Project no. **501986**

Project Acronym: **SIGMEA**

Project title: **Sustainable Introduction of GM Crops into European Agriculture**

Instrument: **STREP**

Thematic Priority: **FP6-2002-SSP1 (Policy Oriented Research)**

# Publishable Final Activity Report

# VERSION 2.0

Period covered: **from 3 May 2006 to 2 November 2007**

Date of preparation: December 2007

Start date of project: **3 May 2004** Duration: **36+6 months**

Project co-ordinator names: **Jeremy Sweet, administrative coordinator, NIAB**
**Antoine Messéan, scientific coordinator, INRA**
Project co-ordinator organisation name: **NIAB** Revision: 2.0

**Project no. 501986**

**Project acronym SIGMEA**

# SIGMEA Sustainable Introduction of GM Crops into European Agriculture

# Publishable Final Activity Report

Period covered: from 3 May 2006 to 2 November 2007
Start date of project: 3 May 2004

Date of preparation: 17/12/2007
Duration: 36 months + 6 month

Project co-ordinators: Administrative Co-ordinator: Jeremy Sweet (NIAB)

Scientific Co-ordinator: Antoine Messéan (INRA)

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**Summary description of project objectives:**

In 2003, the European Commission established the principle of coexistence which refers to "*the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards*" and laid down guidelines defining the context of this coexistence[1].

In order to determine what is needed for the sustainable introduction of GM crops in Europe, the cross-disciplinary SIGMEA Research Project was set up to create a science-based framework to inform decision-makers. SIGMEA has (i) collated and analysed European data on gene flow and the environmental impacts of the major crop species which are likely to be transgenic in the future (maize, rapeseed, sugar beet, rice, and wheat), (ii) designed predictive models of gene flow at the landscape level, (iii) analysed the technical feasibility and economic impacts of coexistence in the principal farming regions of Europe,

[1] Commission recommendation of 23 July 2003 (http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf)

(iv) developed novel GMO detection methods, (v) addressed legal issues related to coexistence, and (vi) proposed public and farm scale decision-making tools, as well as guidelines regarding management and governance.

This publishable version of the final activity report of the FP6 SIGMEA research project, covers the fourteen major issues under investigation.

## Partners involved

- NIAB, UK
- Centre Technique Interprofessionnel des Oléagineux Métropolitains, CETIOM, France
- Institut National de la Recherche Agronomique, INRA, France
- University of Bremen, Uni-Bremen, Germany
- Fraunhofer-Gesellschaft zur Foerderung der angewandten Forschung e.V. FhG/ISI Germany
- Joint Research Centre JRC, Belgium
- Jozef Stefan Institute JSI, Slovenia
- University of Sheffield Uni Sheffield, UK
- Rothamsted Research RRes, UK
- Scottish Crop Research Institute SCRI, UK
- Institute of Grassland and Environmental Research IGER, UK
- Swiss Federal Institute of Technology ETH, Switzerland
- Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria INIA, Spain
- Universita Politecnica delle Marche UNIVPM, Italy
- Istituto Sperimentale per le Colture Industriali ISCI, Italy
- Bundesamt für Verbraucherschutz und Lebensmittelsicherheit BVL, Germany
- Plant Research International PRI, The Netherlands
- ADAS Consulting limited ADAS, UK
- Central Science Laboratory, DEFRA CSL, UK
- University of Hohenheim UHOH, Germany
- University of South Bohemia, Ceske Budejovice USB, Czech Republic
- University of Bern UNIBE, Switzerland
- Institute for Agriculture and Fisheries Research ILVO, Belgium (ex-CLO)
- Catholic University of Louvain KULeuven, Belgium
- Czech University of Agriculture in Prague CZU, Czech Republic
- Danish Research Institute of Food Economics FOI, Denmark
- Research Institut of Organic Agriculture FiBL, Switzerland
- Danish Institute of Agricultural Sciences AGRSCI now University of Aarhus, Denmark
- Technical University of Braunschweig TUBS, Germany
- Consejo Superior de Investigaciones Cientificas CSIC, Spain
- Federal Biological Research Centre for Agriculture and Forestry BBA, Germany
- Silsoe Research Institute SRI, UK (withdrew from the project after year 1.)
- Technische Universitaet Muenchen TUM, Germany
- Cambridge Environmental Research Consultants CERC, UK
- National Environmental Research Institute NERI, Denmark
- University of Paris 11 UPS, France
- Arcadia International Arcadia, Belgium
- Institut de Recerca i Tecnologia Agroalimentàries IRTA, Spain
- Riso National Laboratory RISO, Denmark
- Plant Breeding and Acclimatisation Institute IHAR, Poland
- University of Reading Uni Reading, UK
- ARVALIS - Institut du vegetal ARVALIS, France
- University of Applied Sciences of Weihenstephan FHW, Germany

## Introduction:

Genetically-modified (GM) plants are now widely cultivated throughout North and South America, as well as to a lesser extent in Asia. In Europe, only a few thousand hectares of Bt maize are currently being grown, mostly in Spain. Over the last ten years, European regulatory provisions reinforced the prior evaluation of GM crops, set up rules concerning traceability and labeling, and imposed post-marketing monitoring. In turn, the European Commission established the principle of coexistence which refers to "*the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards*" and laid down guidelines defining the context of this coexistence[2].

What needs to be accounted for if we are to introduce in a sustainable manner GM crops throughout Europe so that coexistence is feasible? The cross-disciplinary European SIGMEA Research Project was set up to provide to decision-makers science-based information about the appropriate coexistence and traceability measures that would be needed.

To this end, SIGMEA brought together the principal teams and thereby the principal programmes studying gene flow in a large number of countries across Europe, representing a wide range of agricultural systems including organic farming. In addition, seven regional case studies were carried out for designing and assessing scenarios for coexistence.

Within the last 5 years, SIGMEA has accomplished a full scope of objectives. They range from the collection and the analysis of all available European data on gene flow and the environmental impacts of major GM crops as well as from the design of predictive gene flow models at the landscape level, to the analysis of the technical feasibility and economic pertinence of coexistence in the principal farming regions of Europe. This has made it possible to propose public and farm scale decision-making tools, as well as guidelines regarding management and governance.

The publishable version of the final activity report of the FP6 SIGMEA research project, covers the fourteen major issues under investigation.

[2] Commission recommendation of 23 July 2003 (http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf)

1. **<u>The largest collection in Europe of data on gene flow and persistence has been organized.</u>**

SIGMEA collated and synthesized experimental data on gene flow and filled gaps in knowledge by designing and conducting further evaluations, particularly at the landscape-scale or over several years of cropping sequence. Maize and oilseed rape were the major crops targeted for this study - other crops under consideration were sugar beet, rice and wheat. Available information from past and current field studies on cross pollination, volunteers, ferals and wild relatives were gathered from 22 SIGMEA partners through a rigorous procedure which ensured quality control through electronic submission of data sets using a standard template or 'data-entry format', thorough checking and retrieval of any missing information, internal review of each data set, and a formal mechanism for completing and 'signing off' data sets. The data were made available to other users within SIGMEA through a secure web server.

The synergies within the project led new research studies, using harmonised protocols, on moderate- to long-distance gene flow, plant demography and characterising volunteer, feral and wild populations. Thanks to those studies that arose within the SIGMEA project, the collated database was significantly enhanced. By the end of the SIGMEA project, the database had over 100 data sets (Fig. 1), constituting more than 150 "experiment-years". Around two thirds of the data involve oilseed rape or close relatives. Information for beet and maize comprised just less than one sixth each. A few data sets were submitted on wheat and rice. Data on crops and volunteers constitute around 35% each, wild relatives 16% and ferals 6%. However, there is little data on ecological impacts — as distinct from gene flow by seed and pollen. Formal submissions from this field study involve Bt maize in Spain and herbicide tolerant oilseed rape.

Due to the very high replication achieved by combining data from different sites, the crop-specific conclusions in SIGMEA on cross pollination and seed persistence in maize and oilseed rape are mostly of very high statistical significance and make it possible to draw general conclusions about given topics. Most of the data sets provide information on scale, climate, geography, biology, as well as spatial and temporal factors associated with pollen flow, cross pollination and seed dynamics, in more detail than appears in refereed publications. The data sets have been extensively used to provide added value through meta-analysis, data mining and the development and verification of gene flow models designed within SIGMEA. Additionally, the database allowed an assessment of three questions about transferability of information: the consistency of measurements at different spatial (or temporal) scales; the differences between agricultural regions in Europe with different climates and soils; and the behaviour of different crop species.

Since much of the research is still not in the public domain, the data sets are presently accessible only within SIGMEA to partners who submitted data, and to others with designated access.

In summary, the SIGMEA database, together with already published information, provided a sound basis to investigate maize, oilseed rape and beet, and draw the conclusions as summarised below.

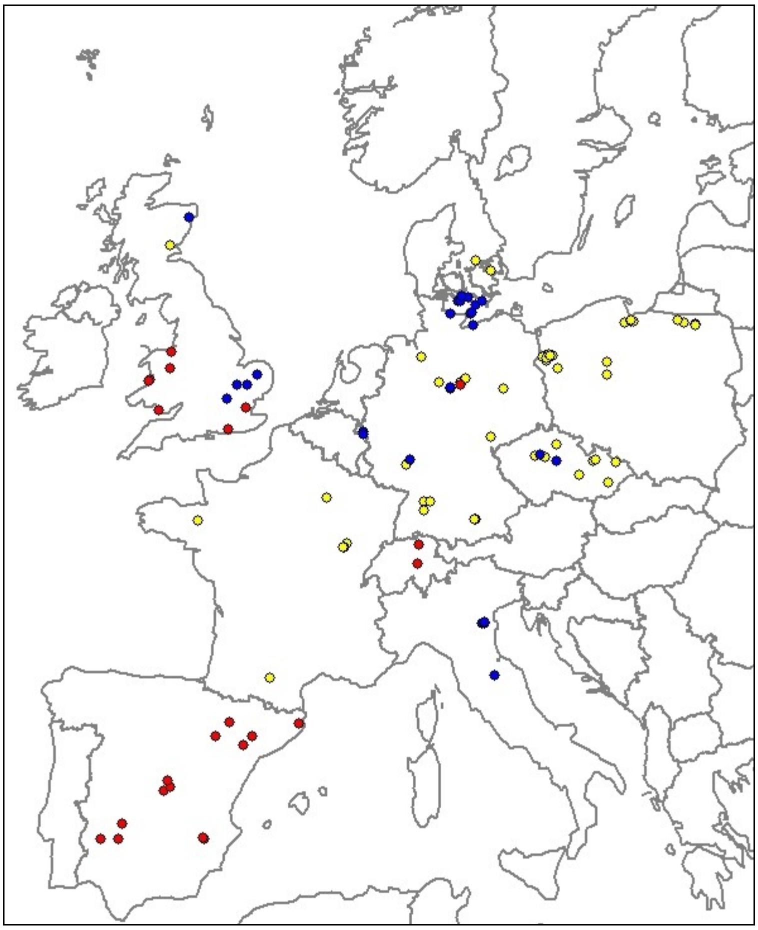

**Figure 1**. Location of main experimental studies available in the SIGMEA database on maize (red), oilseed rape (yellow) and beet (blue). Some locations involved several experiments.

## 2. <u>Enhanced understanding of gene flow informs practical strategies for coexistence in maize, oilseed rape and sugar beet.</u>

Similar biological mechanisms govern the life histories of all crop plants. They produce structures that survive over time and disperse over space and by these means have the potential to transfer genes from one crop to another. Seed-borne genetic impurities can arise by several routes: from plants already present in the field as volunteers (weeds of the same species as the crop) and wild relatives; by seed brought to the field in the sown seed or on farm machinery; and by seed dispersed from feral plants or wild relatives growing around the the field. Volunteers or wild relatives growing in the same field can contribute their own seed to the harvest. Pollen-borne genetic impurities can arrive from another crop and from volunteers, ferals and wild relatives. The seed-borne genetic impurities can arise at any time of the year and from crops grown in the past, while pollen transmission occurs during the relatively short period that both receptor and donor plants are in flower.

*Maize*

Experiments relevant to coexistence of maize in Europe were almost exclusively on cross pollination between crops, since admixture through seeds and pollen from volunteers was thought to be low and relevant only in warmer regions. Maize has no wild relatives and few feral plants are found in Europe. However maize landraces are maintained in some regions, so special consideration was given to the cumulative outcrossing which may occur between modern varieties and landraces.

Cross pollination has been examined in great detail in several European countries, either using GM crops as a donor or using markers such as yellow and white grain colour. The database allows comparisons across scales, from small plots to full sized commercial fields, and in several contrasting climates in Germany, Spain, Switzerland and the UK. The studies are consistent and indicate a steep decline in cross pollination over three orders of magnitude (a 1000-fold) with distances to 100 m from the source of pollen, and an effect on percentage pollination of wind direction and related meterological factors. Cross pollination declined with distance in a similar manner in both experimental plots and full-sized fields. At 100 m from the donor, cross pollination was below 0.1% in most circumstances. Where donor and receptor fields were well dispersed in a landscape, and at a generally low overall density, the average cross pollination was typically 0.01% between 100 m and several kilometers. Where donor and receptor fields were grown close together in similar proportions (as in Spain, a region where commercial crops are grown without coexistence measures), cross pollination rates above 0.9% were sometimes found in situations where non-GM fields were completely surrounded by GM fields and both types flowered at the same time.

In summary, the potential for adventitious presence of GM material in non-GM maize production is:

- moderate for cross pollination between fields, and can be managed through separation, discards or buffers where crops are in close proximity;
- low through volunteers, and this is mainly in southern Europe;
- low for introgression to landraces from modern crop varieties;
- zero through wild relatives as none exist in Europe.

Over most of Europe, therefore, the biology, environment and agronomy of maize have been well characterised, so that coexistence (defined as complying with the official threshold) for hybrid varieties should be achievable through the use of high purity seed, the management of cross pollination by using varieties that flower at different times and/or spatially separating fields, or the installation of buffer zones or the practice of discarding where fields are in close proximity. However, a zero level of adventious presence cannot be achieved or measured in practice. Volunteer maize still needs to be investigated thoroughly in climates where it occurs.

*Oilseed rape*

Genetic impurities in oilseed rape can arise from a wider range of sources than in maize. Pollen is dispersed by wind, hive bees, bumble bees and a variety of other insects. Transfer by seed following seed drop at harvest can be very high, as large seedbanks can form which survive for several years producing volunteers in subsequent crops. Also seed is transported on farm machinery, from which the small seeds are difficult to remove under normal agricultural conditions. Feral plants are widespread along waysides and margins, while wild relatives, notably *Brassica rapa* (the wild turnip), occur locally and cross pollination with crops, volunteers and ferals.

In total, results from over 50 field-experiments on oilseed rape from the Czech Republic, Denmark, France, Germany, Poland and the UK were re-examined in SIGMEA. Results on cross-pollination differed according to experimental designs, regions, cultivars and climates, but a dispersal function with a ‘fat’ tail (power-law) appears to be the most appropriate currently available to predict pollen movement at any scale. Over distances of tens of metres, cross pollination showed a similar decline to that in maize, and was typically less than 0.1% at 100 m from the edge of the donor; but crossing between commercial fields was sometimes as high as 0.1% even at distances between 100 m and 1000 m. The contribution of volunteers to admixture of harvested seed may range from <0.01% to more than 10% for the same crop variety in different management, soil and climatic conditions A range of agronomic practices can be deployed to limit transfer through seed banks such as delaying soil cultivation after harvest to allow germination and destruction of seedlings, increasing the interval between crops and stale-seedbed techniques. Comparison of feral oilseed rape in more than 20 growing seasons across 5 study areas enabled the definitive statement that, though widespread and sometimes persisting in the same place over several years, ferals are a negligible fraction of the total flowering oilseed rape in a region and contribute little to admixture in crops. The abundance of wild relatives differs between regions, and while their progeny may be fertile and as ecologically fit as the parents, they do not constitute a major route for transmission of traits between to crops.

In summary, the potential for adventitious presence of GM material in non-GM oilseed rape production is:

- moderate for cross pollination between fields, which can be managed through spatial separation and use of buffer or discard zones where crops are in close proximity;
- high through seedbanks resulting in volunteer populations that admix with and pollinate non-GM crops - volunteers are ubiquitous, mobile and commonly in high abundance and are of maximum importance to coexistence over time (when non-GM OSR is to be grown after a GM OSR in the same field);
- moderate through wild relatives in those localised areas of Europe where they occur in high abundance in the fields (e.g., *B. rapa* in Denmark)
- low through ferals (with some local exceptions) because of their low overall density compared to crops and volunteers in the landscape.

Problems of coexistence during the first few years of commercialisation can be reduced by management of cross pollination through separation and seed purity. However uncertainties remain over whether the cumulative movement and amplification of volunteers can be managed so as to achieve coexistence in of GM and non-GM oilseed rape in the longer term.

*Beet*

Crop varieties, in-field volunteers, ferals and wild types of beet are all sexually compatible variants of the species, *Beta vulgaris,* and together comprise the Beta complex. Crop beet plants are biennial, producing root bulk in the first season (after which they are usually harvested) and flowers in the second. By contrast most wild and weed beet forms are annual, producing flowers in the year they germinate. Flowers produce small wind-borne pollen that can disperse over large distances. The main source of genetic impurity in commercial crops arises from seed produced in localised areas of Italy and France in fields consisting of male fertile pollinators and male sterile seed mother plants. The male sterile mother plants can also receive pollen from volunteers, ferals and wild sea beet in the surrounding countryside and from other seed production fields in the area. The wild and weedy forms introduce annual genes into the seed crop, which give rise to annual plants that flower in the first year of the crop but produce little or no root and sugar yield. If allowed to set seed, these annual weedy beets give rise to seedbanks lasting many years, from which annual volunteers (bolters) will flower.

Annual traits, whether GM or otherwise, have the potential to spread in commercial production areas, but as indicated above, annual plants rarely give rise to tubers and so contribute little to adventitious presence in sugar beet. Their main importance is as weed. If herbicide tolerant (HT) beets are grown, HT weed beets will arise and pollinate non-GM weed beets and in this way introduce HT genes into non-GM fields. Since this does not translate in adventitious presence of GM in the final crop (roots), and therefore is not a coexistence issue *sensu stricto*, it could create weed management problems. For example, if the HT trait conferred tolerance to glyphosate, this same herbicide would become less effective for weed beet control in the non-GM beet crops.

SIGMEA drew together current and recent research on the Beta complex. Compared to maize and oilseed rape, there is little data on the form of the decline in cross pollination with distance, though in the studies examined pollen was found to move over at least several hundred metres. The work on beet in SIGMEA concentrated on weed and wild beet. Unlike in the other two species examined, the wild form, sea beet, is an important genetic resource within the *Beta* complex, and is used as a source of genetic traits by plant breeders. Genetic assessment of plants growing along both the Baltic and Adriatic coasts, confirmed populations remain highly diverse and distinct from crop varieties. Nevertheless, areas were identified where the crop, volunteer, feral and wild beets exist in proximity and exchange genetic material through movement of seed and pollen. It is considered essential to preserve the diversity of sea beet for any long term, plant breeding strategy, and for conservation and study in its own right.

In summary, the potential for adventitious presence of GM material in non-GM sugar beet production is:

- low through cross pollination between sugar beet crops since the harvest is vegetative,
- low through volunteer (weed beet) populations which arise from impurities in sown seed, since best management should minimise any harvest contamination with roots of these weed beets;
- low though cross pollination from feral plants and wild beet for the reasons given for volunteers.

The main source of adventitious presence is therefore through the seed sown to grow crops of sugar beet. Coexistence should still be achievable by best management of seed production crops, and by strategic siting and separation of seed production fields. Specifically, GM seed production crops need to be sufficiently separated from non-GM crops and from wild and weedy beet (which in time would contain GM individuals) both to keep the non-GM seed pure and to reduce the spread of transgenes into wild, weedy and feral populations. Separate areas or regions for GM and non-GM seed production may be required.

*Wheat and rice*

The knowledge-base for wheat and rice in Europe is much less than for the other crops, but tentative conclusions are that the potential for adventitious presence should be:

- low through cross pollination between crops,

- probably low in rice (to moderate in wheat) through volunteers, but their contribution needs to be clarified under European conditions;
- low in wheat through wild relatives, and low to moderate in rice through the red rice weed, in those areas where it occurs, provided agricultural practices to control this weed are applied.

Further research is needed on cross pollination and the life cycle of these species and their wild relatives in Europe.

*General*

In summary, the general conclusion drawn from gene flow studies of maize, oilseed rape and beet is that adventitious presence due to cross pollination alone can generally be managed through separation distance and related measures to comply with the official EU regulation. However it should be recognised that a zero level of adventious presence cannot be achieved or measured in practice.

Oilseed rape (OSR) was identified by SIGMEA as having major problems in the management of coexistence. The problems arise principally because OSR seeds survive for several years in soil and give rise to volunteers that are competitive and difficult to eliminate,. Thus gene movement and persistence in seeds and volunteers is difficult to manage agronomically. Coexistence issues arising from maize volunteers are manageable using good agricultural practice. The problems associated with weed beet are mostly related to seed production which therefore needs careful management on a regional scale.

There remains uncertainty on the relevance to coexistence of transgenes that might confer differential fitness, for example by being associated with reduced pollen production or resistant to common herbicides. Further measurements at previous GM release sites are needed to assess the persistence and genetic structure of relevant populations (e.g. volunteers, wild relatives). State of the art modelling tools (individual based, spatially explicit, incorporating introgression of multiple events) have been developed to simulate the population dynamics around complex transgenic events, and could be adapted as aids to monitoring following commercialisation.

## 3. A synthesis of available data on environmental impacts of Bt maize and HT oilseed rape within European cropping systems has been produced

SIGMEA reviewed the (a) impacts of gene flow and introgression on within-and-between-species plant diversity and (b) the wider ecological implications of growing Bt maize and HT oilseed rape. It linked several important 'impact' studies, notably those in Spain on Bt maize[3] and in the UK on HT beet, maize and oilseed rape[4], and was closely associated with the EU ECOGEN project on Bt maize[5].

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[3] Monitoring programme of Bt maize in Spain: Farinos et al., 2008. Diversity and seasonal phenology of aboveground arthropods in conventional and transgenic maize crops in Central Spain. *Biological Control*, Volume 44, Issue 3, March 2008, Pages 362-371

[4] Farm Scale Evaluation : Firbank et al., 2003. An introduction to the Farm Scale evaluations of genetically modified herbicide-tolerant crops. *Journal of Applied Ecology* 40, 2-16.

[5] FP5 project ECOGEN (www.ecogen.dk/reports) - PH Krogh & B. Griffiths, 2007. ECOGEN: soil ecological and economic evaluation of Genetically Modified Crops. *Pedobiologia* 51 (2007) 171—173

The approaches to studying environmental impacts in SIGMEA were based on the key elements described in the US Environmental Protection Agency Guidelines of 1998 and the European Food Safety Authority Guidance Document of 2006. The 'exposure' and the 'effect' were considered for a range of ecological indicators of the in-field soil and food web, including soil biophysical status, soil micro- and meso-fauna, plant species, functional groups and assemblages (as affected by introgression and field management, e.g. herbicide), plant-feeding invertebrates and other invertebrate functional or trophic groups. There was little evidence available to SIGMEA (and little evidence generally) of wider effects on, for example, biogeochemical cycles and the quality of water or air. The conclusions reached by SIGMEA for the main crops studied are as follows:

- Maize (Bt varieties, targeted at corn borers). There appears to be no reason on grounds of biosafety not to increase the scale of growing. The most consistent finding is that Bt maize in field trials and crop production in Europe to date had no systematic or reproducible effects on any of the invertebrates or soil organisms studied over a time period of several years. In contrast, over similar time periods, other agronomic factors did have large and measurable effects on the same organisms. Appropriate monitoring should be in place, especially for resistance development in corn borers, and potential effects on certain sensitive non-target biotic groups should be considered in greater depth.

- Oilseed rape (HT varieties, tolerant to glufosinate ammonium or glyphosate). The ranking of HT oilseed rape against the comparator, usually the conventional crop and agronomy, varied with the local context. Negative effects occurred where a) the herbicides used in HT cropping caused a systematic depletion of the weed flora and dependent invertebrates resulting in reductions in biodiversity within fields, and b) the presence of HT volunteers limited future options for use of herbicides and the growing of certain crops such as beans in which volunteers are difficult to control. Positive effects may occur due to the herbicides used with HT cropping being less toxic to non-weed organisms than most other herbicides and crop protection chemicals. Nevertheless, the ecological effects of HT crops compared to non-HT in the same production system are generally smaller than those due to differences between crop species, season of sowing or agronomic practices.

- Beet. The various types of beet - crop, weed, feral, wild - are in genetic contact through seed and pollen. Wild beet needs proactive conservation, since it is a biologically interesting plant form of restricted habitat, a source of genes for future beet breeding and a source of annual impurities in crop beets. HT beet cultivation could also deplete biodiversity within fields for the same reasons as discussed for HT oilseed rape.

In summary, statistically significant effects of GMHT cropping on ecological processes or organisms have been obtained in the field, but most effects are smaller than or at most comparable to those due to general agronomic operations. There is an increasing consensus that future assessment of GM crops considers both negative and positive impacts of GM cropping in a more holistic way than previously. Most important, standards and criteria for environmentally resilient cropping systems are needed against which GM cropping and its non-GM comparator can be assessed. Setting such environmental standards is now an absolute priority.

4. **A landscape generator simulating agricultural landscapes has been designed and is available on-line**.

SIGMEA designed LandSFACTS, a user-friendly windows-based software to simulate crop allocation to fields by integrating typical crop rotations and crop spatio-temporal arrangements within agricultural landscapes. LandSFACTS reproduces the farmers' decision-making process for crop succession and location (rotational and spatial rules). Rules on rotational (equivalent to temporal), spatial and spatio-temporal patterns of crops in agricultural landscapes were determined by analysing existing data from SIGMEA case study areas, by analysing the questionnaires to farmers on the decision process for growing specific crops on specific fields and their links to agronomical and economical rules, and by analysing results of discussions with farmers' advisers. Specific modelling algorithms for simulating crop allocation to fields in a realistic and reliable way were created.

The general structure of LandSFACTS, its interfaces with Geographical Information Systems (GIS) and the generic gene flow platform LandFlow-Gene as well as its user interface were set up through a close liaison with modellers and case studies to ensure its usefulness and quality.

The final version of LandSFACTS was released in June 2007 as open-source software under the GNU Public Licence and is publicly available at http://www.rothamsted.bbsrc.ac.uk/pie/LandSFACTS/.

In summary, LandSFACTS generates an agronomic arena that can act as the input for other research tools, especially models, and for informing various issues related to to spatial agricultural processes. Indeed, agricultural models often need to operate at large spatial scales, such as landscapes or regions over many years. LandSFACTS facilitates the setting up of realistic scenarios at such scales.

5. **An operational, practical and dynamic generic gene flow modelling platform LandFlow-Gene is available for research purposes**

A generic gene flow platform has been designed and validated for research purposes. LandFlow-Gene allows users to evaluate the effects of landscapes, climate, cropping systems, agricultural practices on gene flow and adventitious presence of GM material in non-GM production. LandFlow-Gene is operational for maize and oilseed rape through the use of two previously existing models: MAPOD® (Maize) and GeneSys (Oilseed Rape). These models have been further validated within SIGMEA and have benefited from the largest available data sets collated in Europe in an improved capacity to assess and predict levels of gene flow between crops.

Interfaces with GIS-data sets and the Landscape Generator LandSFACTS are available (figure 2).

LandFlow-Gene thus provides tools to run spatial and temporal simulations of pollen and seed dispersal for rapeseed and maize crops. Given an agricultural landscape, a climate, cropping systems and crop management practices, LandFlow-Gene predicts the adventitious presence of GM in non-GM fields under various scenarios of GM adoption. Figure 3 presents an output of LandFlow-Gene for maize.

LandFlow-gene was used to analyze the regional case studies of SIGMEA and to support the cost analysis.

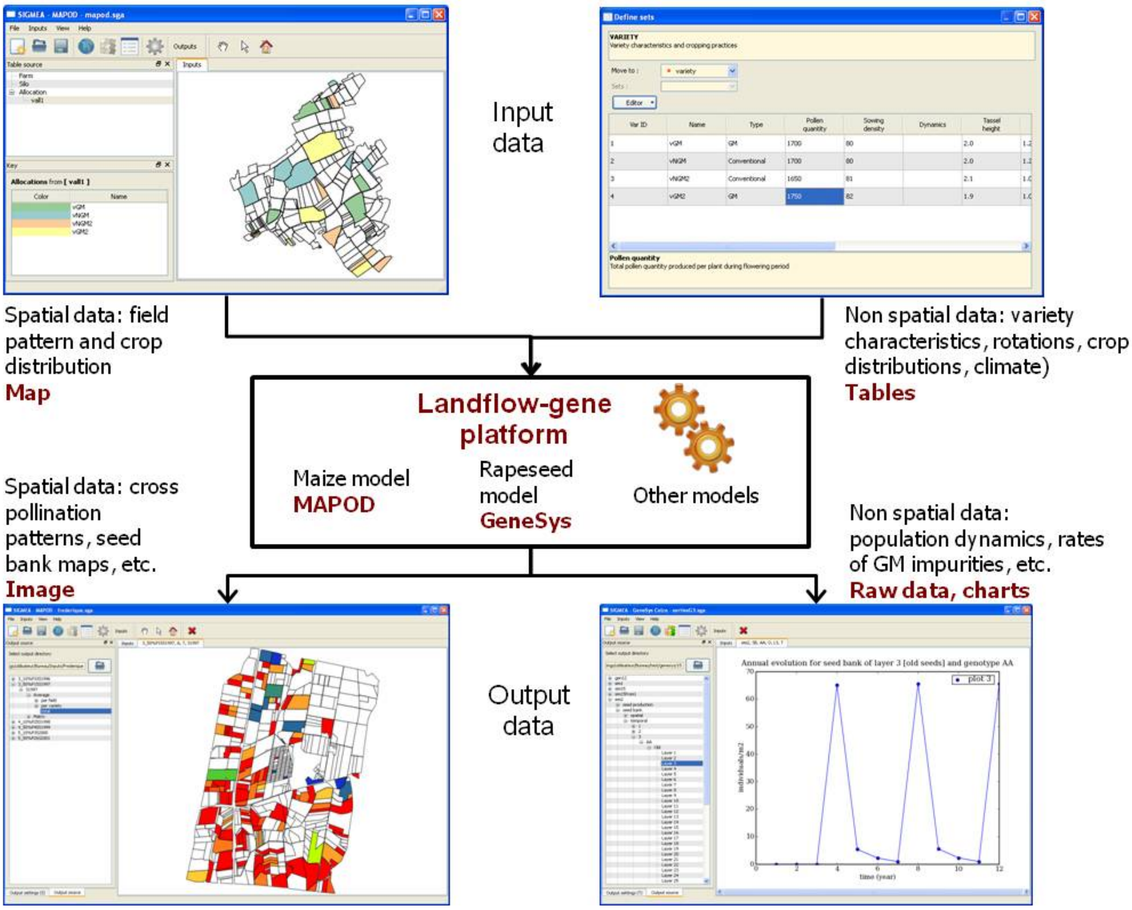


**Figure 2. General Structure of LandFlow-Gene.** Landflow-gene uses spatial information on landscape patterns and crop allocation as well as information on crop management, climate and varieties to estimate the proportion of GM material in non-GM crop production. Outputs can be obtained at the field level (average mean of adventitious presence) or for small units (intra-field adventitious presence).

The following software was developed by SIGMEA[6]:

- Landflow-gene: complete generic platform software for rapeseed and maize.
- Landflow-gene-GeneSys: generic platform for rapeseed;
- Landflow-gene-MAPOD: generic platform for maize;
- Landflow-gene-Viewer: viewer for Landflow-gene outputs;
- Shpconv: converter of shapefile (file coming from GIS) into matricial or vectorial format.

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[6] The three first software products include MAPOD® and/or GeneSys© for rapeseed. Access to MAPOD® and GeneSys for research applications is governed by a license agreement under the European agency for programme protection (http://app.legalis.net/) granted to INRA in 2003 and renewed in 2005 (GeneSys) and in 2006 (MAPOD® ). This helps to protect INRA in the case of liability issues. Members of the SIGMEA consortium have access to these models if they sign a licence agreement. To date, the use is restricted to research purposes.
The two last programmes were specifically produced by SIGMEA partners. Members of the consortium have free access but distribution outside of the SIGMEA consortium requires agreement from INRA to ensure traceability of uses.

In summary, SIGMEA has developed a generic platform to model gene flow at the scale of agricultural landscapes – LandFlow-Gene. For any agricultural plot described using a geographical information system, this platform can test different scenarios of GM introduction, take account of the effects of practices and the climate, and deliver a diagnosis as to the gene flow. The current version is now operational for maize and rapeseed, and could easily be extended to include other species. In addition, the platform could be adapted to take account of other biological flows, such as spore dispersal. SIGMEA thus makes it possible to answer questions such as "what will happen, in terms of gene dispersal, if a particular GM organism is introduced into a particular European region?" and "how can crops be organised so as to maintain the adventitious presence of GMOs in conventional crops within the legal thresholds?

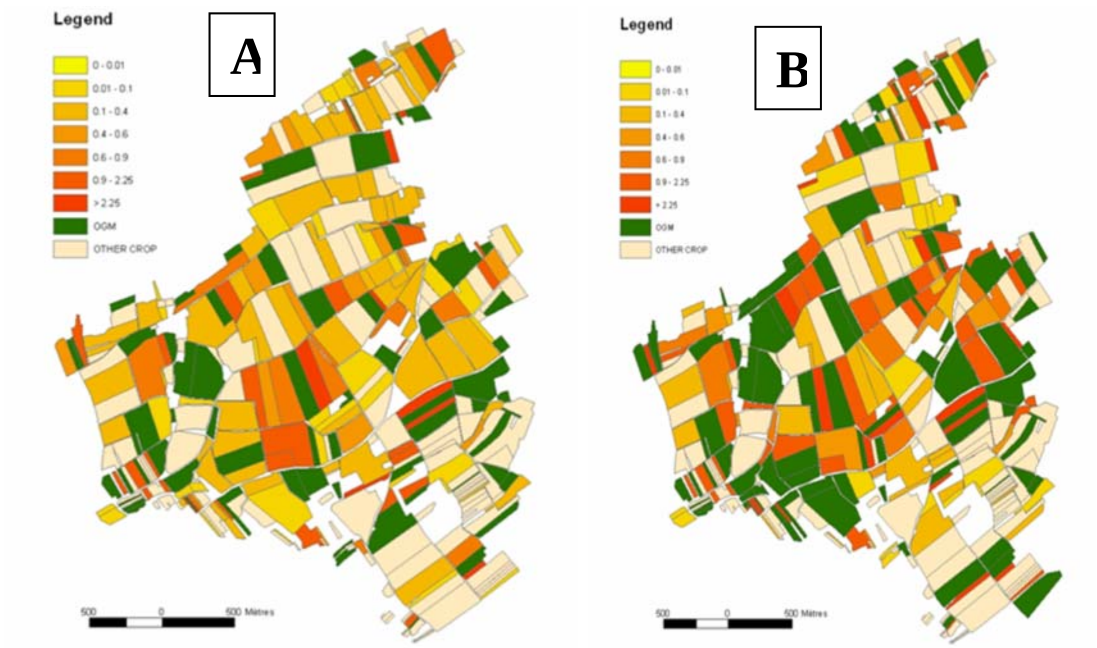


**Figure 3.** Outputs of LandFlow-Gene. This landscape is simulating conditions in Alsace (France) where 70% of the arable land is maize,  10% of maize fields are GM maize. A and B are two different allocations of GM maize: in case B the GM fields are less scattered and the overall GM adventitious presence in non-GM fields is lower (0.18%) than in allocation A (0.23%).

## 6. <u>The feasibility of coexistence and its costs have been analyzed in various European agricultural situations and scenarios for managing coexistence are proposed</u>.

European Agriculture is diverse and landscapes, climate, cropping systems and crop management practices differ across Europe. Managing coexistence in practice has been studied at the regional level by assessing the impact of growing GM crops on gene flow under various scenarios. Regional case studies were conducted at three embedded scales: whole regions, small agricultural regions corresponding to homogeneous farming systems, and small landscapes of a few km² according to the requirements of the simulation tools.

The approach implemented four steps:

- firstly, the case studies were described according to all the main variables influencing coexistence.;
- Secondly, the impact of structural variables (mainly landscapes and cropping systems) was assessed without any coexistence management measures (using the LandFlow-Gene platform);
- Thirdly, identification and management of critical points were discussed according to the opinions of the main stakeholders and considering their views on constraints and leeways. For this purpose, new data were collated from: 1) surveys carried out with individual farmers, 2) working groups of farmers, collecting firms and advisers and, 3) the use of simplified gene flow model based on LandFlow-Gene simulations to test the efficiency of certain strategies;
- Finally, the fourth step set up scenarios based on role-playing games allowing stakeholders to discuss realistic management situations. Simulations were used during the games to predict the consequences of different management strategies.

Seven case studies were chosen, but the whole methodology was implemented only for two of them (Table 1). The work carried out in Aragon, Aquitaine and Fife aimed at comparing the effect of structural variables on gene flow and the management of critical points between case studies. Simulations were carried out in Switzerland and Schleswig Holstein to illustrate specific problems or phenomena such as the management of boundaries (Switzerland/France) or dilution effects (Schleswig Holstein). Although Beauce and Alsace were the main studies, generic conclusions were drawn for other regions as well.

| **Case study** | **Crop** | **Description of regional contexts and crop management practices** | **Assessment of coexistence under current practices** | **Management of critical points (effect of additional measures)** | **Elaboration of scenarios** |
|---|---|---|---|---|---|
| Alsace (France) | maize | ■ | ■ | ■ | ■ |
| French-Swiss border | maize | | ■ | | |
| Aragon (Spain) | maize | ■ | ■ | | |
| Aquitaine (France) | maize | ■ | ■ | | |
| Beauce (France) | OSR | ■ | ■ | ■ | ■ |
| Fife (Scotland) | OSR | ■ | ■ | | |
| Schleswig Holstein (Germany) | OSR | | ■ | | |

Table 1: Regional case studies. Grey boxes indicate the actions undertaken for each case study.

The work carried out suggested a framework to identify and organize the main factors that could determine the implementation of coexistence in specific contexts.

These factors fall into three categories:

1.- **Structural variables** describing the characteristics of the agroecosystem (cropping systems, landscapes, meteorology, crop management) having an influence on gene flow.

2. - **Organizational variables** concerning farmers and grain collecting firms, explaining how they adapt their management according to certain constraints and rooms for manoeuvre. We identified two types of adaptation. Firstly, each actor mobilizes its own resources to various degrees, from technical choices in the short term, to more strategic in the long term: a farmer, for example, may adapt agricultural practices, change his rotations, or decide new investments, while a collecting firm may amend the planning of the grain collection or decide to invest in new storage capacity. Secondly, coordination is crucial, whether between farmers, collecting firms or between farmers and collecting firms. Here arises the question of practical feasibility of collecting and sharing information in a region.

3.- Characteristics of the **introduction of GMOs**. Coexistence implementation also depends on market conditions (relative prices of GM and non-GM products on the marketplace), on considered thresholds (which can differ from what is required by regulation, e.g., specific market requirements) and on traits (some traits –e.g., Bt traits which require refugia areas - may facilitate or constrain certain types of coexistence measures).

For given characteristics of GM introduction (crop density, marketshare of GM, threshold), we have highlighted the variability of structural and organizational factors, between regions and within each of them. Maize case studies, for example, have shown that the comparative sensitivity to gene flow was higher inside one region than between two remote European regions (e.g., Alsace and Aragon). In fact, landscape patterns (sizes and shapes of fields) may differ more within one region than between regions and this greatly affects coexistence features.

Based on the simulation results obtained in regional case studies, we have identified four major types of situations, the so-called pre-scenarios[7], that local stakeholders may have to deal with :
1) segregation at the silo level is feasible without any specific measures at the field level;
2) curative measures at harvest (selection of non-GM fields or parts of fields) allows meeting market requirements in terms of targeted thresholds;
3) preventive measures at the crop level (e.g., sowing dates) or at the system level (crop rotation, spatial arrangement of crops allows meeting market requirements,
4) coexistence is not possible because whatever the agronomic measures undertaken at the crop or system level, the targeted threshold cannot be met or requires non realistic measures.

For a given threshold and a given rate of introduction of GMOs in the landscape, limits between the pre-scenarios are defined by the sensitivity of the landscape to gene flow, as

[7] The word “pre-scenario” is used because the pre-scenarios only cover a component of the overall picture and should then be integrated into overall management scenarios taking into consideration other factors than those affecting farm coexistence (see below).

well as the capacity of actors to put them to work. Oilseed rape (OSR) is a particular problem because of the dynamics of volunteers in the cropping system. If farmers wished to return to conventional varieties after GM cultivation, the fields should be managed differently from those which have never been grown with GM OSR. For these fields, a thorough control of volunteers will be required in order to meet thresholds. Even if GM and non-GM OSR fields are spatially segregated (i.e., if non-GM varieties are never grown in fields previously cultivated with GM varieties), proper management is required to reduce both spatial and temporal gene flow due to volunteers.

Role-playing games carried out in Alsace and Beauce made it feasible to test the relevance of pre-scenarios under realistic management situations. They demonstrated how players (farmers, collectors) would combine different management strategies in a more or less coordinated way, and how these strategies may evolve over time. It thus appears that risk assessment determines actions, such as the selection of "complying" or "non complying" quality harvests by the collecting firms according to their presumed GMO content and the targeted threshold firms are considering.

Risk assessment and management are not static and evolve according to feedback from experience. We observed that the effectiveness of measures undertaken at the field level was ensured only if the rules (i.e., agreement on the way to assess risks and on the measures to be implemented) were shared between the collecting firms and farmers. In addition, the role-playing games demonstrated that collating and sharing information at the territory level is essential to facilitate coexistence. This raises practical implementation problems that are not currently solved.

Three main processes determine how pre-scenarios may be embedded into global management scenarios:

1. the system and rules for collating and sharing information at the territory level,
2. the framework and procedures describing coordination between actors and,
3. learning processes (both individual and collective).

Based on these findings, contrasting global scenarios may be defined by considering different regulation approaches:

- A "bottom-up" approach, which freely allows the private actors (collector, farmers) to choose the best way to achieve the objectives of coexistence and to meet regulatory or market-based threshold requirements;
- A "top-down" approach, based on the strong intervention of public authorities with the implementation of compulsory uniform measures (e.g., isolation distances)
- and a "third way" approach, which provides a focused response of authorities to lift some constraints on information and coordination. between private actors, and allow some flexibility in the measures .

Each approach has advantages and disadvantages : the "bottom up" approach allows more flexible measures than the "top down" one, leading to subsequent lower costs. Moreover, it may help in dealing with management problems out of the scope of the GM regulations, such as specific requirements for “Identity Preserved” (IP) market. However, it may not prevent distrust from the general public and does not solve all the liability issues. The "third way" takes advantage of both local knowledge from individual stakeholders and the ability of public authorities to collect and share information at a large scale, in order to cope with practical problems raised by the implementation of coexistence measures.

## 7. Costs of coexistence highly depend on the framework for implementing coexistence measures and uniform measures are not optimal

The economic perspective of coexistence of GM and non-GM crops with specific applicability to oilseed rape (OSR) and maize in different regions of the EU was investigated by SIGMEA. Three levels of coexistence costs were considered:

- Costs of compliance to the coexistence measures developed to prevent adventitious presence of GM material as a result of cross-pollination;
- Testing for adventitious presence in non-GM crops (hereafter called monitoring costs);
- Costs due to failure of the system (losses due to contamination of conventional crops).

Coexistence costs had already been investigated in former coexistence studies[8]. In addition to standard coexistence measures such as isolation distances, we also considered flexible coexistence measures which allow GM and non-GM crops to be grown in adjacent fields as long as farmers coordinate their activities by:

- implementing a non-GM buffer zone (BZ) within GM fields, large enough to prevent cross-pollination to reach the official thresholds in neighboring fields cultivated with the same crop;
- discarding a non-GM strip (discard zone - DZ) within non-GM fields (again large enough to ensure the remaining parts of non-GM fields comply with thresholds). The crop from the discard strip could be delivered as a GM product by either party involved; the non-GM farmer gets a compensation for the income forgone, either from the GM farmer or from an insurance.

Various sizes of buffer and discard zones have been considered (from 10 to 100m[9]). These scenarios require a good coordination between farmers and they were compared to compulsory isolation distances between fields (various distances have also been considered for this measure).

We assumed that farmers growing GM varieties could benefit from GM technology by saving costs (e.g., herbicides or insecticides) or by higher yields (Bt traits). Different percentages of such benefits were considered. Non-GM farmers could receive a premium in an Identity-Preserved (IP) market and they might want to undertake additional measures to meet such IP requirements, as long as the price premium covers these costs.

The coexistence costs were addressed in the same regional case studies as those considered for assessing the technical feasibility of coexistence:

- coexistence costs for oilseed rape were examined in the Beauce region (France) and in the Fife region (Scotland);
- coexistence costs for maize were discussed in the Aragon region (Spain) and in Alsace (France);
- the potential costs of transboundary coexistence between France and Switzerland were analysed.

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[8] See for example Bock et al, 2002 and Messéan et al., 2006

[9] Large sizes of BZ or DZ have been considered as they would drastically reduce cross pollination and thus might avoid monitoring measures on the non-GM field or on the truck delivering the non-GM commodity to the elevator.

For calculating the coexistence costs, spatial simulation models taking into account the economic incentives for coexistence were used. Using a Geographical Information System (GIS) data set and Arcview® software, a set of simulations of realistic coexistence scenarios were carried out in order to assess the costs of coexistence in the different regions. We assumed that each GM and non-GM field was managed independently but that farmers agreed that buffer zones or discard zones were cultivated with non-GM varieties of the same crop species. It was also assumed that other sources of adventitious presence were controlled (e.g., no GM presence in non-GM seeds, or novolunteers in non GM crops)[10].

Generally speaking, results obtained in different regions demonstrated that coexistence costs depend on the agricultural context (landscapes, cropping systems, climate, practices), the share of GM crop (maize or oilseed rape) in the Agricultural Used Area (AUA) and the willingness of GM and non-GM farmers to cooperate.

Uniform non-flexible coexistence rules, such as standardized large isolation distance requirements between GM and non-GM crops, while providing a margin factor for adventitious presence of GM in non-GM production, might impose a severe burden on GM crop production in the European regions investigated in this study. Indeed, cross-pollination highly depends on structural factors like field patterns, agronomic practices and climatic conditions and, in most cases, small isolation distances would be sufficient to meet the official threshold of 0.9%. Large uniform isolation distances, as implemented by most European countries, are not flexible and, therefore, not proportional to the actual risk of adventitious presence.

In addition, large and/or fixed isolation distance requirements may lead to a domino-effect[11]. so that farmers would have few, if any, fields complying with these isolation distances and would be unable to cultivate GM crops. This domino-effect can also occur with smaller fixed isolation distances in areas with lots of small fields and a high density of cropping with the same crops. This effect is particularly important at low levels of GM adoption as the probability of a GM field of having a non-GM field nearby is higher even though the overall cross-pollination potential is lower. Conversely, the domino-effect would be less of a problem for higher adoption rates of GM crops. The domino-effect exacerbates the non-proportionality of wide isolation distances by reducing GM crop planting options in the landscape and raising opportunity costs for GM crop adopters.

Flexible measures based on buffer zones or discard zones may require compensation of loss of income by non-GM farmers, whenever and wherever it occurs, but lead to lower overall coexistence costs and are proportional to the incentives for coexistence and, consequently, less counterproductive for European agriculture. However, they require a high level of coordination between farmers and hence assume that farmers will cooperate and accept additional transaction costs and financial risks. Under these conditions, flexible measures

[10] These hypotheses do not alter general conclusions but prevent us from providing quantitative estimation.

[11] The domino-effect is a dynamic spill-over effect of farmer decisions induced by enforcing wide isolation distances on potential GM crop adopters. It consists in the iterative process of farmers switching their planting intentions from 'GM' to 'IP' crops to comply with isolation distances and hereby restricting planting options of neighbouring farmers.

lead to a natural minimization of coexistence costs as farmers will negotiate the measures that reduce overall costs and reflect their incentives for coexistence in the long-run.

GM seed price premium had no significant effect on costs of coexistence, as non-GM seed price might also increase, while coexistence costs increased with the Identity Preservation (IP) price premium, due to factors such as greater demand for non-GM crops. The benefits of GM crop adoption are generally higher than the costs of coexistence (transaction costs not considered). It was concluded that GM crop adoption is not an issue of costs of compliance to coexistence measures but rather one of the incentives for adopting or rejecting the technology. From the economic point of view, coexistence is only a subject of concern when there is significant preference for non-GM crops with respect to to GM crops.

As far as flexible coexistence are considered (buffer or discard zones), the average per-hectare coexistence management costs, although variable, were relatively independent from the GM adoption rate in moderately dense areas such as Aragon (maize) or Scotland (oilseed rape) . There are, however, large differences regarding the monitoring costs which are related to GM crop adoption rates: the higher the GM adoption rate, the lower the additional per-ha costs of coexistence[12].

In Alsace, SIGMEA was able to test the impact of the agricultural structure on coexistence costs by comparing a region with small farms and small field sizes (Heiwiller) with a region with medium-sized farms and larger field sizes (Ensisheim). The coexistence costs are higher in those regions with a smaller scale of agricultural structures (fields, farms) . This is due to higher transaction costs on the one hand and a higher share of monitoring costs and discard zone areas on the non-GM maize area on the other hand. The latter leads to higher compensation costs for loss of income by the non-GM farmers.

The perceived effectiveness of the implemented coexistence measures, the non-GM farmer's willingness to take the risk of non-compliance with IP market conditions and the non-GM farmer's trust in liability or insurance procedures in the case of system failure are critical for the evaluation of the coexistence costs for non-GM farmers producing for the IP market. Monitoring can be a significant cost for non-GM farmers so that, in some situations, overall coexistence costs of non-GM farmers can be decreased by increasing discard zone sizes as this can result in lower monitoring requirements and costs. However, in some cases, the respective discard zone area required exceeds up to 99% of the envisaged non-GM maize area. As a consequence of these large discard zone areas, IP maize production in those cases is impossible.

Flexible coexistence regimes without discard zones would lift spatial constraints but is likely to increase the number of downgraded non-GM maize lots (fields not complying with the official threshold or any other IP requirements). Such regimes may be economically viable if the assumed insurance fee (e.g., 14 €/ha used in our work) could cover the compensation of non-GM farmers for downgraded IP maize produce. This is more likely to occur for small adoption rates. Nevertheless, such flexible coexistence regimes would not work at all in situations where GM-free production is required. As a consequence, downstream supply chain actors who demand pure GM-free IP produce might not be willing to accept deliveries from non-GM farmers in regions with flexible coexistence regimes. Thus, even though GM

[12] Monitoring costs of non-GM fields might increase but would be supported by a larger GM acreage.

farmers would be able to compensate potential income forgone of the IP maize farmers with the insurance, those non-GM farmers might be excluded from IP maize market channels. Coexistence in this case would thus be impossible due to market exclusion of the non-GM farmers.

Finally, we addressed transboundary issues by analyzing the situation of maize farmers cultivating land along the border between France and Switzerland and considering that GM varieties were sown in France while GM cultivation was not permitted in Switzerland due to a five year moratorium. Swiss fields cultivated along the borders would be affected by cross-pollination with GM maize grown in the neighbouring country. In this case, low thresholds could not be met without implementing a strategy for coexistence in the non-GM growing country which may lead to legal issues. Growing non-GM maize in the border region would require exchange of information (location of GM crops, coexistence strategies, liability and thresholds) and additional measures to avoid admixture of GM and non-GM crops.

In summary, these SIGMEA studies demonstrate that the economics and appropriateness of different measures are mainly determined by the spatial and temporal patterns of fields and crops. This indicates that coexistence management measures should be as flexible as possible and based on local information on field characteristics whereas regional and national governance provides only general guidelines and rules.

## 8. SIGMEA has produced the first large-scale empirically based estimation of the economic impact of a GM crop for EU farmers.

Currently the only GM crop authorised for commercial cultivation in the EU is Bt maize, resistant to certain stem borer pests. Spain has the largest surface of Bt maize in the EU and over 9 years of commercial experience in cultivation. The Spanish case presented an opportunity to study *ex-post* the agronomic and economic performance of a GM crop in the EU. Analyses of GM crop impacts on farm economics are usually based on surveys of farmers cultivating GM crops under commercial conditions. A face-to-face survey was conducted among Spanish commercial maize farmers with the aim both of obtaining data on the agronomic and economic performance of *Bt* maize during three growing seasons (2002–2004) and of comparing the socioeconomic profile of farmers who adopted *Bt* maize versus those who did not. The survey was conducted in the three leading *Bt* maize-growing regions (Aragon, Catalonia and Castilla-La Mancha), which accounted for ~90% of the *Bt* corn–growing area in Spain in 2006. A province was selected within each region based on the importance of maize cultivation and the presence of farmers growing *Bt* maize (the provinces of Zaragoza in Aragon, Albacete in Castilla-La Mancha and Lleida in Catalonia).

Survey results found that *Bt* maize, like other pest-control technologies, produced variable impacts on maize yields in different provinces, ranging from neutral to 11.8% yield increase. The regional variability depends mainly on local variations of pest pressure and damage. Yield gains for growers of *Bt* maize were translated into revenue increase since no differences were found in the price paid to farmers for *Bt* or conventional maize. Regarding production costs, Bt maize growers paid more for the seeds than conventional growers, but had reduced insecticide use and costs. On average, growers of conventional maize applied 0.86 insecticide treatments/year to control borers and other insects, versus 0.32 treatments/year applied by Bt maize growers. All things considered, the impact of *Bt* maize adoption on gross margin obtained by farmers in different provinces ranged from neutral to € 122/ha per annum. In the survey, the reason most quoted by farmers for adopting Bt maize was "lowering the risk of maize borer damage" followed by "obtaining higher yields".

Finally, the survey compared the socio-economic profiles of farmers adopting or not *Bt* maize varieties. No differences were found for the two groups of farmers for variables such as land ownership, farm size, experience as maize grower, education or training. The conclusion is that the differences in yields and gross margin should therefore be attributable to the adoption of Bt maize varieties.

SIGMEA has also produced the largest survey to estimate *ex ante* the potential adoption by farmers of three GM crops not yet authorized in the EU but widely grown elsewhere: Herbicide Tolerant (HT) oilseed rape, HT maize and Bt/HT maize (combining herbicide tolerance and insect resistance). It has also looked at the impact of proposed coexistence measures on the willingness of farmers to adopt GM crops. A face-to-face survey of 1214 European farmers with a questionnaire specifically designed for this study was the main source of data. Germany, France, Spain, Hungary, United Kingdom and Czech Republic were chosen as countries to be studied. All these countries are major producers of maize and/or oilseed rape.

Analyses of farmers' responses show that there is high potential adoption of HT oilseed rape and HT maize, as well as Bt/HT maize. On average, forty-one percent of the farmers surveyed in the six countries are prepared to plant these GM crops. This figure nevertheless depends to a large extent on the coexistence measures put in place by EU member states.

| Trait/Crop | Country | (1) Likely+very-likely % | (2) Unlikely + Very-unlikely % | Ratio *(1)/(2)* |
|---|---|---|---|---|
| **HT rapeseed** | **Germany** | **53** | **31** | **1,68** |
| | **United Kingdom** | **44** | **25** | **1,73** |
| | **Czech Republic** | **43** | **28** | **1,56** |
| **HT maize** | **Spain** | **36** | **38** | **0,95** |
| | **France** | **37** | **33** | **1,12** |
| | **Hungary** | **38** | **38** | **1,00** |
| ***Bt/HT maize*** | **Spain** | **48** | **35** | **1,38** |
| | **France** | **46** | **28** | **1,62** |
| | **Hungary** | **25** | **57** | **0,44** |
| | **Total average** | **41** | **35** | **1,18** |

**Table 2: Potential adoption of GM crops by EU farmers: results of an ad hoc survey conducted in 6 countries covering 41 regions/provinces in 2007..**

An analysis of the sensitivity of farmers to the imposition of coexistence measures was carried out by asking them to classify comprehensive list of technical and non-technical factors according to their impact on farmers' willingness to adopt. Measures strongly affecting potential adoption of GM crops are the obligation to pay compensation to nearby farms in case of unintended admixture, a GMO tax or the introduction of an insurance scheme to cover dissemination risks. These can be considered as non-technical measures which have been so far ignored by stakeholders and scientists. In addition, if mandatory separation distances for GM crops were excessive, then many farmers would not adopt GM crops.

## 9. A framework for designing multi-attribute decision-support systems has been proposed

GM crops have become an option in modern agriculture but they also raise concerns about their ecological and economic impacts. Decisions about GM crops are complex and call for decision support. SIGMEA has been examining decision tools which would help stakeholders and decision-makers to better understand the implications of growing GM crops.

A first model, the so-called "Grignon" model, is a qualitative multi-attribute model for the assessment of ecological and economic impacts at a farm level of GM and non-GM maize crops which was developed together with the EU ECOGEN research project. The model is applied for one agricultural season. This is an ex-ante model developed according to multi-attribute decision tree methodology. In this model, cropping systems are defined by four groups of features: (1) crop sub-type, (2) regional and farm-level context, (3) crop protection and crop management strategies, and (4) expected characteristics of the harvest. The impact assessment of cropping systems is based on four groups of ecological and two groups of economic indicators: biodiversity, soil biodiversity, water quality, greenhouse gasses, variable costs and production value. The evaluation of cropping systems is governed by expert-defined rules.

The "Grignon" model has been used to assess hypothetical and real maize-based cropping systems. For each system, we are able to obtain a qualitative overall assessment together with its 'profile', i.e., its performances for the main economic and ecological attributes. Moreover, one can 'drill-down' into lower levels of the model to identify the most sensitive components.

It represents a practical means encapsulating a complex system as it integrates findings of different specific disciplines, such as agronomy, biology, ecology and economics (although it cannot capture specific details of any of these disciplines), and provides a general overview to the assessment of cropping systems which can then easily support discussion among experts and stakeholders.

The issue of coexistence was also considered : is it possible, under which conditions and to which extent, to grow both GM and non-GM (conventional) crops simultaneously or in close proximity and ensure that non-GM crops would meet a targeted threshold of adventitious presence? As stated above, the answer can be extremely complex as coexistence involves many variable factors, which are difficult to assess, predict and control such as pollen flow, volunteers, feral plants, mixing during harvesting, transport, storage and processing, human error, and accidents. The LandFlow-Gene platform has been designed to assess gene flow at the agricultural landscape level. At present LandFlow-Gene cannot be used on a real-time basis by end-users as quite a lot of data describing landscapes, climate and practices are required. To allow farmers to carry out a preliminary in-field diagnosis, SIGMEA developed a decision-support tool called *SMAC Advisor*, which is aimed at providing advice to farmers and other decision-makers (advisors, administrative workers, policy makers) who want to assess the achievable level of maize coexistence on a given field and in a given agricultural environment. The assessment is based on a qualitative multi-attribute decision-support model, which was constructed from two sources: (1) MAPOD® gene-flow simulations under constrated situations and (2) expert-provided rules.

SMAC Advisor formulates the decision problem as follows:
*Suppose a farmer wants to start growing GM maize on field F. In the neighbourhood, there are some other fields, $E_1$, $E_2$, …, $E_n$, on which this or other farmers grow (or want to grow) non-GM maize. Then, the question is: to what extent will the plants grown on F genetically interfere with the plants on E's? Will this interference be small enough to allow coexistence?*

The "interference" between plants is expressed and measured in terms of *adventitious presence* (AP). AP refers to the unintentional and incidental commingling of trace amounts of one type of seed, grain or food product with another. EU regulations have introduced a 0.9 % labelling threshold for the AP of GM material in non-GM products (Regulation 2003/1830/EC). Thus, in order to approve the coexistence between GM and non-GM crops, we usually require that the achieved AP is 0.9 % or less. Now, some supply chains may require lower levels of AP (e.g., organic farming). In SMAC Advisor, the target threshold is a user-defined parameter.

SMAC Advisor requires basic information from the user about the: (1) emitting field *F*, (2) neighbouring fields $E_1$, $E_2$, …, $E_n$, (3) relation between *F* and each $E_i$ in terms of distance, relative size, prevalent wind direction, etc., (4) type and characteristics of used seeds, (5) environmental characteristics (e.g., background GM pollen pressure), and (6) use of machinery (e.g., sharing with other farmers). All these elements can easily be provided by the end-user (e.g., farmers) through a user-friendly interface (figure 4).

On this basis and through a multi-attribute decision tree (figure 5), SMAC Advisor determines the *achievable AP*, that is, the expected level of GM impurities in harvests of the neighbouring fields, and compares it with the required *target AP*, which is provided by the user. SMAC Advisor completes the analysis giving one of the following "colour-coded" *recommendations*: (1) "Green": GM farming allowed or possible, (2) "Red": GM farming disallowed, (3) "Yellow": coexistence is possibly achievable but further risk assessment is needed, and (4) "Orange": the target AP is currently not achievable, continue assessing additional coexistence measures.

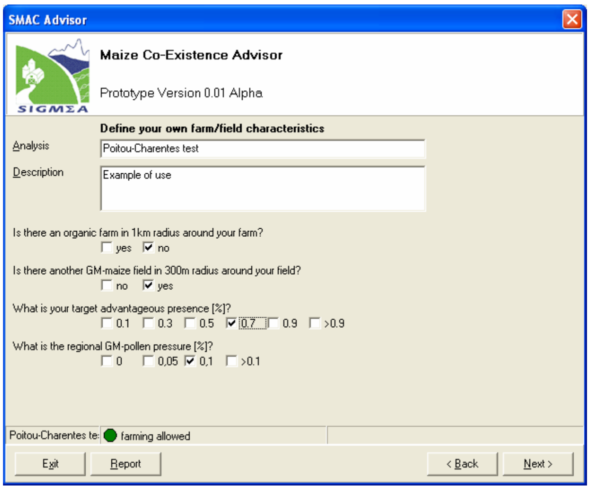


**Figure 4.** Description of SMAC Advisor user interface.

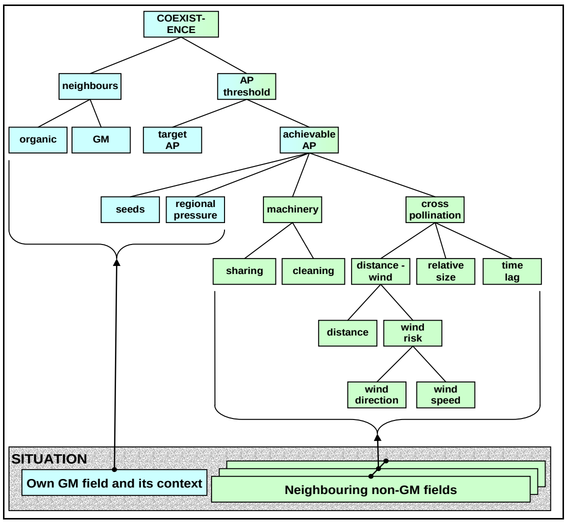


**Figure 5.** Description of SMAC Advisor hierarchical attribute structure.

## 10. On-site novel methods for GMO detection have been designed

A pre-harvest method to estimate the GM content of conventional maize fields, employing a duplex RT-PCR detection and quantification assay for MON810 for use on the Cepheid SmartCyclerII on-site instrument as a model, was developed and validated through an international ring-trial. Assay performance met minimum requirements as considered by the European network of GMO Laboratories (ENGL). Complimentary to this, two field-level sampling procedures have been further investigated with suggestions for practical implementation. Together, both elements (method and sampling procedure) constitute the basis for a strategic 'prototype' on-site decision tool for assessing GM adventitious presence pre-harvest. In addition, a protein based strip-test, based on a commercial kit, was also validated in-house for use in a semi-quantitative capacity against maize, and in support of the RT-PCR method.

In addition, an in-house validated qualitative strip-test for Round-up Ready oilseed rape, originally commercialised for use with soybean, was shown to function adequately.

As it was considered more appropriate to make such method information available in a more established and purpose built database for public access, the GMOs Method Database hosted by the Joint Research Centre's Institute for Health and Consumer Protection (IHCP), Ispra, Italy (http://biotech.jrc.it/home/ict/methodsdatabase.htm#Database) has been selected to host the these details. For copyright reasons, this will be finalised once the methods have been published in a peer reviewed format.

With respect to the maize field-level sampling schemes, as part of the delivery of the prototype pre-harvest predictive tool, a number of important conclusions from both studies towards accurate estimation of field-level GM presence highlight the necessisty to sample kernels from cobs on many plants, and not from single plants. In this way the probability distribution of cross-pollination is also better sampled. Therefore it is better to sample a few kernels from many cobs, rather than many kernels from a few cobs, although the former is more problematic in practice - it would be less prone to plant-to-plant variation and sampling error. In addition, further investigation of optimal in-field sampling schemes should be performed to take into account the intra-field distribution of cross-pollination (boundaries have a higher cross-pollination level).

## 11. Monitoring issues for EU were discussed and recommendations have been made

A coherent structure for GMO monitoring in Europe is still under development. This refers not only to the central level of European institutions but refers also to member state and to the regional regulatory levels. In many member states, biodiversity assessments are not implemented in ways that provide results relevant to GMOs. Standard environmental and agricultural monitoring are not always appropriate for capturing the relevant effects and associating them with GMOs. Methods require further development which is is still “in progress”. One reason for slower implementation may be the regulatory statement that the notifiers are held responsible for this task in financial terms. Notifiers have to cover the relevant expenses either by executing the required tasks or compensating for required activities by the authorities. It seems questionable whether this is appropriate for GMO monitoring as environmental monitoring is also a sovereign responsibility.

The molecular analytical effort of the Central Reference Laboratory together with the European Network of GMO Laboratories ENGL are primarily focused on GMOs. These are the most comprehensive structures established for GMO assessment and are largely institutionalised by the EU as a precondition for efficient regulation. This is reasonable to fulfil sovereign tasks of identifying approved and unapproved GMO presence in a range of imported and manufactured products. A similar network is required for the assessment of anticipated and unanticipated long-term and combinatory effects of GMOs. The necessity of sovereign engagement becomes also apparent in the context of data collection and synthesis requirements. Evaluating completeness, consistency and quality standards of measurements and drawing conclusions have to be done at an administrative level. Therefore, it appears useful that the European Union as well as the member states expand their initiatives in this field – to provide basic data, model-supported synthesis capacities and decision making. To develop such regulatory steps competent authorities will need to be well informed on the scientific rationales for monitoring and prepared to integrate monitoring activities both nationally and internationally.

As a background material for discussion, potential topics for monitoring were systematically assessed. As an overarching criterion for systematization, the hierarchical structure of biological organization was used. Potential monitoring targets on the level of molecular interactions, the level of individual organisms, populations, ecosystems and landscapes were discussed. Methodological approaches suitable for these levels of biological organization were compiled. This gives an overview how to assess undesirable effects as soon as they might arise. Monitoring of genetically modified organisms was thus characterized as a task that requires competence in various fields of scientific expertise going well beyond a specific discipline (like e.g. molecular detection only). Furthermore, an overview of institutions and relevant authorities on the EU and member state level was compiled and is available.

## 12. <u>The current regulatory regimes of EU and member states, liability and redress issues have been analyzed and recommendations have been made.</u>

Following the research carried out on liability and redress issues and analysis of scenarios, the following conclusions are drawn for the regulatory regime in the EU.

***Does GMO pose novel problems for the law?***

There are no novel problems posed at the present time by GMO for the questions of liability and redress. The sorts of harms, the causation issues and contributory issues can be seen in a number of analogous risk activities (e.g., asbestos injuries, smoking related illness, drug regulation, product liability, and food production). These analogous situations have been met by different legal solutions both at the national, regional and international level. However, it could be that long-term difficulties emerge that are not foreseen at the present time.

***Are there any problems which make particular established legal tools unsuitable as options for the GMO problems?***

There is a range of established legal tools available to regulate GMOs. Civil regimes, insurance-based regimes, and compensation-based state regimes were all studied and none shows any particular technical problems. There is, of course, the question for the insurance model of whether a market can be established to make this a viable regime.

***Is there any particular regime that suggests itself as appropriate to the GMO issue?***

There is no particular regime that stands out as appropriate for use in the GMO issue. However, this is not because all the models are equally appropriate and attractive. Rather it is because of a number of significant external factors which were considered in drawing conclusions for this report.

***Recommendations***

- The first and only concrete recommendation that can be made is that the trans-border issues relating to GMO make the desirability of an EU-wide single legal regime very strong. This would eliminate costly conflict of laws problems between member states. This would, however, require a degree of agreement over the desirability of GMOs in the Union, which on current form is unlikely.

- Whereas a regime could be entirely no-fault based, there could be arguments for the application of the polluter pays principle where this would be seen to act as a deterrence against deliberate harmful actions, recklessness, negligence and carelessness. It could also raise the industry standards. However, the polluter may not be able to pay, requiring a mandatory insurance (with enforcement). This in turn depends upon the viability of a market for insurance (i.e. a financial return for the insurance industry). The question of deterrence may be better served through criminal sanctions and a blanket, no-fault compensation scheme.

- The question of responsibility clearly needs resolution before the choice of regulatory regime can be set. It would seem logical that those who encourage the development of the technology, be it state or consumer, actively or passively, bear levels of responsibility for the consequences of those choices. This requires consideration in relation to the farmer and producer as agent of the state and consumer (with the analogous issues of liability where the individuals outside the terms of the agency – e.g. in this case, where the farmer acts deliberately or recklessly).

- There is the over-riding question of who actually pays. There is the question of how far that liability (fines, etc.) are passed down the chain to the last individual (consumer) who cannot pass on costs. There is no guarantee that the added costs of a system requiring the investigation of proof and blame will be more efficient than a compensation scheme.

- Equally, there is the question in a taxation system of why someone who does not want to participate in the new technology must pay for the liability and redress issues caused by such a technology.

- So the overall choices of regulatory regime concern the causation, foreseeability, responsibility, and participation. These must be considered in relation to the cost and practicality of the scheme. The great number of harmful, risky activities in modern society produce a vast range of analogous situations which provide evidence that any legal model could be applied.

- There is also a broader question of why GMO is taken in isolation and treated as a special case. Indeed, there are also harms and issues concerning liability and redress in non-GMO agriculture, organic and non-organic. There is a strong argument for taking into consideration non-specific issues within the broader agricultural questions.

## 13. Recommendations for the decision-making processes relating to the market release of GM crops under progress can be derived from SIGMEA outcomes

Although gene flow is a common phenomenon for crop species, its implications for Genetically Modified Plants have raised new concerns. Undesirable effects related to gene flow may result in ecological or agronomic considerations (persistence of resistant volunteers, creation of new weeds, multiple resistances) as well as commercial considerations (unintended presence of GMOs in conventional crop production affecting its competitiveness in the marketplace). The coexistence between different types of crops is an important issue and has to be addressed once GM crops are approved in the EU. The European Union has issued guidelines designed to allow for the coexistence of various kinds of agriculture in support of its policy that “farmers should be able to cultivate freely the agricultural crops they choose, be it GM, conventional or organic” (Recommendation 2003/556/EC). New GMO regulations have been introduced as a basis for Member states to develop appropriate coexistence and traceability measures for delivery of food and feedstuffs complying with the labelling thresholds.

SIGMEA has produced a practical toolbox for addressing GM impacts in agriculture:

1. A unique database including more than 100 data sets on geneflow and ecological impacts which may inform decision-makers on factors driving gene flow at the landscape level and on the variability of such processes across Europe, help regulators to set up coexistence measures at National levels as well as help scientists

to identify further research priorities in that area.

2. LandSFACTS is a user-friendly windows-based software to simulate crop allocation to fields by integrating typical crop rotations and crop spatio-temporal arrangements within agricultural landscapes and could be used for a practical implementation of coexistence measures
3. The generic gene flow platform LandFlow-Gene, including validated rapeseed and maize modules and interfaced with the landscape generator LandSFACTS and GIS softwares, is now available as a prototype. It has been used to support regional case studies analysis and to set up scenarios for coexistence. This platform could be extended to other crops to provide a general framework for informing coexistence in all cropping systems of Europe.
4. A user-friendly decision-support system (SMAC-Advisor) to assess maize coexistence feasibility at the field level was designed.
5. Structural and organisational factors affecting coexistence in practice have been identified and strategies for managing coexistence at the regional level have been proposed;
6. A comprehensive overview of monitoring and legal issues has been provided but, due to the delay in implementing regulations in most member states and the low development of commercial GM cropping in Europe, only general recommendations have been made.

Altogether, these tools and outcomes can be combined to assess coexistence at various spatial scales (field, farm or region) and various decision-making levels (farmers, elevators, member states, EU). Depending on the decision problem and the amount of information available, various SIGMEA tools can be used.

SIGMEA findings make it possible to address issues such as "what will happen, in terms of gene flow, if a particular GM organism is introduced into a particular European region?" and "how can crops be deployed at the landscape level so as to maintain the adventitious presence of GMOs in conventional crops within the legal thresholds, or any specific market-driven requirements?".

The outcome of both field and modelling studies carried out in SIGMEA is that best practices for coexistence are highly variable and depend on local characteristics, crop practices, environments as well as farmer strategies and preferences, and that the feasibility of coexistence directly depends on the targeted threshold.

Based on regional case studies findings, contrasting global coexistence scenarios may be defined by considering different regulation approaches:

- A "bottom-up" approach, which would let the private actors (collectors, farmers) free to choose the best way to achieve coexistence guidelines and to meet regulatory or market-based threshold requirements;
- A "top-down" approach, based on the strong intervention of public authorities with the implementation of compulsory uniform measures (e.g., isolation distances);
- and a "third way" approach, which provides a focused response of authorities to lift some constraints on private actors.

It has been stressed that a coexistence regime based on “uniform isolation distances”, as implemented so far in several member states, is not optimal, not proportional and may lead to unnecessary additional costs or render coexistence impossible in practice.

SIGMEA thus recommends that coexistence measures should be as flexible as possible and depend on local climatic, agronomic and environmental factors. This approach would lead to more cost-efficient measures. However the current regulatory framework to support such an approach is still to be developed.

SIGMEA has developed tools to support the definition and implementation of flexible measures. Predictive gene flow models are now available (currently only for maize and oilseed rape but easily extendable to other crops). These can help decision-makers assess the feasibility of coexistence at the field, farm and silo level for the various targeted thresholds under various environmental and agronomic conditions. In addition simple decision-support tools, like SMAC Advisor can be used by farmers or advisors who would like to quickly assess coexistence feasibility using limited amounts of information at a local field level.

### 14. SIGMEA is providing the scientific community as well as decision-makers with adequate information about gene flow and its implications in terms of coexistence.

To date, SIGMEA partners have published more than 100 refereed papers on issues associated with gene flow, coexistence and gene detection and further papers are being submitted for publication. In addition, SIGMEA contributed to book chapters on GMO issues, European and National government reports and public debates.

SIGMEA was very directly involved in the organization of the conferences on coexistence (GMCC05 in Montpellier, GMCC07 in Seville and GMCC09 in Melbourn, see http://www.coexistence-conference.org). At GMCC07 there were 17 oral presentations by SIGMEA partners including papers summarising scientific knowledge on gene flow in maize, oilseed rape and sugar beet from the SIGMEA data sets and other papers reporting findings from SIGMEA studies. There were also 24 poster presentations.

13 PhD theses and 5 Masters were submitted during the period of the project. SIGMEA partners were also involved in events related to communication to extension services and farmers as well as in public debates, press articles, radio/TV interviews.

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