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A framework for a European network for a systematic environmental impact assessment of genetically modified organisms (GMO)

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Abstract

The assessment of the impacts of growing genetically modified (GM) crops remains a major political and scientific challenge in Europe. Concerns have been raised by the evidence of adverse and unexpected environmental effects and differing opinions on the outcomes of environmental risk assessments (ERA). The current regulatory system is hampered by insufficiently developed methods for GM crop safety testing and introduction studies. Improvement to the regulatory system needs to address the lack of well designed GM crop monitoring frameworks, professional and financial conflicts of interest within the ERA research and testing community, weaknesses in consideration of stakeholder interests and specific regional conditions, and the lack of comprehensive assessments that address the environmental and socio-economic risk assessment interface. To address these challenges, we propose a European Network for systematic GMO impact assessment (ENSyGMO) with the aim directly to enhance ERA and post-market environmental monitoring (PMEM) of GM crops, to harmonize and ultimately secure the long-term socio-political impact of the ERA process and the PMEM in the EU. These goals would be achieved with a multi-dimensional and multi-sector approach to GM crop impact assessment, targeting the variability and complexity of the EU agro-environment and the relationship with relevant socio-economic factors. Specifically, we propose to develop and apply methodologies for both indicator and field site selection for GM crop ERA and PMEM, embedded in an EU-wide typology of agro-environments. These methodologies should be applied in a pan-European field testing network using GM crops. The design of the field experiments and the sampling methodology at these field sites should follow specific hypotheses on GM crop effects and use state-of-the art sampling, statistics and modelling approaches. To address public concerns and create confidence in the ENSyGMO results, actors with relevant specialist knowledge from various sectors should be involved.

Keywords

GM crops, field testing network, environmental risk assessment, post-market environmental monitoring, typology of EU agro-environment, stakeholder involvement, socio-economic impact assessment

Introduction

Cultivation of genetically modified (GM) crops in European agriculture is, compared to other developed countries, limited due to the significant public opposition and scientific research on their potential adverse effects (Lemaire et al. 2010; Myhr 2010; FOE 2011). The concerns centre on the potential risks of GM crop cultivation, evidenced by adverse direct or indirect environmental and health effects (Heard et al. 2003; Giovannetti et al. 2005; Relyea 2005, Benachour and Séralini 2009; Graef 2009; Lang and Otto 2010; Séralini et al. 2011). In relation to potential environmental effects in soil, a number of unexpected research results have been reported, for instance on the transfer of engineered genes from transgenic plants to soil bacteria (Gebhard and Smalla 1998; Nielsen et al. 2000), and the release of insecticidal and fungicidal toxins by the roots of transgenic plants into the surrounding environment (Saxena et al. 1999; Turrini et al. 2004).

The resulting societal attention to risk demands a robust and independent regulatory system. The regulatory system that has evolved is subject to criticism, particularly with regard to inadequately designed GM crop testing and introduction studies (Hilbeck et al. 2011), and differing conclusions of the ERAs, for instance with respect to health risks or nutritional assessment studies due to financial or professional conflicts of interest (Diels et al. 2011). There has been insufficient attention given to full environmental problem-formulation, protection and developmental goals, and other societal concerns (Nelson et al. 2009). This has fed scepticism. Other factors underpinning uncertainties in the environmental safety of GM crops that have engendered public distrust in regulatory practices around GM crops include a) conflicting or negative results of GM crop effects on non-target organisms (NTO) (Castaldini et al. 2005; Lovei and Arpaia 2005; Rosi-Marshall et al. 2007; Bøhn et al. 2008, 2010), b) lacking environmental baseline data from prospective GM crop cultivation areas as required by Directive 2001/18/EC (European Commission 2001), c) poor monitoring designs (De Jong 2010), d) missing studies and/or data relevant to the approval process (Graef et al. 2010), e) undesirable impacts on organic farming (Binimelis 2008; Henle et al. 2008), and f) the differing interpretations of Directive 2001/18/EC among EU Member State authorities (BfN et al. 2011). Doubts have been raised about whether the EU regulations, and especially their implementation, appropriately protect public interest and goods, and are instead biased towards supporting unsustainable high input agriculture. The insufficient involvement of local stakeholders and insufficient transparency in regulatory processes feed the scepticism about GM crop import and cultivation, and have led to polarized discussions and strong reactions from the public, for instance destruction of field trials (Lemaire et al. 2010).

These shortcomings are partly related to lack of independent biosafety research and to prevailing simplistic and sometimes misleading research approaches, which generally undervalue the complex network of interactions governing ecosystem functions. The selection of field sites, indicators, detection methods, assessment schemes and other components among the ERA for GMOs often contain a significant degree of arbitrariness (Hilbeck et al. 2011). In particular, monitoring of single trait transgenic proteins can be burdened with substantial systematic errors (Székács et al. 2010) rendering corresponding literature data hardly comparable to each other. Such research and monitoring methods require better standardisation among laboratories (Székács et al. 2011) and should also respect particular characteristics of the different receiving environments. Also, the insufficient consideration of regional particularities (Schermer and Hoppichler 2004; Graef et al. 2005) and of the socio-economic context of European farming systems (Ohl et al. 2007; Binimelis et al. 2009) in many cases has contributed to questionable relevance of field studies submitted in dossiers seeking approval from European authorities for field trials, cultivation or import. Previous EU research in this area (European Commission 2010, 2011; Biota 2011) has placed little emphasis on these issues, despite the critical importance of these aspects for achieving the desired outcomes from the EU Directives.

Requirements and challenges for a European-wide network for systematic GMO impact assessment (ENSyGMO)

According to the EU Directive 2001/18/EC, GM crops considered for placing on the market must be subjected to satisfactory field testing at research and development stages in all those ecosystems which could be affected by their use (European Commission 2001). Furthermore, GM crop introduction into the environment must be carried out following a precautionary approach by using the "step-by-step" principle, gradually increasing the scale of release if data obtained at previous steps does not provide evidence for biosafety concerns (Hilbeck et al. 2011). GM crop introductions in the EU must follow this regulatory framework that requires a systematic environmental risk assessment (ERA) and mandatory post-market environmental monitoring (PMEM) after approval. While the ERA is primarily based on short-term and small-scale introduction of the GM crops, PMEM is intended to handle uncertainties about remaining potential adverse environmental effects after the ERA, comprising immediate, direct, indirect, delayed, long term as well as combinatorial and cumulative effects (European Commission 2001). The approval process of GM crops in the EU must consider both the sustainability of agricultural systems and environmental protection goals. However, both intentions need long-term interdisciplinary perspectives and systemic assessments, including social and economic ones, for generalising possible GM crop impacts across the variable European agricultural and environmental conditions (Ohl et al. 2007; Graef et al. 2010; BfN et al. 2011).

Taking a long-term view and allowing for systematic pre-release and continued assessments of GM crops introduced into differing receiving agricultural and natural environments will require that representative indicators are identified, developed, validated and harmonized with regard to the different ecological and socio-economic contexts within Europe. Also, detection methods and a process of selecting representative field test sites across the biogeographic and agro-ecological regions and socio-economic contexts of the EU need to be established in a transparent and scientifically sound manner, taking into consideration specific regional protection goals.

To achieve these ends, we propose the establishment of a Europe-wide network for systematic GMO impact assessment (ENSyGMO) that simultaneously targets the following core issues:

- Harmonized and whenever possible standardized key indicators and sampling methods to quantify possible impacts (EFSA 2010a). This leads to reliable and comparable data within representative testing sites across Europe and can be used as a scientific basis for a realistically differentiated EU-wide ERA.
- A representation of the variability of agro-ecosystems and its biological and socio-economic components into which GM crops are proposed for introduction.
- Design of statistically robust representative field tests on the European scale, and protocols for data analysis as a basis for the ERA and PMEM studies. The challenge here is not so much to ensure the detection of adverse effects in agricultural systems, but to discriminate measured effects with regard to cause-effect relationships, for instance potential impact of GM cropping on other agricultural practices, taking into account also the dynamics of agricultural and environmental changes.
- Stakeholder involvement for i) communication of field test regions and sites; ii) feedback from the relevant local actors, such as the farming communities and bee keepers among others, on the design of comparisons (including identification of salient indicators) between GM cropping and non-GM cropping systems; iii) a sound basis for socio-economic assessments and monitoring of conflicts (Henle et al. 2008); and iv) effective dissemination of methods, procedures and approaches to the administration and decision makers, and other stakeholders and users.
- Public and scientific validation on development, application and improvement of ERA procedures and protocols through enhanced stakeholder involvement and transparency.

We suggest establishing the ENSyGMO framework for the ERA (and in part for the PMEM) using as the first cases the GM crops authorised for cultivation and comparative assessment with near isogenic lines or other conventional counterparts in regionally differing agricultural systems with specific crop rotations. However, since conventional non-GM agriculture may also create adverse effects, the assessment of these effects should not be restricted to comparative approaches only, but include additional sustainability criteria for agriculture and its environment. This will require modifications to existing frameworks. For example, the PMEM design may be inadequate to cover such effects and will require a more advanced monitoring approach (BfN et al. 2011). ENSyGMO must aim primarily to create trust in its scientific independence, robustness and societal utility. Accordingly, the participation of relevant stakeholders from the public sector, researchers, and the private sector is central in the ENSyGMO approach. Where appropriate this includes attunement of prevailing scientific indicators and parameters to relevant stakeholder (e.g. farmer) knowledge and concerns.

Objectives of the ENSyGMO framework

The overall goal of the ENSyGMO framework is to design and apply harmonized procedures for detecting and analysing GM crop effects across the variability of European agricultural environments and socio-economic contexts. A further key goal is to make the EU regulatory framework as well as the appraisal of GM crop introduction proposals more scientifically, socially and technically robust. These overarching goals can be broken down into the following objectives:

1) The development of a harmonized catalogue of evaluated indicator organisms, from both a pan-European and regional view, based on defined criteria for identifying indicators (e.g. functional groups, traits, communities, red list species, etc.) that capture possible impacts on biodiversity and other national or regional protection goals.

2) The development and validation of a harmonized catalogue of standardized sampling, analyses and evaluation methods, as a basis for ERA and for possible long-term PMEM studies.

3) The creation of a database of current agro-environmental (baseline) characteristics of the main biogeographic regions in Europe, consisting of a) a biogeographical inventory of indicator organisms and their variability across European agricultural areas and b) the typologies of agricultural systems and surrounding environments with respect to potential GM crop introductions.

4) The design and establishment of a pan-European network of representative sites tested and verified for ERA, and for long-term PMEM studies and representative for EU biogeographic regions and farming systems.

5) The analysis of the socio-economic impacts of GM crop cultivation and its management (e.g. including co-technology such as herbicides used) in relation to the eco-social context of introduction, non-GM crop cultivation contexts, and regionally differing agricultural practices.

6) The participation of a wide community of stakeholders representing diverse social and ecological values and criteria of performance and the communication of the ENSyGMO framework design, activities and results with all relevant stakeholders and the public, beyond those already involved.

These objectives should be designed for regulatory authorities of relevant regional to European levels, field assessors, farmer representatives, and scientists in the relevant fields (inter alia agronomy, ecology, and socio-economy). The ENSyGMO framework also includes an analysis of its potential to expand the network structures and protocols, for instance the methods to derive appropriate indicators for specific GM crops. A general task of the ENSyGMO framework is the development, testing and application of the harmonized ENSyGMO outcomes to serve as a model and basis for future ENSyGMO refinement, and for the development of other network systems that assess and/or monitor technology and innovation impacts in agriculture, environment and socio-economy, which are still missing in the EU (Henle et al. 2008; The Royal Society 2009). The results gained by such a network could be also used for other stressors in agricultural landscapes. For instance, the pesticide registration procedure in EU requires distinguishing between bio-geographic regions in Europe (European Commission 2009), yet its implementation is seriously hampered by the lack of basic data on the composition of organism communities (EFSA 2010b).

Design of the ENSyGMO framework

The ENSyGMO framework must encompass all relevant dimensions for a comprehensive and regionally specific GM crop assessment scheme, including adaptability to future scenarios and challenges. For designing and implementing the ENSyGMO framework, we suggest six interlinked Thematic Clusters (TC) reflecting the main aforementioned objectives and directly leading to core products (Figure 1). The core products are: a harmonized catalogue of evaluated indicator organisms and sampling methods to quantify possible GM crop impacts (TC1); a database of baseline variability of EU agro-ecosystems (TC2); an EU network scheme for statistically-based representative field tests (TC3); a socio-economic impact assessment framework (TC4); public and stakeholder participation and dissemination, thus improved public legitimacy (TC5);

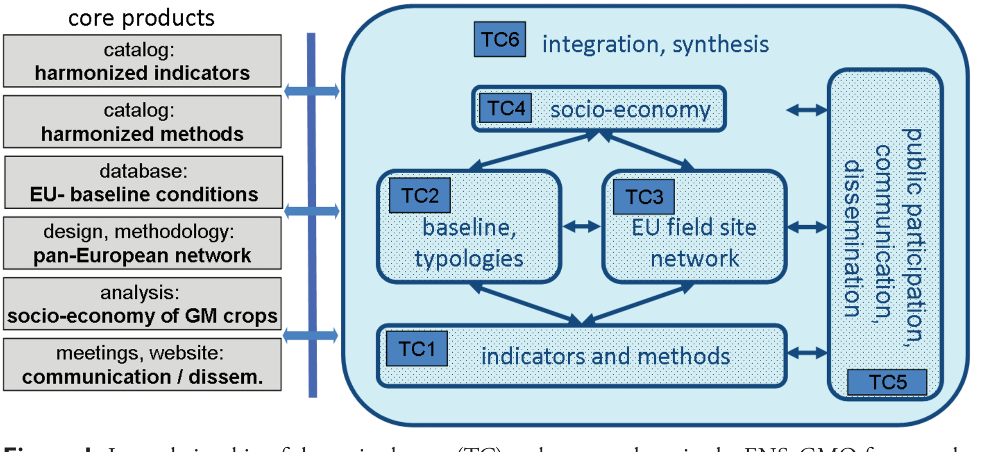

Figure 1. Interrelationship of thematic clusters (TC) and core products in the ENSyGMO framework: Indicator and sampling methods are selected (TC1) and baseline data and typology generated (TC2), which are then integrated and validated in the field testing network under real agricultural field conditions (TC3) and the socio-economic context (TC4). Based on the GM crop field testing results the field network is successively adapted to represent the EU typology of European agro-ecosystems and biogeographic regions (TC2). Field trial results and supplementing GM cropping data, as well as the stakeholder analysis (TC5), need to be included with the socio-economic impact assessment of the GM crops (TC4). Between the TCs 1-4 there are feedback loops to iteratively and mutually adapt/improve the ENSyGMO framework. All themes are integrated, evaluated and synthesised (TC6) to ensure the applicability of ENSyGMO products to the ERA, PMEM and SEIA regulatory frameworks.

and an integration and synthesis of the different scientific improvements across these ENSyGMO domains, (TC6) particularly taking care of the need to transfer the ENSyGMO products to the regulatory framework.

Indicators and sampling methods (TC1)

The identification of indicators and sampling methods for detecting potential GM crop impacts is a crucial step in the ERA methodology. A proposed ERA concept (Hilbeck et al. 2008a, 2011) that was partially included in the EFSA (2010a) guidelines places the whole GM organism at the centre of the assessment. The concept includes potential adverse effects arising from direct and indirect exposure to the GM crop and also secondary stressors such as inherent management practices to the specific GM crops (e.g. the application of broad spectrum herbicides) (Andow and Hilbeck 2004).

To achieve a comprehensive and solid foundation for indicator identification, hypotheses and evidences about ecological impacts of GM crop cultivation in various regions and environmental conditions have to be compiled. Both direct and indirect effects must be covered. Direct effects include, for instance toxic effects on non-target fauna, mainly invertebrates but also mammals and microbes (Relyea 2005; Giovannetti et al. 2005; Benachour and Séralini 2009). Indirect effects refer for instance to altered rotation and other production schemes, pesticide applications rates and timing, and tillage system (Graef 2009). Also combinatorial or cumulative effects, for instance alterations in biodiversity or food webs, and pest-resistance development should be covered (Heard et al. 2003). Furthermore, the relevant environmental compartments (terrestrial both below- and above-ground, and aquatic systems) and land-use forms (agricultural sites and other potential receiving environments) should be represented (EFSA 2010a; BfN et al. 2011).

Indicators must be then selected in a step-wise process, which begins with identifying the most important ecological functions and protection goals relevant to sustainability in agriculture and continues with the identification of possible exposure pathways, relevant species in the local ecosystem, their suitability for testing, their sampling methods, and their practical testing (Hilbeck et al. 2008b). Such indicators are a) organisms at the species and/or community level including functional groups such as earthworms (Bouché 1977), trophic groups such as nematodes (Yeates 2003) or trait groups such as aquatic invertebrates (Liess and Beketov 2011); b) direct functional endpoints such as litter decomposition, biogeochemical cycles completion; c) indirect functional endpoints such as ecological functions provided by single species or communities (Hilbeck 2008a, b; Schmitt-Jansen et al. 2008) and ecosystem services such as biodiversity and habitat provision and/or pollinators securing food crop production (Faber and van Wensem 2012; Mace et al. 2012); and d) landscape-scale related indicators such as land use diversity which may be affected by altered rotation and other production schemes (Graef 2009). They must represent not only arable areas, but neighbouring receiving environments including wild habitats, where the GM crops may have a potential impact or could occur. There should be a representation of at least a) the main environmental compartments (terrestrial below- and above-ground, aquatic); b) functional groups such as predators, herbivores, saprophages, and symbionts; and c) different physiological, taxonomical groups, for instance, mainly arthropods but also oligochaetes, microbes and/or fungi (Hilbeck et al. 2008a; Römbke et al. 2009).

Detecting possible impacts on indicators requires appropriate laboratory testing methods suitable for the ERA, as well as field testing and monitoring methods (Hilbeck et al. 2006, 2008b; EFSA 2010a). These methods should be preferentially standardised, for instance, by OECD, ISO, VDI or IOBC methods (Fink et al. 2006; VDI 2010). Depending on the selected indicator species, these methods may require modifications or new methods must be developed. Sub-lethal endpoints, such as reproduction, should be included as criteria since they can also give indications of possible long-term effects and are more sensitive than acute (lethal) harm (Römbke et al. 2009). The methods identified have to be examined in practice, preferably in inter-laboratory comparison tests, and developed into a comprehensive testing protocol.

The hypotheses on GM crop effects need to be practically tested using the selected indicators and laboratory methods. Current ERA procedures are expected to undergo considerable improvement (EFSA 2010a). Lab tests should be performed with the GM plant material as well as with mixtures of GM plant and conventional counterpart material, and compared to a non-GM conventional counterpart. Test data-sets must be statistically evaluated to control the test method performance under routine conditions and to help focus subsequent field testing (Römbke et al. 2009). Field tests are also essential in higher tier evaluation, and must be performed, even if the proposed mode of action is well understood and laboratory tests indicate no observed effect on a given species (Romeis et al. 2011).

Finally, assessing socio-economic impacts of GM crops in European agro-ecosystems and regions require specific indicators as part of the ENSyGMO framework. These indicators need to combine the relevant socio-economic impact assessment (SEIA) factors, GM crop environmental monitoring data, and the associated agricultural management practices (Henle et al. 2008). Using regional rules derived inter alia from the research we propose and/or scenarios for identification and measurement of socio-economic indicators is particularly useful, for instance, relating to management or co-existence inputs of GM crops compared to non-GM crops, in the specific eco-social context of the GM crop receiving environment (Binimelis 2008).

Baseline conditions of European agro-ecosystems (TC2)

In 2008, the European Commission mandated the EFSA to develop methodologies and recommendations for establishing relevant GM crop baseline information. The guidance (EFSA 2010a), however, does not yet provide substantial improvement in this regard. Europe covers a wide range of agro-environmental conditions, which are reflected in a wide variety of agro-ecosystems with specific biodiversity, climate, land use and management systems and agricultural productivity. Spatial classification of information and geographical data is essential for their analysis and communication (Metzger et al. 2005). Increased availability of spatial environmental data and advances in spatial data processing has led to a range of new European classifications and typologies of biophysical regions (Hazeu et al. 2011; EEA 2011). However, few attempts have been made to develop useful classifications and/or typologies focussing on environmental impacts of agricultural innovations. This requires the linkage of information on farming systems and information on the biophysical endowment (Kempen et al. 2010).

For the ENSyGMO framework, we suggest establishing a comprehensive spatial agro-ecosystems typology and regional baselines of EU agro-landscapes and the wider potential receiving environments. This should build on or be co-developed with existing stratifications, typologies and classifications (Andersen et al. 2007; Petit et al. 2008; Hazeu et al. 2011; EEA 2011) with biophysical data relevant for discriminating potential environmental GM crop effects on the previously identified indicators (TC1) from the continuously changing agro-environment. Ecological information on habitats, species, sites with local biological diversity importance, and protected areas should also be integrated. Scale-related omissions in geographic regions represented, habitats, ecosystems and taxa must be identified throughout the ENSyGMO framework in order to collate additional data if possible (Dalgaard et al. 2003).

Baseline information primarily for the aforementioned environmental and socio-economic indicators must be compiled at the European level to efficiently assess the sensitivity of European regions and agro-ecosystems, particularly in relation to potential adverse effects of GM crops within differing protection, developmental and socio-economic goals (Dziock et al. 2006). Other baseline information and indicators are essential for explaining GM crop effects. These may relate, for instance, to characteristics of farming systems, biophysical and ecological conditions for agro-ecosystems, and protected wildlife and habitats, and ecosystem functions (Settele and Kühn 2009; Biota 2011; Jänsch et al. 2011), and should refer to EEA and OECD standards (OECD 2008; EEA 2010). Established environmental monitoring programmes (EMP) may also provide baseline information needed for targeting field sites and for field testing. EMPs are established and integrated, for instance, under the Water Framework Directive, the Habitats Directive (Graef et al. 2008) and for the Long-Term Ecosystem Research Network sites (LTER 2011) but exist also at the national level (Schmeller and Henle 2008; EuMon 2011).

The ENSyGMO baseline information on European agro-ecosystems must be managed and analysed with a geo-database including onthology, its access, maintenance and meta-data information. This geo-database should include the spatial agro-ecosystems typology and the indicators determined (Andersen et al. 2007), and should be accessible through standard database browsers and (Web-)GIS-programmes (Kleppin et al. 2011).

EU wide network for GM crop field testing and monitoring (TC3)

Practical field testing and PMEM in the EU and worldwide are lacking a scientifically robust and spatially representative design (BfN et al. 2011). GM crop introduction trials in general are concentrated on one or a few locations only and are restricted to short-term studies (Lövei and Arpaia 2005). These shortcomings, together with the fact that GM plant approval dossiers sometimes crucially rely on tests done in non-EU overseas regions are major reasons for public concerns and for the often contradictory comments of EU Member State experts during GM crop application and decision-making processes (Graef et al. 2010). The only larger scale experiments conducted this far in the EU are the Farm Scale Evaluations in the UK (Firbank et al. 2003, Heard et al. 2003). Thus, the step-by-step principle of gradual spatial increase of the GM crop introduction as required by Directive 2001/18/EC (European Commission, 2001) is not implemented in practice. Methodologies for designing regionally representative field tests are scarce (e.g. Stein and Ettema 2003; Graef et al. 2005); and networks for carrying out these studies do not exist yet. Both ERA and PMEM require a representation of the variable European agro-environment (EFSA 2010a). Therefore, we consider that the implementation of a comprehensive network approach such as the ENSyGMO in the near future is critical to address these deficiencies in current practice.

Given the inherent agro-biodiversity in the EU a fully functioning representative network cannot be implemented right from the start. Rather, initially this has to be a prototype requiring incremental adaptations and refinements, based on field testing results and multi-/trans-disciplinary experience gained (Lindemayer and Likens 2009). Hence, the proposed ENSyGMO must be based on a statistically verified experimental field study design comprising a test site network. Being based on the agro-environmental baselines and typologies developed, this design should have sufficient power to explain the EU-wide variability of different indicators. The network should not only cover present GM cultivation regions (FOE 2011) but include environments where potential future GM crop cultivation could take place. Existing field test sites of agricultural companies and/or authorities and of agricultural research institutions could provide the core of such a network (Figure 2). The initial design, depending on the typology outcome, may include 8–10 sites including sufficient replications (Figure 2). To achieve public acceptance of the GM crop cultivation and the assessment process the involvement of local or other stakeholders into design and conducting the field experiments is crucial (Lemaire et al. 2010).

Practical field testing using established indicators and sampling methods should be done under controlled conditions in parallel at all sites. ENSyGMO sites will also serve as facilities for socio-economic impact assessments (SEIA). To assess laboratory and field level indicators and methods for their suitability and extrapolation, field testing in additional GM crop cultivation regions outside Europe, for instance those with significant levels of GM crop cultivation, (e.g. Brazil, India and China) should be undertaken. It is expected that at least the same taxonomic or functional groups can be used in the different areas.

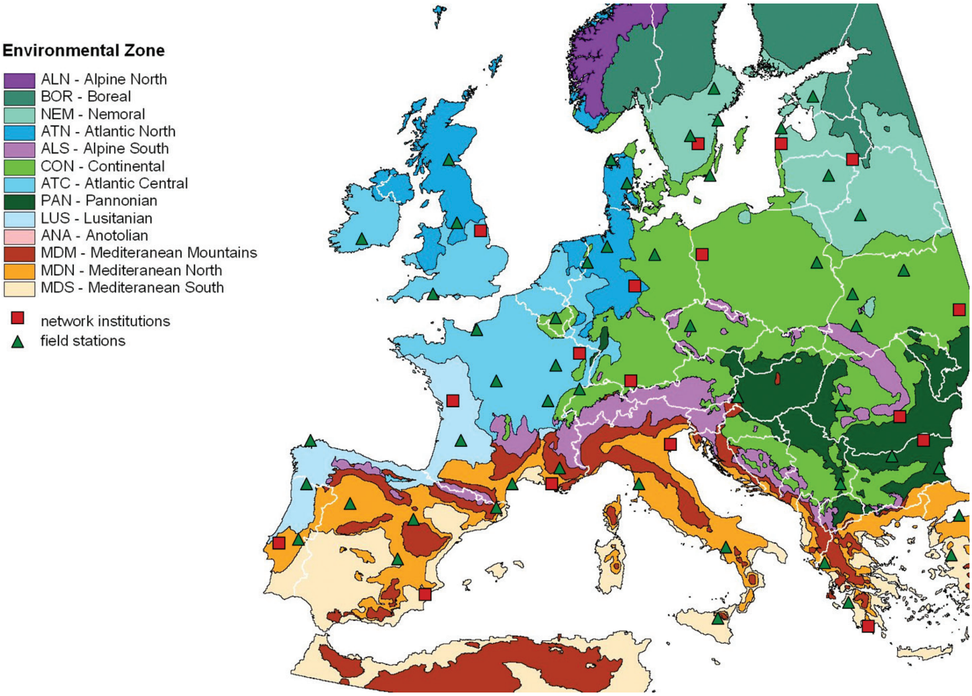

Figure 2. Potential distribution of research institutions and available field research stations in an ENSyGMO representing the Environmental Stratification of Europe (Metzger et al. 2005). Field station sites for practical testing of GM crops should be located in all agro-ecosystems relevant for GM cropping.

Managing the ENSyGMO field testing data requires a well-designed database, one that can be used to analyse the ENSyGMO data in present and future ERA and PMEM assessments (Reuter et al. 2010) and also store additional data collected from various sources. The data may also be used for feeding decision support systems with appropriate inputs and for creating predictive models from the field testing data (Bohanec et al. 2008).

To achieve sustainability of an ENSyGMO framework, structural, financial, and organisational requirements need to be identified. This analysis should also include the potential for other institutions with wider environmental, ERA and monitoring expertise to co-operate and give further methodological input. For long-term establishment of the ENSyGMO sites, local or other relevant stakeholders are expected to be involved (Lemaire et al. 2010).

Socio-economic impact assessment (TC4)

Analysis of the current research shows that a significant amount of work on SEIA is narrow in scope and contested in terms of assumptions, applied methodologies and findings (Desquilbet and Bullock 2009; Demont et al. 2010; Glover 2010). We find that:

- most socio-economic impact research focuses on ex-ante and purely economic parameters of a limited number of GM crops cultivated in only a few regions, which creates a knowledge gap on the actual impacts after GM crops are introduced into the environment (Smale et al. 2009);
- comprehensive comparative analysis between GM and non-GM crop production systems (e.g. conventional, GMO-free, organic) along the production chain and implications of co-existence (Coléno 2008) are missing. This approach includes the analysis of entangled socio-economic and ecological relationships. For instance, potential undesired processes, such as gene flow resulting in transfer of GM pollen to honey, may have implications at the commercial (e.g. honey with GM pollen would require a specific authorisation for its consumption) (European Court of Justice 2011), managerial (e.g. beekeepers moving their bee colonies to other areas to avoid contamination) (Lezaun 2011), and the ecological level (e.g. displaced bee colonies may significantly reduce pollination of plants in agricultural and natural ecosystems);
- socio-economic impacts that might go beyond the monetary assessment analysis are rarely considered (Binimelis 2008);
- usually adequate costs and benefits analyses are unfeasible, due to restricted knowledge on both potential adverse effects and benefits of GM crops in the medium and long term (Messéan et al. 2009);
- integrated socio-economic analysis with respect to other impacts, including unintended environmental effects, usually is ignored (Pavone et al. 2011);
- only a small community of researchers is involved in SEIA, restricting the variety of research perspectives and narrowing the range of methodologies mainly to agro-economic aspects such as yield, prices, cost of production, profits and consumer acceptance (Smale et al. 2009).

These shortcomings are tackled in the ENSyGMO framework in light of the recognition of the multifunctionality of agriculture (The Royal Society 2009), by a) including the intertwined relationship between the ecological and socio-economic context where GM crops are introduced, and b) facilitating the participation of relevant stakeholders as central in the ENSyGMO methodological approach for a comprehensive SEIA.

Accordingly, the SEIA of the ENSyGMO framework includes, in a first step, defining potential or observed adverse socio-economic impacts of GM crops. This is based on a) an analysis of the existing cases of GM crop introductions, b) existing information and knowledge provided by integrated SEIA methods and experiences, c) analysis of the socio-cultural and institutional context of GM crop introductions, taking into account the private sector (farms, traders, supply chains) and the public sector (national, regional governments and communities), d) identification of protection goals in relation to socio-economic welfare and sustainable development, and e) identification of relevant knowledge gaps.

The SEIA framework of GM crops must be developed from the baseline information obtained prior to or simultaneous with their introduction. This includes consultation with relevant private and public sector stakeholders. In the ENSyGMO framework, relevant stakeholders refer to the different actors along the GM crop value chain that are affected in monetary and non-monetary socio-economic terms and include, inter alia, GM and non-GM farmers, the agribusiness sector (e.g. importers of inputs for GM crop production and traders), local communities and families surrounding the GM crop cultivation, consumers, policy and decision makers, and practitioners of SEIA. The SEIA consultation process includes the identification of a) relevant environmental, cultural, institutional and political factors with socio-economic impacts; b) socio-economic and development protection goals, c) monetary and non-monetary implications at farm and community level (TC6); and d) a decision support system for a comprehensive and comparative assessment of socio-economic impacts of GM crops.

Finally, the SEIA of the GM crops tested within the ENSyGMO framework need to be validated. This requires the implementation of the SEIA on the value chain of the GM crops under the EU relevant scenarios, taking into account the regional specificities, environmental and socio-economic protection goals and data availability in different test site regions. Moreover, complementary studies in GM crop commodity-exporting countries such as Argentina or Canada should be included in order to attain a more comprehensive knowledge base on the interrelated socio-economic pathways. Adaptations of the SEIA framework based on the experience gained from implementation and feedback from actors and stakeholders involved, and integration in terms of approach, findings, lessons learned and policy recommendations, would be the final steps in this framework.

Communication and dissemination in the ENSyGMO framework (TC5)

The benefits and potential adverse effects of GM crops are highly contested in the scientific, public and policy spheres. In these debates environmental and socio-economic harm has typically been viewed as a purely scientific matter. In the framing of harm, benefits and risks the analysis of social conditions (Myhr 2010) and human values (Wynne 2001) also are considered. These are relevant for assessing impacts (Felt et al. 2007) as it corresponds to the Problem-Framing within the Problem Formulation and Options Assessment (PFOA) framework for ERA (Nelson et al. 2009). The ENSyGMO framework recognizes the importance of the social, cultural and ethical factors relevant to different actors and stakeholders. As a result the framework includes a two-way communication approach as an essential component of good scientific research practice, as well as for social and ethical considerations in policy and decision making (Dalgaard et al. 2003). This allows a multi-sector and multi-disciplinary dialogue among the major groups of stakeholders (i.e. private sector / policy-makers / researchers / civil society).

Communication within the ENSyGMO framework takes place in various forms, including information provided through scientific conferences and other meetings, scientific journals, policy reports and technical reports, also more proactive exchange of knowledge (e.g. workshops). Moreover, the ENSyGMO methodology and results – being cross-cutting issues – should be actively communicated to the full range of GM crop ERA and SEIA practitioners, for instance, the European Commission and national Competent Authority scientists, environmental agencies, land managers, and policy-makers.

Communication in the ENSyGMO framework must also include pre-assessment communication. This should refer to the dissemination of project aims, particularly field trial objectives, design, requirements, and envisaged uses in conjunction with the other ENSyGMO framework actors through a) an early-established multi-lingual interactive website that is regularly updated and informs scientists, policy-makers, authorities, NGOs and the interested public and also elicits public and other stakeholder responses, and b) stakeholder-dialogue meetings in selected Member States (Myhr 2010). Long-term commitments of local and other stakeholders need to be established for conducting the field trials and the agro-environmental and socio-economic monitoring.

Stakeholder knowledge and concerns should be included in the assessment planning itself (Wynne 2001). Both public and private stakeholder knowledge and concerns about GM crops and site-specific or more widespread potential hazards, which could contribute to the scientific ERA and the SEIA, need to be retrieved. This requires analysis of the ENSyGMO interactive website, analysis of responses from the stakeholder dialogue meetings, the combined evaluation of the ENSyGMO lab, field test and SEIA results, and application of the PFOA framework (Nelson et al. 2009). It also requires input from GM crop cultivation scenarios (TC6), and from EFSA stakeholder and public consultation processes (Koutalakis et al. 2007).

The ENSyGMO framework should include training and capacity building through approaches adapted to the different audiences, targeting a) the broad range of actors and stakeholders; b) practitioners including social scientists, especially at postgraduate levels; and c) EU, Member States and developing country policymakers. The purpose is to provide understanding of the nature and conduct of such field trials and assessments necessary to satisfy GM crop regulatory requirements.

Integration, evaluation and synthesis in the regulatory context (TC6)

The interpretation and implementation of the ERA and PMEM principles, as laid down in Directive 2001/18 and Annex III of the Cartagena Protocol, is an ongoing process defining and refining what is needed and how it can be achieved (Hilbeck et al. 2008a,b, Myhr 2010, BfN et al. 2011). Scientific, legislative and regulatory requirements, as well as societal or political perceptions, frame the ERA, PMEM and the SEIA. The ENSyGMO framework aims at providing sound data with the field studies for the ERA and PMEM, providing appropriately harmonised and, if possible, standardised methods and indicators for detection and analysis (VDI 2010). It aims at transferring the ERA mainly based on short-term observations to an ecosystem-based integrated assessment of the GM crop impact on the farming systems, environment and socio-economic context specifics. The ENSyGMO framework also requires continuous review and adaptation including and targeting new and/or unforeseen developments, new knowledge, and change in cultivation practice and field sites in the EU. Accordingly, the ENSyGMO framework is an iterative process for constantly reviewing and improving research hypothesis and methods in the ERA, PMEM and SEIA.

Hence, an integrating platform is required to create maximum impact and usability of core ENSyGMO products (Figure 1) for the existing ERA, PMEM and SEIA frameworks. This platform requires the permanent involvement and inputs of all ENSyGMO partners and vice versa. The core objective of this platform is the development and synthesis of a comprehensive, interdisciplinary scenario framework for GM crops adoption and associated changes in EU agriculture. This is based on inputs by the ENSyGMO actors and themes (indicator organisms, sampling methods, baseline requirements, overall network design, socio-economic impact, stakeholder dialogue) and on previous or ongoing EU scenario oriented projects, for instance, ALARM, SEAMLESS and SENSOR (Rounsevell and Metzger 2010). The scenario framework should be applied to check the usability and predictive power of the ENSyGMO results and for deriving suggestions for the ERA, PMEM and SEIA frameworks. For instance, GM crop cultivation scenarios could serve to extrapolate the results on field testing, regional protection goals, and regional farming systems to possible future situations.

The ENSyGMO lab and field studies require synthesis and comparison to other GM crops, and other studies (including peer-reviewed literature) to attain an overall ERA, PMEM and SEIA of GM and non-GM farming systems in the EU. This entails the following steps, a) process-related findings using tested assessment methodologies and protocols from lab and field trials. The pros and cons, as well as required technical, financial and person-power input of each methodology should be analysed and recommendations for use formulated; b) synthesis of lab and field trial data and results using state-of-the-art statistics. The predictive power of lab studies indicating environmental impact need to be evaluated by modelling and comparing the ENSyGMO and other lab data to field findings; c) evaluating remaining uncertainties and their impact on the accuracy of the ERA; and d) the evaluation of lab and field trial and other data using the SEIA framework.

The transferability of the ENSyGMO framework results to the existing ERA, PMEM and SEIA framework in the EU and the Cartagena Protocol on Biosafety has to be ensured. Therefore, the TCs should be monitored and supported from the beginning to provide appropriate baseline information, methodologies and input to existing protocols. The ENSyGMO outputs require synthesizing and fulfilment of their objectives for use by decision makers and relevant stakeholders on regional, Member States, European and global scales. The final recommendations require a consensus-building process within the ENSyGMO framework. Representing different interests of diverse groups in society and regulatory science requires transparency, accountability and participation of stakeholders along the ENSyGMO implementation. A series of stakeholder meetings are required for applying and enhancing the PFOA methodology (Nelson et al. 2009). Finally, the PFOA needs to be tested as a tool for accompanying field introduction trials and PMEM by validating the outcomes of the ERA against the initial ERA assumptions.

Outlook

The ENSyGMO framework endeavours to address the many concerns about GM cropping systems. These concerns centre, for instance, on inadequately designed GM crop testing studies and PMEM, the lack of environmental baseline data and representativeness, non-consideration of regional environmental and socio-economic specifics, the conflicting interpretation and under-implementation of EU regulations, and the poor involvement of local and other stakeholders. It is, however, neither a "cure-all" for addressing conflicts, nor can it provide answers to all uncertainties connected to GM agriculture. However, the ENSyGMO can provide a long-term scientifically sound basis for the ERA of GM crops and for long-term monitoring studies in the EU. For the proper PMEM as defined by the EU Directive 2001/18/EC additional sites in real GM cropping regions and farming systems are required, generally with a more prolonged timeline. The ENSyGMO framework as proposed in detail here requires field implementation and validation to effectively contribute to broadening the scope of requirements and potentials linked to the ERA, PMEM, SEIA and the regulatory framework of GM crops. ENSyGMO is a flexible framework that will be improved based on the experience gained, the changing contexts and the development of novel GM crops. As a result and taking into account that the framework operates on a case-by-case and step-by-step basis, an additional outcome of ENSyGMO is the potential for organizing permanent or ad hoc expert working teams or sub-networks, depending on the GM crop (e.g. Bt-Maize working teams) or the potential impacts (e.g. biodiversity or socio-economic impacts working team). The ENSyGMO framework is not only applicable to GM crop impact assessment, but to assessing and monitoring the implementation, impact and sustainability of EU policies and/or impacts of other agricultural technologies and innovations, (e.g. synthetic fertilisers, harvesting systems, plant protection products and the production of non-food crops). In particular, the ERA of plant protection products, currently under review, would clearly benefit from the activities in the ENSyGMO framework.

Acronyms

EEA European Environment Agency
EFSA European Food Safety Authority
ENSyGMO European Network for Systematic GMO impact assessment
ERA environmental risk assessment

GMO	genetically modified organism
IOBC	Int. Organisation for Biological Control of Noxious Animals and Plants
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
PFOA	Problem formulation and options assessment
PMEM	post-market environmental monitoring
SEIA	socio-economic impact assessment
TC	thematic cluster
VDI	Verein Deutscher Ingenieure

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