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SITOX - SOCIETÀ ITALIANA DI TOSSICOLOGIA Prof. Giorgio Cantelli Forti - President

SIV - SOCIETÀ ITALIANA DI VIROLOGIA Prof. Giorgio Palù - President Coexistence of Traditional, Organic and Genetically Modified Crops

Consensus Document

Introduction

With the European Commission's orientation on the subject of agrobiotechnology and the world's steady increase in acreage planted with genetically modified species, Italy is again facing the issue of the cultivation of genetically modified plants and hence coexistence of traditional, organic and GM crops.

The debate that arose in Italy when the law on coexistence was approved, first by the Council of Ministers and then by Parliament, has led to the re-emergence of opposing positions that fail to take account of scientific evidence. Indeed, numerous studies conducted around the world have tested and identified the best ways of ensuring the real, sustainable coexistence of the different farming systems.

The scientific associations and academies listed below, representing about 10,000 Italian researchers, feel the need to focus their attention on agrobiotechnology in order to shift the debate on coexistence to a more balanced, scientific plane, giving citizens, farmers and lawmakers a useful tool in view of the definition of rules and procedures that would ensure the coexistence of traditional, organic and genetically modified crops.

Accademia Nazionale delle Scienze, detta dei XL Accademia Nazionale di Agricoltura ANBI - Associazione Nazionale dei Biotecnologi Italiani **ARNA - Associazione Ricercatori Nutrizione Alimenti ASPA - Associazione Scientifica di Produzione Animale** FISV - Federazione Italiana Scienze della Vita **NFI - Nutrition Foundation of Italy** SIB - Società Italiana di Biochimica e Biologia Molecolare SIC - Società Italiana di Chemioterapia SICi - Società Italiana di Citologia SIF - Società Italiana di Farmacologia SIF - Società Italiana di Fisiologia SIFV - Società Italiana di Fisiologia Vegetale SIGA - Società Italiana di Genetica Agraria SIMGBM - Società Italiana di Microbiologia Generale e Biotecnologie Microbiche SIMTREA - Società Italiana di Microbiologia Agro-alimentare e Ambientale SIPav- Società Italiana di Patologia Vegetale SISF - Società Italiana di Scienze Farmaceutiche SISVet - Società Italiana delle Scienze Veterinarie SITOX - Società Italiana di Tossicologia SIV - Società Italiana di Virologia

Before we review the current scientific knowledge on coexistence, we would like to recall some key points that should underlie any discussion hinging on the analysis of scientific data:

1. Scientific knowledge is not made of absolutes but constantly strives for a better understanding of the facts. For this reason knowledge is not static and absolute, but apt to be improved and perfected.

2. Research should be cultivated and valued in such a way that existing findings are not lost

to visions that jeopardize the good that science has already produced or could produce for humankind¹.

3. Technology is born when scientific knowledge becomes applicable to reality. What makes a technology successful is not its "perfection," but its ability to satisfy specific needs more appropriately than was previously possible. Only an evaluation that considers the ratio of costs to benefits can afford an equable judgment of any given technology.

4. Opinions can only be properly formed if they are based on an analysis of the best available knowledge.

The aim of this document is to present the world's current knowledge about coexistence, so that participants in the debate will be fully informed about the state of the art and thus free to take educated positions.

This text has been written after careful evaluation of the most significant literature on coexistence, focusing specifically on studies of Italian and international scope.

GMOs and agriculture |

Genetically modified organisms (GMOs) are organisms whose DNA has been modified through genetic engineering techniques^{2,3}, and are one of the most innovative products of advanced biotechnology. In agriculture, these techniques have been used to create new characteristics in plants that make them more easily farmed (e.g. resistant to certain insects or herbicides), more nutritious (richer, for example, in pro-vitamin A⁴, iron, or other nutrients like essential aminoacids or fatty acids), or more useful in the healthcare sector (for producing plant-derived vaccines and drugs).

The use of GMOs in agriculture - worldwide, but especially in Europe - is governed by regulations that are unparalleled elsewhere in the food or environment industry. Consequently, as emphasized in a previous Consensus Document signed by Italy's major scientific associations⁵, the products released into the environment or sold on the market meet the highest safety standards.

The direct modification of DNA as a means of genetic improvement, in combination with precise, complex rules for the evaluation of risk, may lead some to conclude that genetically modified plants (GMPs) are radically different from what farmers have been growing for centuries. Such a conclusion is very weak for those familiar with the history of human development and genetic selection in plants. Traditional genetic improvement techniques make profound alterations to plant genomes without our full knowledge of their molecular makeup. Generally speaking, the varieties grown today are quite different from those of the past.

Despite the intense genetic changes brought about by traditional breeding techniques, these species remain perfectly distinct and distinguishable. Genetically modified plants are no exception. In the field these plants behave just like varieties developed with conventional methods⁶ and are just as able to interbreed and produce fertile plants. For this reason, their impact on neighbouring crops has to be evaluated case by case, and the rules of coexistence defined on a "crop by crop" basis.

What is coexistence?

Coexistence does not concern environmental or health issues, as these are already governed by Directive 2001/18⁷ and by Regulation 1829/2003⁸, which guarantee that all GMPs and products made therefrom that are authorized for sale are safe for humans, animals and the environment⁹.

Coexistence, while based on plants' physiological ability to cross-breed (and thus to exchange genetic material) with plants of the same or related species, is an economics issue. What must be guaranteed is the chance for farmers to grow both GM and conventional and/or organic crops, and for consumers to choose among genuinely different products¹⁰.

The possibility for coexistence thus depends on three key factors: 1) traceability, 2) labelling, and 3) the ability of farmers to provide products (in whatever supply chain) that comply with the regulations.

The purpose of this paper is to determine under what conditions and with what precautions farmers can choose to grow GM, conventional or organic crops to provide products that comply with the law.

Coexistence practices

Rules for ensuring coexistence have been around far longer than GMPs and involve, for example, certified seed purity, mandated crops (such as durum wheat for pasta), and organic farming practices. Therefore before analysing what applies to GMPs it is advisable to look at other cases for which coexistence rules are in force and to examine the principles on which they are based.

Wheat and other crops

In Italy, it is against the law to use soft wheat in the production of dry pasta. It is possible, however, to find a certain percentage of soft wheat in durum wheat (and vice versa) as a result of accidental contamination in the post-harvest phase. As a result, the industry has agreed internally to limit the amount of soft wheat in durum to 3%. In 2001, a presidential decree made that tolerance threshold official¹¹.

Other species are also subject to specific tolerance limits, such as high erucic acid canola (HEAR) or waxy maize.

• Hear

Because erucic acid is cardiotoxic, its presence in rapeseed oil for use in food products is only tolerated at less than 2%. Keeping HEAR crops 100 meters away from edible oilseed rape makes it possible to keep the erucic acid content below 0.5%.

• Waxy maize

In this type of corn, amylopectin makes up more than 99% of the total starch content, making it especially useful in the food industry. It sells for a premium of about 9%, but only if the final product is at least 96% pure (4% tolerance level).

Organic

Organic farming does not allow the use of chemical fertilizers, pesticides or herbicides, and seeds and seedlings must also be certified as organic. However, since there are objective limi-

tations on the procurement of certified seeds/seedlings, it is sometimes impossible to prevent the treatment of nearby crops from affecting organic ones, and there are agricultural problems that cannot be solved with organic methods. Thus, a European regulation¹² allows various exceptions, generally to accommodate for periods when certain ingredients are not available or farming methods are not feasible.

GMOs and coexistence

Since organic and conventional farming have coexisted for many years and there are long-standing rules of coexistence¹³ that guarantee success, there is clearly a need to regulate the farming of GM crops in our country, so as to preserve the nature and particularities of Italian agriculture while offering farmers the freedom to adopt this new technology.

If the market offers different prices for different products (GM, conventional and organic), the violation of laws regarding the adventitious mixing of crops could compromise the earnings of farmers. This is the case for organic or conventional farmers forced to label their products as containing GMOs (i.e. where the accidental presence of GMOs exceeds 0.9%), but also when a special transgenic product loses value because it fails to meet the required degree of purity.

Of vital importance, therefore, is the proper governing of accidental commingling between GM and non-GM crops - caused by seed impurity, cross-pollination, spontaneous growth (mainly from earlier plantings), or harvesting, storage and transport practices - and of the potential economic consequences.

GMO legislation

To outline effective coexistence measures, we need to know what laws exist as well as what tolerance levels for adventitious presence are allowed. The basic regulation on GMOs is European Regulation 1830/2003, which requires products to be labelled as "containing genetically modified organisms" if they include traces of GMOs in excess of 0.9% of all ingredients¹⁴. These thresholds, the European Commission emphasizes in a subsequent recommendation¹⁵, "apply to conventional and organic farming alike," unless specific regulations exist setting different limits for products labelled as organic.

Retracing coexistence standards in other contexts, the Commission has outlined the operating principles that should form the basis for the development of coexistence practices for GMOs. In short, such practices should be:

Transparent

National strategies and best practices for coexistence should be developed with the cooperation of all relevant stakeholders and in a transparent manner.

• Science-based

Management measures for coexistence should reflect the best available scientific evidence on the probability and sources of adventitious mixture between GM and non-GM crops.

• Based on existing segregation methods and practices

Management measures for coexistence should be based on existing segregation practices/ methods and should take account of experience in the handling of identity-preserved crops and seed production methods.

Proportional

Measures for co-existence should be efficient and cost-effective, and proportionate. In other words, they should not be stricter than is necessary for ensuring that adventitious presence of GMOs stays below the tolerance thresholds established by EU legislation. This will also avoid creating unnecessary costs for the chain.

Specific

Best practices for coexistence should take into account the differences between crop species, crop varieties and product type (e.g. crop or seed production). Differences in regional aspects (e.g. weather conditions, topography, cropping patterns and crop rotation systems, farm structures, crop-specific GMO share in a region) that may influence the degree of adventitious mixture between GM and non-GM crops should also be taken into account to ensure the suitability of the measures.

• Subject to monitoring and evaluation

The management measures and instruments adopted should be subject to ongoing monitoring and evaluation to verify their effectiveness and to obtain the information necessary for improving the measures over time.

Scientific evidence

In light of the European recommendations, effective rules of coexistence can clearly only be written on the basis of the best scientific evidence available.

For several years, theoretical and field studies have been conducted using marker or GM plants, which have made it possible to define with precision what agricultural and management practices permit coexistence in European and Italian farming.

• Maize

Maize plays a prominent role in European and Italian agriculture, especially in northern Italy, where it is the major source of nutrition for livestock raised to produce some of the best-known Italian foods. It is also one of the most important crops in the history of biotech innovation. For these two reasons, maize has been the subject of intensive coexistence experiments throughout continental Europe (in Germany, France, Spain and Italy) and in the United States.

Reproductive physiology

Maize is a cross-fertilizing anemophilous species, that is, it reproduces through wind pollination. Because maize pollen is relatively heavy and unviable, however, it does not spread very far. Studies conducted from the 1940s to the 1980s showed that maize pollen's ability to fertilize drops dramatically with distance, to below 1% beyond a distance of 20-25 meters¹⁶.

The literature

• *France*. The POECB study considered insect-resistant GM maize fields larger than two hectares. Admixture was found to be less than 0.9% about 25 meters from the fields grown with GMP. The researchers also measured the increase in adventitious presence that can occur during the product processing phase, concluding that GM and conventional crops can be managed sequentially without exceeding the threshold of 0.9%¹⁷.

• *Germany*. The InnoPlanta study was conducted at 30 locations in 7 German Länder, using a transgenic variety of maize resistant to insects. Although the size of the GM planted fields varied from 1 to 20 hectares, the study found that in any configuration, the percentage of GMOs outside the field grown with genetically modified maize was below 0.9% at a distance of about 20 meters¹⁸.

• *UK*. A coexistence study (DEFRA) was conducted as part of the FSE (Farm Scale Evaluation) project¹⁹, whose aim was to measure the effect on biodiversity of certain GM crops resistant to a particular class of herbicides. Coexistence analyses were performed on 55 fields of varying size (5-10 hectares) over a period of three years. According to the results, a distance of 24.4 meters was sufficient for satisfying the 0.9% threshold, while a limit of 0.3% required a distance of 80 meters.

• Spain. Spain is the only European country with extensive crops of genetically modified maize and is thus the nation most experienced with coexistence. For several years it has been following a national monitoring plan known as IRTA. Thus far, observations on 0.25-hectare experimental fields show that the presence of GMOs falls below 0.9% within 40 meters downwind. Researchers have also found that four rows of conventional maize planted around the GM field (which is necessary anyway to maintain insect resistance) is enough to ensure coexistence. In any case, this applies only to neighbouring fields of less than one hectare; for larger fields, the study concludes, such precautions are not necessary since the concentration of GMOs in the harvest is diluted to less than 0.9%²⁰.

• *Switzerland*. A study (Agroscope FAL) conducted in Switzerland and later applied to the entire country found that accidental commingling with GMOs could be kept below 0.5% at 50 meters and below 0.9% at 25 meters. Projections also suggest that if an isolation distance of 100 meters (four times the distance needed to respect the EU tolerance threshold) were imposed, more than 90% of Swiss territory would have no coexistence problems²¹.

• *Italy*. The CINSA study commissioned by COOP-Italia was conducted in two locations, in Emilia-Romagna and in Tuscany. Since the researchers were not allowed to use GMOs, they used conventional varieties with colored kernels serving as a tracer. In the first location, using 300 colored-kernel plants (about 40 square meters), the researchers detected the tracer at a maximum distance of 25 meters. In the second case, with a 20-sqm field planted with the tracer, the tracer was found up to five meters away. The study also concluded that by planting a field of yellow maize with 20% coloured corn, the presence of coloured kernels in the product falls to 1.2%, while with 2% mixing of the seeds there is just a 0.13% presence of coloured kernels in the harvest. The study was repeated in 2004 and the results were very similar to the previous one. It showed that pollen dispersal literally disappeared between 30 m and 50 m. It was not possible, though, to evaluate the precise number of plants with coloured kernels.

In another study commissioned by CNR and the Italian Environment Ministry, islands of maize were planted at pre-established distances separated by unsown land to measure the maximum distance pollen can travel without losing its ability to fertilize. The tracer was detected at less than 1% at 40 meters, and at technical zero at 80 meters²².

A third study carried out in 2005 and coordinated by C.R.A. Bergamo and Polo Tecnologico Padano involved the maize chain (APSOCLO, CEDAB). The field research covering a total surface of 40 hecta-

res was carried using coloured conventional varieties and using 4 different experimental designs in seven different locations in the Region of Lombardy. Besides evaluating gene flow in optimal conditions, the study evaluated the efficacy of different containment measures such as buffer zones, open spaces and flowering times. The results indicate that in optimal conditions adventitious mixture below 0.9% was obtained on average at 17.5 meters from the field, 0.5% at 30 meters, while the value of 0.1% was not obtained (maximum distance used in the field trial was 120 meters). In the worst case with favourable winds 0.9% was registered at 29 meters. Researchers also concluded that the use of 15 meters wide buffer zones indicate that gene flow levels in the adjoining field can be kept below 0.9%. Differences in flowering time (over 3 days) can also contribute to a substantial reduction in gene flow. Open spaces between fields appeared to be less effective.

Country	Variety used	Field size (hectares)	Threshold sought (%)	Distance (meters)
Germany	GM - Bt	1-20	0.9	20
France	GM - Bt	>2	0.9	20
Spain	GM - Bt	0.25	0.9	40
Switzerland	GM - Bt	1	0.5/0.9	50/25
UK	GM - HT	5-10	0.3/0.9	80/24.4
Italy	Adonis Blue/8515	0.002/0.004	0	25/5
Italy	GM - Bt	0.006	0/1	80/40

The results of these studies are summarized in the table below:

These results are in line with existing statistical models²³ and with the study recently produced by the European Joint Research Center²⁴.

Information is also available for crops other than maize. However, since these are either unaffected by biotechnological innovation, of little importance to Italian agriculture, or irrelevant to the issue of coexistence, only a brief summary of results is provided below.

Oilseed rape

Oilseed rape has a nectar-rich flower that favours dispersion by way of insects. This makes it the most difficult crop to manage in terms of coexistence. Studies and simulations²⁵ indicate that adventitious GMO presence falls below 0.9% at about 25 meters, while at 50 meters it amounts to 0.2 to 0.7%. Even when extremely receptive varieties are used, a distance of 100 meters keeps accidental presence within 0.55%.

• Beets

Beets do not pose gene flow problems, since for commercial purposes, only the root is used and the beet is harvested before it flowers. Account should be taken, however, of the relatively small percentage of plants that pre-flower, which is a serious problem for beet growers and is thus already monitored with care²⁶.

Potatoes

There are no particular issues with potato cultivation, since potatoes are tuber-propagated. With current farming practices, in any case, it is possible to keep accidental commingling below 0.3%²⁷.

• Soy

Gene flow is not an issue for soy, whose self-fertilization rate exceeds 99%²⁸. Also, soy pollen has very low mobility: the cross-pollination rate is 0.4% at one meter and just 0.03% at five meters²⁹.

Propagation of adventitious presence along the supply chain

In addition to the above, true coexistence can only be achieved if adventitious presence is kept below the 0.9% threshold required for non-GM products during the processing phases or as a result of seed contamination. In this regard, the European Commission's Scientific Committee on Plants estimated potential rates of commingling in various stages of processing for different crops. The results³⁰ are summarized below:

Sources of contamination	Oilseed rape (fully fertile)	Maize	Sugarbeet
Seed	0.3%	0.3%	0.5%
Drilling	0%	0%	0%
Cultivation	0%	0%	0%
Cross-pollination	0.2%	0.2%	0%
Volunteers (prior year)	0.2%	0%	0.05%
Harvesting	0.01%	0.01%	0.01%
Transport	0.05%	0.01%	0.01%
Storage	0.05%	0.05%	0.1%
% achieved	0.81%	0.57%	0.67%

Conclusions

On the basis of experience and the results of the studies described above, the following conclusions can be drawn:

• Transgenic plants exhibit the same field behavior as conventional varieties, except for the desired characteristic achieved through modification.

• The criteria used to build coexistence plans for conventional varieties are rational and can be extended to transgenic varieties.

• For the principal crops, farming practices are already available that respect the 0.9% limit for non-GM products required by European Regulation 1830/2003. In no instance is there a policy of zero tolerance.

• Such practices, if correctly implemented, do not significantly raise operating costs and are adaptable to Italian farming.

• Although the evidence thus far indicates that crops behave uniformly in the different settings analysed, it would be wise to take account of soil, weather and environmental conditions, in order to render measures as effective as possible and make sure they do not present more of a burden to farmers than is necessary.

• Field research and statistical models indicate that in the case of maize, a distance of 25-40 meters between genetically modified and conventional crops is sufficient to keep the rate of cross-pollination below the 0.9% threshold allowed by the European Union in order to declare products "non-GM."

Thus, the coexistence of different farming methods is possible, as long as national and regional institutions respect the EU recommendations of transparency, scientific basis, proportionality and specificity, and see to the monitoring and management of coexistence practices.

Bologna, march 15, 2006

¹ Guns, Germs and Steel - Diamond, J. (1997). Italian edition: Armi, Acciaio e malattie, Ed. Einaudi.

² Directive 2001/18 on the deliberate release into the environment of genetically modified organisms.

³ Suslow TV et al. (2002) Biotechnology Provides New Tools for Plant Breeding. University of California. Division of Agriculture and Natural Resources. See anrcatalog.ucdavis. edu for a compendium of the most common genetic engineering techniques.

⁴ Paine JA, 2005. Improving the nutritional value of Golden Rice through increased pro-vitamin A content. Nature Biotechnology 23, 482 - 487

⁵ Food Safety and GMOs. 2004. Consensus document on GMOs signed by 19 Italian scientific associations (including ANBI, the national association of biotechnologists), representing more than 10,000 researchers

⁶ Crawley MJ, 2001. Biotechnology: Transgenic crops in natural habitats. Nature 409, 682 – 683

⁷ DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

⁸ REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed

⁹ Food Safety and GMOs. 2004. Consensus document on GMOs signed by 19 Italian scientific associations (including ANBI, the national association of biotechnologists), representing more than 10,000 researchers

¹⁰ COMMISSION RECOMMENDATION of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming

¹¹ Presidential Decree 187 of 9 February 2001. Art. 6, par. 5

¹² Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

¹³ Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

¹⁴ REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

¹⁵ COMMISSION RECOMMENDATION of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming (2.2.3)

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¹⁷ POECB, 2004. Operational Programme for Evaluation of Biotechnology Crops.

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¹⁹ Farm Scale Evaluation (2003-2005) http://www.defra.gov. uk/environment/gm/fse/

²⁰ IRTA, 2004.

²¹ Agroscope FAL, 2005. Koexistenz einer Landwirtschaft mit und Gentechnik.

²² Sorlini C. et al., 2004. Biodiversità e organismi geneticamente modificati. Ministry of the Environment. CNR. COOP Italia. 2004. GMOs and field studies

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²⁴ AK Bock, K Lheureux, M Libeau-Dulos, H Nilsagård, E Rodriguez-Cerezo (2002) Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture (IPTS - JRC); Ingram, J. 2000. Report on the separation distances required to ensure crosspollination is below specified limits in non-seed crops of sugar beet, maize and oilseed rape. MAFF Project no. RO0123. Accessed 7/8/2002 at; C Norris and J Sweet (2002) Oilseed Rape and Gene-flow, NIAB; Ellstrand N.C., Prentice H.C. & Hancock J.F. (1999) Gene flow and introgression from domesticated plants into their wild relatives. Annual Review of Ecology & Systematics 30 pp 539 - 563; ACRE (2002) Background Paper Gene Flow From Genetically Modified Crops

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²⁶ http://www.agrimodena.it/bietola/avviso.htm

²⁷ ACRE (2002) Background Paper Gene Flow From Genetically Modified Crops; Bock A.K., Lheureux K., Libeau-Dulos M., Nilsagård H., Rodriguez-Cerezo E. (2002) Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture (IPTS - JRC)

²⁸ aphis.usdagov/brs/soybean

²⁹ Ray JD, Kilen TC, Abel CA, Paris RL (2003) Soybean natural cross-pollination rates under field conditions. Environ Biosafety Res. 2:133-8.

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