enriched with ascorbate, β-carotene, and folate [59], and folate-biofortified rice [60] are key examples of successful biofortification achieved through EU public sector research [50]. However, because of the regulatory burden on GE crops, no nutritionally enhanced varieties are likely to be grown for consumption in the EU [5,61] or in developing countries that are economically dependent on trade and/or aid from the EU (http://www.adelaide.edu.au/cies/publications/present/CIES_DP1012.pdf).

DNA sequencing has revealed that biotechnology is less disruptive to the genome than conventional plant breeding because the transgene insertions are localized [62]. Transgenic plants with novel traits also resemble the parental variety more closely than those generated by introgression [63]. GE biosafety research in Europe over the past 25 years has cost more than €300 million and can be summarized in one sentence: GE is no more dangerous than crop modification by any other method. This has been confirmed by a recent EU study that revealed no greater risk from the consumption of GE maize than any conventional variety [64] (ftp://ftp.cordis.europa.eu/pub/fp7/kbbe/docs/a-decade-of-eu-funded-gmo-research_en.pdf).

Even with this extensive research to support the safety of GE crops backed up by 15 years of consumer safety in the USA and elsewhere [65], GE varieties must undergo compositional, allergenicity and toxicity testing, molecular characterization, and environmental impact assessments from which conventionally bred varieties are exempt even if they are identical in every way to the GE variety [66]. Effectively, EU regulations do not focus on the product, only on the process [67].

Medical innovation – giving with one hand, taking with the other

In addition to malnutrition, several key diseases prevalent in developing countries are major global health challenges, including HIV/AIDS, tuberculosis, malaria, and rabies. Many people die from these diseases because of the lack of drugs, often reflecting poverty and limited access to medical facilities rather than the availability of those facilities *per se* [68]. The EU has invested in research projects focusing on the development of inexpensive diagnostics, drugs, and vaccines, and the platforms to produce them in developing countries (http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/pdf/infectious-diseases-leaflet09_en.pdf; http://www.pharma-planta.net/).

GE crops provide an alternative platform to chemical synthesis for the production of pharmaceutical molecules because they can produce large amounts of biomass that can be scaled up and down as required to meet demand [69–72]. Diverse pharmaceutical products have been produced in plants, including vaccines, antibodies, and enzymes [69,73]. Innovative plant-derived pharmaceuticals include edible vaccines [74], microbicides to prevent the transmission of HIV [75], and recombinant versions of insulin and human growth hormone [76]. The slow adoption of pharmaceuticals produced in whole plants in the field reflects the slow development of the regulatory process, which involves not only the European Medicines Agency (EMA) but also the EFSA, which has a mandate to consider non-food plants as well as those used for food [77]. The cultivation of GE plants for pharmaceutical use needs to meet the requirements stated in Directive 2008/27/EC, which regulates 'the release' of GE plants into the field, and Regulation 1829/2003/EC, which sets out rules governing food and feed products. Finally, plant-derived pharmaceuticals must meet the specific guideline established by the EMA to regulate the production process to determine the final safety of the pharmaceutical product (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003154.pdf).

Similar to the other benefits of GE agriculture, pharmaceutical research is being hindered by the huge investment required at the precompetitive stage so that novel products can negotiate the regulatory pathway beyond the proof-of-principle stage. Drugs that can be produced inexpensively in plants are currently produced in cultivated mammalian cells at great expense [72], beyond the reach of developing countries. The luxury of onerous regulation in the EU is costing lives in the developing world.

Concluding remarks and recommendations

The EU has enacted a series of strategies whose stated aim is to develop the most competitive knowledge-based bioeconomy in the world. So far this has failed. One reason for the disappointing performance is the paradoxical nature of the agricultural policies described in this review, many of which are contradictory, anticompetitive, and actively promote the practices they claim to discourage. In many cases, this is because policies are based on political expediency and short-term economic goals rather than rational scientific evidence and long-term economic models.

To reverse this situation, the EU needs to consider rational principles as the basis for policy development, removing inconsistencies surrounding the cultivation and import of GE crops, and the acceptable levels of pesticide residues and mycotoxins. This would make the EU agricultural industry more competitive and international trade would be harmonized. Most importantly, by rationalizing its policy framework, innovative new crops, drugs, and novel and efficient production methods would come to market more rapidly and the EU would become a leading influence in the use of technology to save lives. Following the current path, the EU faces being left behind technologically, economically, and in terms of its humanitarian policies, to the detriment of the EU population and the rest of the world.

Acknowledgments

Research at the University of Lleida is supported by the Ministerio de Ciencia e Innovación (MICINN), Spain (BFU2007-61413; BIO2011-23324; BIO02011-22525; PIM2010PKB-00746; AGL2011-23996); the European Union Framework 7 Program SmartCell Integrated Project 222716; the European Union Framework 7 European Research Council IDEAS Advanced Grant (to P.C.); Program-BIOFORCE; COST Action FA0804: Molecular farming: plants as a production platform for high value proteins; Centre CONSOLIDER on Agrigenomics funded by MICINN, Spain and RecerCaixa. We thank Gustavo Slafer and Roxana Savin for useful comments and suggestions.

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