COMMENTARY

Going to ridiculous lengths—European coexistence regulations for GM crops

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Even if a GM crop can surmount Europe's excessive product registration process, any farmer hoping to plant it must then navigate tortuous, arbitrary and scientifically unjustifiable coexistence regulations.

enetically modified (GM) crops now G cover over 100 million hectares of arable land in >20 countries, and this trend toward increased uptake and deployment is growing at a steady rate¹. Inevitably, GM and non-GM crops of the same species will be grown near each other, a concept defined by the term 'coexistence'². There has been an extraordinary and sustained campaign mainly in the European Union (EU; Brussels) that has united certain stakeholders, including organic producers, certification bodies and environmental groups, against GM/non-GM coexistence. The escalating battle has drawn in producers, retailers, governments, regulatory bodies, scientists and, of course, the general public. The outcome in the EU is a mess: a haphazard and inconsistent set of rules that has no rational scientific underpinning, which obstructs GM producers, misleads the public and adds unnecessary layers of complexity to international trade. GM/non-GM coexistence is now a loaded term, used by opponents as a *de facto* criticism of GM agriculture and a self-fulfilling reason to impose restrictions. Is there any way to encourage a rational approach to the coexistence debate?

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Special treatment required? Keeping GM corn pollen grains (like this one pictured at a magnification of 795×) segregated from conventional corn is one of the purposes of Europe's coexistence regulations.

Adventitious presence

The basis of the campaign against GM/non-GM coexistence is "adventitious presence," which is defined (in the context of GM agriculture) as the presence of unwanted GM material in non-GM commodities. The adventitious presence of GM material can occur in many ways (Fig. 1), but most often through outcrossing, the growth of volunteer plants from stray seeds and admixture after harvest³. The adventitious presence of GM material in non-GM commodities is often presented as disastrous by opponents of GM technology and described using terms such as 'contamination' and 'adulteration'. However, it is important to recognize that the reasons it is thus regarded

differ according to different stakeholders. Environmental pressure groups are keen to promote uncertainties about the impact of GM crops on human health and the environment and oppose coexistence on the basis that the adventitious presence of GM material is a safety issue, even though the safety of GM crops must be demonstrated to regulators before licensing for commercial production. Organic producers, on the other hand, oppose coexistence because they fear their organic status and associated organic price premium may depend on the absence of GM material, prompting legal challenges and lobbying against GM agriculture both within the EU and elsewhere^{2,4}. The European Commission (EC; Brussels) has confirmed that coexistence is purely an economic issue by defining it as "...issues relating to the economic consequences of adventitious presence of material from one crop in another and the principle that farmers should be able to cultivate freely the agricultural crops they choose, be it GM crops, conventional or organic crops..."5.

Intimately intertwined with the political coexistence debate is the European public's antipathy to GM products and preference for non-GM products. Public uncertainty about the safety of GM products is exaggerated by environmental pressure groups and some parts of the media, thus helping to create the preference. Many suppliers and retailers, responding to consumer pressure, have therefore imposed restrictions on the use of GM material and its presence in food products, encouraging producers to segregate GM and non-GM crops. A vicious circle has been created.

Coexistence practices in non-GM agriculture

What often gets forgotten in the heat of the GM/non-GM coexistence debate is that different varieties of the same crop species have coexisted for generations and that adventitious presence is recognized as an inevitable consequence of coexistence that can be minimized but not entirely eliminated. Therefore, almost all traded agricultural commodities anticipate some degree of inadvertent mixing, and thresholds exist that are recognized in laws, regulations and/or voluntary standards.

Such thresholds have resulted in the development of a series of measures that are applied during cultivation, harvest, transport and storage to minimize outcrossing, the growth of volunteer plants and inadvertent mixing³. These best practices were established decades ago and have evolved to deliver high purity seed and grain to support the production, distribution and trade of products from different agricultural systems. The principles of these coexistence practices are dependent on context (which crops and where they are grown), consistent, proportionate to need, fair and practical. Examples of successful coexistence practices in non-GM agriculture include production systems for certified seeds (e.g., hybrid seed), organic crops coexisting with conventional crops and commodity crops coexisting with specialty crops (e.g., field corn with sweet corn and/or popcorn, and specialty corns such as high-amylose, high-oil, white, waxy, hard endosperm and nutritionally dense varieties)⁶.

Perhaps one of the best-studied examples of coexistence in conventional agriculture is standard rapeseed varieties and specialty high erucic acid rapeseed (HEAR) varieties for industrial use, particularly because HEAR is regarded as antinutritional and undesirable in food (and therefore constitutes an actual risk rather than a consumer preference, as is the case for GM crops). Contracts for growing HEAR crops require that only certified HEAR seed is used, equipment should be cleaned and segregated and that there should be an isolation distance of between 50 m (e.g., in the UK) and 100 m (e.g., in Germany) from other rapeseed crops. The admixture threshold for HEAR in food rapeseed is 2% although recorded levels are usually much lower. For example, the 100-m separation distance in Germany generally delivers seed lots with HEAR levels <0.2%, and only a few seed lots contain >0.5%. In the UK, coexistence research shows that separation distances as low as 9 m still provide bulk rapeseed harvests containing <0.5% HEAR².

Growing phase - - -Seedbed Storage Supply preparation Sowing Growing Harvest Post-harvest processing chain start material transport a Potential avenues for on-farm mixing between gentically modified (GM) and non-GM crops Mixing in Mixing during Volunteers Seeds: Cross Volunteers from GM mixing in fertilization machinery on-farm pre-cultures: machinery during sowing Dispersal of during harvest storage and . dispersal of GM seeds via processing; GM seeds via straw and/or mixing during straw and/ manure transport to collection point or manure **b** On-farm coexistence measures to ensure the purity of a crop

dis ch po iso	(isolation mach stances); field remo	ing of inery; val of ters space machi	inery; volunteers; euver specific tillag e for operations;	e processing rooms; f cleaning of transport

Figure 1 The many routes to adventitious presence of GM material in a conventional crop. (a) Stages where on-farm adventitious mixing between GM and non-GM crops can occur. (b) On-farm co-existence measures to ensure crop purity during production (reproduced from ref. 3 with permission from EDP Sciences).

Coexistence practices in GM agriculture

The United States and Canada have embraced GM agriculture, and their agricultural systems support the coexistence of conventional, organic and GM crops under a common set of practical guidelines⁷. In contrast, GM crops in the EU are treated very differently from other specialty crops. Because of the precautionary approach adopted by EU regulators, they are subjected to more extensive and stringent safety testing than their conventional counterparts, even though the safety of GM crops and products is demonstrated before they are given approval to enter the agricultural production system. Once approved for commercial release and marketing, there should be no grounds for treating the coexistence of conventional and GM crops any differently from, for example, the coexistence of conventional and HEAR varieties of rapeseed, but the prescribed practices set at national and regional levels are much more strictly regulated, with lower adventitious-presence thresholds, larger isolation distances, harsh economic liability provisions on the producer and the proposal of mandatory additional preventive measures³.

GM adventitious-presence thresholds in the EU are the strictest in the world^{8,9}. In the United States, Canada and Japan, non-GM products may contain up to 5% GM material before they must be labeled as GM. Other countries have lower tolerance thresholds (e.g., 1% in Australia, New Zealand, South Africa, Brazil and China). The EU has a twotier tolerance policy (Regulation (EC) no.

1830/2003; ref. 10), with a 0.9% limit applied to approved products and a zero tolerance threshold applied to unapproved products, replacing the temporary 0.5% second-tier limit previously approved by the European Food Safety Authority (Parma, Italy). Additionally, Recommendation 2003/556/EC (ref. 5) provides guidelines for the development of national coexistence strategies and best practices that, where necessary, can be applied to prevent non-GM products exceeding the labeling threshold, which means coexistence is officially a matter of 'national competence' where each member state is responsible for the establishment of a legislative framework on a crop-by-crop basis. Some EU member states (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Germany, Hungary, Latvia, Luxemburg, Portugal, Romania and the Slovak Republic) have already started adopting regulations governing the planting and handling of GM crops, whereas others are still in the process of developing their regulations. The lack of overarching regulation means that the crops covered in each member state's regulations, and the minimum isolation distances that are imposed, vary greatly (Supplementary Table 1). The adoption dynamics of GM crops in Europe differ among and even within member states, as discussed below. At the current time, the only GM crop cultivated in the EU is Bacillus thuringiensis (Bt) corn expressing the insecticidal protein Cry1Ab, and this accounts for <2% of the total EU corn output, compared with 75% in the United States¹¹.

Spain is arguably the most enthusiastic adopter of GM agriculture in the EU, allowing the cultivation of GM crops without a complete regulation regime. The establishment of coexistence rules has been prevented by disputes between the Spanish Ministry of Agriculture (influenced by farmers' lobbies) and the Ministry of Environment (influenced by ecological lobbies). Coexistence is currently determined by seed company guidelines together with some specific regulations¹², but there are no compulsory training courses, no specific liability rules and 50-m isolation distances are standard¹³. Despite successful coexistence in Spain, market forces have created region-by-region segregation. In the productive agricultural regions of Catalonia and Aragon, 55% and 42% of corn, respectively, is GM^{14} . In contrast, Asturias and the Basque Country have declared themselves GM free with the support of regional governments and some farmers' associations.

Several EU member states require farmers to gain official approval before they are allowed to plant GM crops. In Austria, farmers need approval from local authorities for each field and crop (similar procedures are being considered in Hungary, Ireland and the Slovak Republic). Austria has the strictest regime, and even though there are some coexistence measures (zero-risk seed purity regulation, compulsory training courses and strict liability policies), the Austrian authorities are against GM crops and strive to avoid coexistence instead of promoting it¹⁵. Austrian provinces have approached the EU to establish GM-free regions, but in September 2007 the European Court of Justice finally rejected general statutory regional bans on GM crops, arguing that a statutory ban is a denial of the freedom of choice for farmers and consumers¹⁶. Poland and Belgium are also seeking to avoid the deployment of GM crops (120 communities in Belgium have already declared themselves GM free). Portugal has a complete system of regulation (established before commercial planting) with compulsory training courses, strict anti-cross-pollination measures and a public compensation fund. Even so, this still allows some flexibility in isolation measures depending on voluntary agreements among neighbors. This kind of collective initiative avoids complicated anti-cross-pollination measures and expensive double farm facilities.

How far is far enough?

EU coexistence guidelines (Recommendation 2003/556/EC) state that "...Management

measures for coexistence should reflect the best available scientific evidence on the probability and sources of admixture between GM and non-GM crops..."5, but it is quite clear that this recommendation is being ignored in many EU member states. Some countries require vast isolation distances that bear no relationship to the underpinning scientific evidence. For example, Luxemburg requires 800 m between GM and non-GM corn and 3 km between GM and non-GM rapeseed. Latvia requires 4 km between GM and conventional non-GM rapeseed and 6 km if the non-GM rapeseed is organic (Supplementary Table 1). Such isolation distances impose immense costs on GM farmers because they have to negotiate with a much larger number of neighboring farms and, in practical terms, simply remove their choice in relation to adopting GM crops¹⁷.

The minimum isolation distances imposed on GM producers in the EU should be those that are sufficient to maintain the adventitious presence of GM material below 0.9% in neighboring organic and conventional plots. The current isolation distances were based on the assessment of biological and physical processes that affect outcrossing^{3,4,18,19}, and these tend to differ between studies if factors such as pollen viability; male sterility; flowering synchrony; wind speed and direction; weather conditions; field size and shape; and distance, topography and vegetation between the pollen donor and recipient fields are not standardized. Maize pollen is released in very large quantities, between 4.5 and 25 million pollen grains per plant over a typical 5- to 8-day period²⁰, but is larger (90–125 μ m) and heavier than the pollen of most other wind-pollinated plants, and therefore dispersal is limited to about 10% of the range covered by other species, often settling within a few hundred meters of its source.

A research study conducted by the Spanish Institute for Agriculture & Food Research and Technology (Madrid) demonstrated that in field trials, the average presence of the Bt gene in conventional maize separated from Bt maize by just 2–10 m is $<0.9\%^{21}$. In another study, the maximum distance over which any cross-pollination between GM and non-GM maize occurred was 200 m (a single kernel event), with further events also observed at 150 m and 100 m (that is, a total of three pollen grains from a 4,000-m² plot of GM maize²²). Monitoring of gene flow between adjacent GM and non-GM maize fields by the Portuguese Ministry of Agriculture between 2006 and 2009 has shown that in 80% of cases, the mean level of cross-pollination was <0.3%, with the highest level being $0.7\%^{23}$.

A meta-analysis of existing cross-fertilization studies⁴ concluded that an isolation distance of just 50 m between GM and non-GM seed production fields would be sufficient to maintain cross-fertilization levels below 0.5% at the border of the recipient corn field, showing that the 800-m separation required in such countries as Bulgaria, Hungary and Luxembourg is completely unjustified on scientific grounds. In 2001, the EC Scientific Committee on Plants (Brussels) proposed tolerance thresholds of 0.3% for crosspollinating crops and 0.5% for self-pollinating and vegetatively propagated crops²⁴.

Toward successful coexistence in Europe

GM crops could enhance European agriculture through higher productivity, better use of resources and reduced environmental impact, but the acceptance of GM technology by European consumers remains low. The principle of coexistence predates the deployment of GM crops and has been used successfully for many years to preserve the purity of seed stocks and specialty conventional crops, allowing different varieties of sexually compatible, outcrossing species to be grown in close proximity. Isolation is the primary method to reduce adventitious presence, and isolation distances for different varieties of conventional crops have been defined according to scientific investigations of gene flow.

This scientific process appears to have been discarded by the EU and its member governments in the case of GM agriculture. Not only are the thresholds for adventitious presence far stricter than for conventional crops, but the isolation distances implemented to achieve such thresholds are arbitrary, excessive and appear to be politically motivated rather than to reflect scientific reality. Insisting on such inflated and capricious isolation distances places economic and regulatory pressure on farmers, who face stern punitive measures if outcrossing (or 'contamination') occurs with nearby conventional crops. The US and Canadian systems place more emphasis on the balance between GM and non-GM crops, the isolation distances are based on scientific principles and both GM and non-GM farmers have a stake in preventing adventitious presence. These practices have enabled the successful coexistence of GM and non-GM (including organic) crops outside Europe for many years without government involvement, and there should be no rational objection to the adoption and standardization of such practices throughout the EU.

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Note: Supplementary information is available on the Nature Biotechnology website.

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COMPETING INTERESTS STATEMENT

The authors declare no competing financial interests.

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