Socio-economic Considerations in Regulatory Decision-making on Genetically Modified Crops

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Abstract

The growing adoption of genetically modified (GM) crops worldwide can have socio-economic benefits for society and farmers, including increased farm profitability, income stability and ease of operation, along with decreased labour and pesticide use, crop losses, and exposure to toxic chemicals. Thus, in addition to national and international regulations on biosafety, countries are increasingly aware of the importance of formalising the inclusion of socio-economic considerations (SECs) into regulatory decision-making. In practice, the complex and varied character of SECs can lead to technical and procedural challenges. Market introductions of biotechnology products have inherent microeconomic and competitive benefits and drawbacks. Socio-economic impacts can be positive or negative: in most cases, both occur but are not necessarily specific to GM crops. Socio-economic analyses generally compare the resources used or gained by a project with either (1) the prevailing situation or (2) an alternative scenario to determine the better option. SECs are highly dependent on context, especially the type of GM crop, the geographical location of use and the type of users. The distribution of benefits and costs amongst growers, consumers, food manufacturers, retailers and technology developers can make impact assessment rather complex. Modern biotechnology and its regulation are subject to public and political debate in many parts of the world. On top of environmental safety assessments, socio-economic assessments can contribute to balanced decision-making on market releases, future investments in research and development, and technology deployment. However, systematic and clearly outlined procedures and data/information gathering are needed to guide policy formulation and decision-making on biotechnology applications. This article (1) reviews the role of SECs in biosafety decision-making and (2) discusses the opportunities and challenges of integrating SECs into regulatory decision-making.

Keywords: biosafety, genetically modified crops, GMO regulatory framework, impact assessment, international, SECs, socio-economic considerations, technology introduction.

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Riassunto

A livello mondiale l'adozione degli OGM sta crescendo e in letteratura sono stati riportati svariati benefici socio-economici per la società e per i coltivatori. Essi comprendono la redditività dei coltivatori, la diminuzione della perdita dei raccolti, aumentata stabilità del reddito, facilità di utilizzo, quantità e quindi risparmi sui costi del lavoro e sull'uso di pesticidi, risparmio di tempo e riduzione dell'esposizione a sostanze chimiche tossiche. Oltre ai regolamenti nazionali e internazionali sulla biosicurezza, i paesi quindi riconoscono sempre di più l'importanza di formalizzare l'inclusione di considerazioni socio-economiche nel processo decisionale normativo. In pratica, questa inclusione è accompagnata da numerose sfide tecniche e procedurali dovute al carattere vario e complesso delle considerazioni socio-economiche. L'introduzione di prodotti derivanti dalle biotecnologie intrinsecamente hanno vantaggi e svantaggi micro-economici e competitivi. L'impatto socio-economico può essere sia vantaggioso che svantaggioso, ed è importante sottolineare che nella maggior parte dei casi si verificheranno entrambe le situazioni e che non sono necessariamente peculiari delle coltivazioni GM. Le analisi socio-economiche in generale si riferiscono alle risorse usate o acquisite da un progetto confrontate a (1) quelle della situazione prevalente o (2) a scenari alternativi per decidere quale sia l'opzione migliore. Le considerazioni socio-economiche sono molto legate al contesto, specialmente in riferimento al tipo di coltivazione GM usata, la zona geografica e il tipo di utenti. La ripartizione dei benefici e dei costi tra coltivatori, consumatori, produttori alimentari, rivenditori e sviluppatori di tecnologie può costituire una valutazione d'impatto piuttosto complessa. Le moderne biotecnologie e la loro regolamentazione sono soggette a dibatto pubblico e politico in varie parti del mondo. In aggiunta alla valutazione della sicurezza ambientale, la valutazione socio-economia può contribuire a un processo decisionale equilibrato riguardo alla commercializzazione, ai futuri investimenti in ricerca e sviluppo e allo sviluppo tecnologico. Ciò tuttavia richiede procedure e raccolte dati chiare e ben definite per orientare il processo decisionale sulle applicazioni biotecnologiche. Questo articolo fornisce (1) una panoramica sul ruolo delle considerazioni socio-economiche nel processo decisionale della biosicurezza, e (2) informazioni sia sulle opportunità che sulle sfide dell'integrazione di tali considerazioni nel processo decisionale normativo.

1. INTRODUCTION

Regulation has been fundamental to the debate on the use of agricultural biotechnology because of: (1) the possible safety implications for the environment and human health; and (2) non-safety implications such as socio-economic considerations (SECs). Effective and useful regulation ensures an adequate level of safety while enabling access to safe products that will benefit society in general and local communities in particular. As such, regulation aims to obtain a balance between costs and benefits: costs can be economic but can also include risks to humans and the environment; and benefits can be profit but can also include welfare, quality of life or environmental improvement. Apart from identifying and measuring the costs and benefits, the distribution of each is also very important: who bears the costs and who incurs the benefits? Many of these are classified as socio-economic considerations (SECs).

National and international regulations increasingly acknowledge the importance of formalising the inclusion of SECs in decision-making (Secretariat of the CBD, 2010). Currently, most commercial biotechnology applications relate to agricultural products (i.e. genetically modified [GM] crops); thus, SECs in this area tend to focus on factors that influence the food supply chain as a whole. SECs include both economic and social effects at the farm level, on the supply chain and on the end user (i.e. the consumer). The wide range of SECs covers everything considered socio-economically relevant; this can complicate their implementation and operationalisation in regulatory decision-making. It is therefore important to set out a clear framework indicating what is meant by SECs and how they can be measured. The assessment and inclusion of socio-economic impacts in regulatory decision-making for GM crops is complex but the amount of research and data on SECs is increasing (Smale *et al.,* 2009; Hall *et al.,* 2013; Brookes & Barfoot, 2017). Over the years, the methodologies used for socio-economic impact assessments have improved with increasing experience of GM crops (Morris, 2011; Garcia-Yi *et al.,* 2014; Kathage *et al.*, 2016).

This article reviews the use of SECs in regulatory decision-making, either in parallel to or as part of biosafety decision-making. First, a brief introduction to the international legal provisions for including SECs within regulatory decision-making will explore the most commonly used categories of SECs for GM crop cultivation. Next, the different aspects and challenges of measuring, implementing and using SECs in regulatory frameworks will be explored. Many countries recognise the importance of SECs and have mentioned them in their biosafety regulations. However, relatively few have formally implemented them into the actual assessment of genetically modified organisms (GMOs). This review aims to provide greater insight into both the opportunities and challenges of integrating SECs into regulatory decision-making.

2. LEGAL BASIS: ARTICLE 26, CARTAGENA PROTOCOL ON BIOSAFETY

The legal basis for including SECs in biosafety decision-making is primarily Article 26 of the Cartagena Protocol on Biosafety (CPB)[1], a legally-binding international agreement negotiated, concluded and adopted in the framework of the Convention on Biological Diversity[2]. It was established to guide Parties in developing countries in the environmentally-sound management of modern biotechnology practices, specifically focusing on transboundary movements. Parties to the CPB are expected to establish functional regulatory systems that have the capacity to access state-of-the-art research and development (R&D) facilities along with a platform for exchanging scientific and technical information. Following the CPB, a number of capacity-building initiatives have assisted (and continue to assist) developing countries to build functional regulatory systems. The CPB addresses all aspects of biosafety regulation, including the use of SECs (see Box 1).

Box 1. The Cartagena Protocol on Biosafety

Article 26 states that:

1. *The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.*
2. *The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.*

According to Article 26 of the CPB, the inclusion of SECs in regulatory decision-making (1) can apply to import decisions; (2) can apply to issues included under domestic laws and regulations; and (3) is voluntary; and furthermore, (4) if countries chose to include them, then the assessment needs to be consistent with international obligations, for example, according to the World Trade Organization (see also Falck-Zepeda *et al.,* 2016). Finally, Article 26 of the CPB also suggests that SECs should have a specific focus: there should be direct causality from adopting GM crops to effects on biodiversity.

The importance of formalising the inclusion of SECs within national regulations is increasingly acknowledged, particularly in developing countries. There are, however, no standard provisions to include SECs in domestic legislation of Parties to the CPB: this creates possibilities and flexibility, as well as challenges, in implementing SECs at

[1] https://bch.cbd.int/protocol

[2] The Convention on Biological Diversity (https://www.cbd.int) is a multilateral treaty with the objective to develop national strategies for the conservation and sustainable use of biological diversity.

national and international levels (Tung, 2014). Before addressing these challenges, SECs will be explored in more detail.

3. SPECIFYING SOCIO-ECONOMIC CONSIDERATIONS

There is no strict definition of socio-economic considerations, nor is there an exhaustive list of factors that encompass SECs. SECs can be wide-ranging: they can relate to direct to indirect impacts, be technology-specific or relate to non-specific impacts. Moreover, the impacts can be positive or negative, and sometimes affect different groups of stakeholders at the same time in different ways. The specific impact and characteristics of SECs depend on the context in which they are used. The context of biotechnology applications can differ depending on the following variables: the **type** of application, as well as its geographical **location** and technology **users** (i.e. what, where and who).

- **Type** of application: this determines which SECs are relevant for analysis. Different types of GMOs are developed for a range of goals and contexts: for example, GM crops for use in an agricultural context and GM mosquitoes to eliminate vector-borne diseases in a human health-related context. GM crops are primarily developed to increase yield, increase farmers' income and, further down the line, increase food security. The primary purpose of developing GM mosquitoes is to reduce disease incidences; they can have a direct (beneficial) effect on human health, but also a secondary (beneficial) effect on employment and income in local communities. Different SECs will be relevant for different situations; alternatively, the same SECs can have a different level of importance when assessing a specific GMO application. This review primarily focuses on the application of various types of GM crops: insect-resistant, herbicide-tolerant, virus-resistant or biofortified.
- Geographical **location**: the location of release/use can influence the socio-economic impact of a GM crop. For example, the impact on food security is likely to be negligible in developed countries because agricultural inputs have already been optimised in many areas (such as irrigation, fertiliser, weed management and pest management). In developing countries, such as in Africa, 30–50% of crops (and thus, harvests) can be lost because of insect pests (Deloitte & Touche, 2015). Introducing an insect-resistant GM crop can therefore have a big impact on food security in rural communities in these countries.
- Technology **users** (or stakeholders): SECs can have a varying impact on different users, known as 'the distribution of effects'. The socio-economic impact of a specific GM crop can vary amongst different groups of stakeholders (i.e. farmers, retailers and consumers) or within the same group of stakeholders (i.e. adopters and non-adopters of GM crops).

The following sections discuss the most commonly used SECs and their impacts on farming, on coexistence measures, on environmental economy, along the supply chain, and on food security and consumers.

3.1. Farm-level Impacts

GM crops can generate benefits for adopting farmers, including increased yield and profit increases, as well as less tangible benefits, such as less variability in yield and more flexibility in time management (for example, a wider time window for applying herbicides). However, not all farmers may profit equally from adopting GM crops. The extent of potential benefits will depend on the characteristics of the specific agricultural plot and of farm management, such as the previous incidence and severity of pest attacks, amongst others (Hall *et al.,* 2013). To determine the underlying mechanisms of socio-economic effects, a socio-economic analysis should start by profiling the typology of farms, farmers and adoption rates in the area under research (Kathage *et al.,* 2015). Adoption rates can be measured by (1) calculating the number of hectares planted with GM crop(s) divided by total hectares by crop or total hectares of arable land by country or region; (2) the number and proportion of farmers adopting GM crops (*ex post*); or (3) the number of farmers willing or unwilling to adopt a GM crop (*ex ante*). Farm typology relates to both **farm** characteristics (e.g. location [country/region], size, income by crop and livestock type, ownership and organic certification) and **farmer** characteristics (e.g. education, age, sex, household income, off-farm income and time dedicated to farming).

Socio-economic impacts at the farm level include all direct and indirect effects (see Box 2) of a GM crop while it is being produced. These impacts can affect the farmer, farm workers or other farmers in the same region and can have income, health, social, and ethical or cultural aspects.

Box 2. Direct and Indirect Effects

Socio-economic impacts can be the direct or indirect consequences of technology use, as illustrated in the following examples.

Conventional (i.e. non-GM) crops such as maize need regular applications of pesticides. The incorrect or unprotected use of pesticides can poison field workers (Damalas & Eleftherohorinos, 2011). Insect-resistant GM crops produce a specific protein that functions as a pesticide. These GM crops will generally need fewer pesticide spraying applications than a comparable non-insect-resistant crop. Thus, insect-resistant GM crops can have the direct effect of reducing pesticide use. As an indirect effect, insect-resistant GM crops can decrease the number of cases of pesticide poisoning in field workers (Kouser & Qaim, 2011; Racovita *et al.*, 2015).

Herbicide-tolerant GM crops can facilitate a change in crop management system that requires a different herbicide to be applied and can result in a reduction in soil preparation (tilling). Such low- or no-till agriculture can indirectly reduce soil erosion as well as fossil fuel use and greenhouse gas emissions due to reduced tractor use.

Virus-resistant GM crops can directly reduce local viral loads, which can indirectly cross-protect nearby non-GM crops sensitive to the same virus.

3.1.1. Income-related aspects

Income-related aspects of farm-level impacts contribute to the balance between inputs (expenses) and outputs (income). Farmers rely on different types of input, that is, expenses related to: seed and agrochemical (e.g. fertiliser, pesticides, herbicides) purchase; irrigation (depending on the climate); and fuel/machinery and labour. The output is the yield, which the farmer will sell for a certain price depending on crop quality and local market characteristics. Crop quality can be determined by seed quality and crop management efficiency, which also influences the overall input/output balance on a technical and allocative scale. For example, efficient management may result in more time available to generate off-farm income from other activities.

There is no general formula for calculating the gain in income from adopting a GM crop. The potential increases in yield and economic return depend on a variety of factors (Table 1). The more heterogeneous these factors are, the more variable will be the resulting benefits and costs. The effect of a change or improvement in one factor may be mitigated by other factors. For example, the use of an insect-resistant GM crop may result in suboptimal yield if other factors are limiting.

Table 1. Factors determining changes in yield and economic returns

Factor	Variability
Current crop	Has the farmer already cultivated this crop?
Trait characteristics	What type of GM crop is introduced (e.g. herbicide-tolerant, insect-resistant, virus-resistant, biofortified)?
Incidence(s) of pest infestations	Low or high pest pressure? Single or multiple pests?
Agricultural practices	Low or high tech?
Climate conditions	Temperature, humidity, precipitation, etc.?
Soil conditions	Nutrient level, need for fertiliser?
Seed costs	Premium for GM seed?
Market characteristics	Are GM crops already on the market? What is the demand? Level of societal acceptance?

Farmers who do not adopt GM crops may also be affected by the cultivation of GM crops by others. The availability of GM crops on the market can influence the availability of non-GM seeds and output prices. Non-adopting farmers will probably face the additional costs of segregation measures or damage (if cross-pollination or admixture occurs; see Section 3.2). However, they may also benefit from crop protection spill-overs (i.e. a local reduction in pest pressure caused by insect-resistant GM crop cultivation).

3.1.2. Health aspects

These relate to factors influencing the health of the farmer, farm workers and local community. For example, a change in pesticide management may influence not only income and yield but also affect the health of workers, leading to longer, healthier and more productive working lives (Bennett *et al.,* 2006; Krishna & Qaim, 2012; Racovita *et al.*, 2015). Increased yields or better-quality crops (with increased nutritional value) can benefit health. Finally, other less-quantifiable factors may influence people's health, such as a reduced need for physical labour or improved working conditions (Bennett *et al.,* 2006). Health aspects can be quantified economically using morbidity/mortality data associated with the use of pesticides and chemicals or with nutrition.

3.1.3. Social aspects

The social, ethical and cultural aspects of farm-level impacts relate to factors influencing working conditions such as working hours and overtime, wages and health insurance, training and education, and the availability of machinery and safety equipment. These aspects influence quality of life at the farm level. Additionally, there can be an impact on social interactions between farmers (i.e. between adopters/non-adopters or a shift/change in buyers and supplier). Impacts at the farm level can include ethical and cultural effects, such as a change in moral values (for example, concerning good agricultural practice and the exploitation of natural resources), the use of indigenous knowledge and cultural practices concerning farming (versus high-tech agriculture) or the distribution of justice (accessibility of the technology and the influence on any inequality between adopting and non-adopting farmers). Social effects can be mapped qualitatively using interviews or questionnaires.

3.2. Impact of Coexistence Measures

Cultivating GM crops has implications for the organisation of agricultural production. GM-crop-adopting farms might have an unintentional impact on non-GM-adopting farms due to unwanted pollination between their fields or admixing of their products. Therefore, it is necessary to establish systems to enable the coexistence of GM and non-GM crops (conventional agriculture, including organic certified agricultural systems). Coexistence is defined as the ability to successfully produce and market products from both GM and non-GM crops within the same agricultural system. This enables farmers to choose a production system that helps meet demands for niche markets by maintaining crop integrity within a system and preserving the economic value of the harvest.

It should be noted that the issue of coexistence of GM crops with non-GM crops is not a safety issue as legal GM products on the market have passed health and environmental safety reviews and regulations. Rather, coexistence is an economic issue that is market-driven.

The socio-economic impacts of coexistence include all direct and indirect effects of measures to prevent the unintentional presence of GMOs or admixture from GM crop farming to conventional and organic certified systems (see Box 3). Coexistence measures can influence farm-level costs and GM crop adoption dynamics.

Box 3. Coexistence Measures to Minimise Adventitious Mixing

Coexistence systems aim to reduce the likelihood of admixing crops grown via GMO, conventional, organic or subsistence agriculture. Admixing can occur before, during and after crop production.

Before crop production, admixing of seeds can occur. Ensuring seed purity is the first step in preventing GMO contamination. The risk of seed mixing depends on the type of seed system in use. Formal, well-organised seed systems are generally used by commercial farmers, whereas informal systems are used by smallholders or subsistence farmers. In an informal seed system, the seeds are saved by farmers and then distributed by registered or unregistered traders and vendors. Therefore, seed mixing and the adventitious presence of GMOs are more difficult to control in informal systems than in formal systems.

During crop cultivation, the unwanted presence of GMOs may result from gene flow due to cross-pollination between GM plants and non-GM plants of the same type. Whether cross-pollination actually occurs depends on several factors: the crop type; pollen and seed dispersal; and the distance between fields. Coexistence management measures are therefore crop-specific. The European Coexistence Bureau of the European Commission has developed crop-specific guidance documents[3] for best practices in coexistence management.

Admixing can also occur after crop production: during harvest, transport and post-harvest crop handling (such as storage and drying). Therefore, GM and non-GM harvests must be handled separately to prevent co-mingling. A contributory factor is that (smallholder) farmers often share harvesting machinery, transport wagons and storage facilities. The difficulty and costs of separating production chains depends on many factors, for example, the adoption rate of GM crops and the availability of separate means of storage and transport.

Two strategies are generally used to implement coexistence: precautionary (*ex ante*) and damage control (*ex post*) strategies. The first strategy aims to prevent admixture and gene flow, whereas the second provides measures to handle the situation after any admixture has occurred. Ideally, both systems must be in place because admixture is almost impossible to prevent. Examples of coexistence measures for both strategies are shown in Table 2.

Besides technical and practical measures to ensure effective coexistence, other measures include: careful record-keeping and administration and regular testing; training/education for farmers and farm workers; and good cooperation and communication between farmers and the operators of shared agricultural equipment. These measures provide transparency and may reduce or prevent disputes between neighbouring farmers.

Coexistence can increase farming costs such as operational costs, transaction costs, opportunity costs and testing and remediation costs. The type and scale of these costs

[3] http://ecob.jrc.ec.europa.eu/documents.html

can vary between GM crop adopters, conventional farmers and organic farmers[4]. The need for coexistence measures can influence GM crop adoption dynamics, such as the rate of adoption, spatial configuration of adoption, and the rate and stability of GM crop expansion. Finally, admixture can also have a social impact by damaging the level of trust between neighbours, leading to conflict or even lawsuits (Levidow & Boschert, 2011).

Table 2. Measures to promote coexistence (adapted from Czarnak-Kłos & Rodríguez-Cerezo, 2010; Devos *et al.*, 2009)

Precautionary measures (*ex ante*)	**Damage control measures (*ex post*)**
Mandatory segregation: • ensure seed purity • provide rigid/flexible refuge areas • have voluntary GM-free zones • maintain isolation distances* • adjust planting/flowering distance and/or timing • keep machinery & equipment clean • seal and label seed containers	Compensation funds
Identity preservation/traceability	Insurance schemes
Minimum GMO tolerance levels**	Marketplace liability

* The isolation distance is the distance maintained between fields of crop plants to minimise cross-fertilisation by pollen flow. The minimum isolation distance depends on factors such as the fertilisation mechanism of the species (self- or cross-pollinated crop) and the pollination agent (wind or insect).
** Because zero admixing is not achievable in agricultural systems, a legal threshold for the products of adventitious mixing must be set. This varies, but for most countries the legal tolerance threshold for authorised GMOs in non-GM products is 0.9 %.

3.3. Environmental Impacts

Besides farm-level impacts, GM crop cultivation can also have environmental impacts, both positive and negative (Raven, 2010; Mannion & Morse, 2012; Knox *et al.,* 2013; Garcia-Yi *et al.,* 2014). Environmental impacts related to SECs are limited to those with an economic effect, such as pesticide use and carbon emissions. After all, an environmental risk assessment has already been conducted during the decision-making process. Environmental economic effects are crop-specific and relate to herbicide and insecticide use, crop yields and the effects of unwanted gene flow. They can include effects on soil, water and air conditions; biodiversity, the use of resources

[4]These differences are based on the relative costs compared to the consequences. Conventional farmers may lose part of the non-GM price premium for conventional crops and may be affected from not being able to sell the crop as non-GM. For organic farmers, the consequences can be more severe, as they can lose their organic certification which is based on the adherence to principles, such as not using pesticides or GMOs.

and fuel consumption. For example, drought- or salinity-tolerant GM crops can reduce the need for resources (water) and fuel (reduced use of machineries), which can affect soil, water and air conditions in the area.

The use of GM crops may avoid the need for agricultural inputs and practices that might harm the environment, such as tilling. It can also change the type or quantity of herbicides/insecticides in use (Brookes & Barfoot, 2016), which may benefit soil and water conditions if the replacement herbicide/pesticide is less toxic. Apart from these direct effects, the use of GM crops can have indirect effects due to changes in agricultural practices, such as reduced use of machinery and fossil fuel resulting from fewer herbicide applications (e.g. CO_2 emission and carbon sequestration). Overall, improving crop yields without increasing the use of land and water resources could reduce total land use and help minimise impacts on biodiversity (Brookes & Barfoot, 2017). GM crops approved for commercial cultivation have undergone a thorough environmental risk assessment and are considered safe. To date, no incidents of approved GM crops causing direct harm to the environment or human health have been confirmed by governments or competent authorities (Nicolia *et al.,* 2014). Nevertheless, GM crops are associated with more general concerns related to industrial agriculture and pesticide use, both of which are considered unwanted or undesirable to the environment by certain stakeholders (Mampuys & Brom, 2015). Whether these factors should be considered SECs remains under debate.

3.4. Impact Along the Supply Chain

Socio-economic impacts along the supply chain include all direct and indirect effects of the GM crop, from the technology provider and/or producer to intermediaries (food industry, companies and retailers) and on to consumers. Changes resulting from the introduction of GM crops can affect the structure or performance of the supply chain or the distribution of costs and benefits within the supply chain (i.e. *shift*). The supply chain can be affected either upstream or downstream of the crop farming sector by various factors.

- **Bidirectional effects.** These include (inter)national GMO regulations, enforced local or national coexistence rules, voluntary and mandatory GMO certification schemes, and the protection of intellectual property rights (e.g. patents, licences).
- **Upstream effects.** GM seed companies and manufacturers of complementary products (such as herbicides) may profit from GM crop-adopting farmers buying their products, while competitors selling non-GM seeds and other herbicides may lose market share. Similarly, GM insect-resistant crops: companies that sell insecticides might experience reduced sales because less pesticide is used compared with a non-GM crop. Further upstream, GM crop adoption can also affect innovation, for example by increasing or decreasing investment in R&D.
- **Downstream effects.** These include all socio-economic effects on intermediaries between the farm level and consumer. GM crops can affect market access and (national) trade interests, logistics, governance mechanisms (coexistence). The

market power of different actors (i.e. ability to influence the price of a commercial item), and the price elasticities of supply and demand for the crop can also be affected. The scale of these effects will depend upon whether the country is a large or small producer (i.e. a price-setter or price-taker), whether the country trades the crop internationally (i.e. has a closed or open economy), adoption rates, and the nature and magnitude of the supply shift caused by GM crop adoption. The cost of identity preservation and traceability for GM crops affects the entire supply chain (Kalaitzandonakes *et al.,* 2009). In addition, the feed industry might benefit from lower prices for raw materials if increased GM crop cultivation leads to higher yields combined with lower prices. Likewise, the organic industry might capitalise on the demand for non-GM feed. Although livestock producers may benefit from less expensive feed, those in the organic sector may have to pay a higher premium for GMO-free feed as it becomes scarcer as more GM crops are cultivated. The food industry depends on the acceptance of GM crops for food production and any related GMO labelling requirements.

The commercialisation of GM products under different enforced coexistence rules, labelling schemes and intellectual property rights can impact the supply chain structure (both vertically and horizontally) and performance (e.g. efficiency, effectiveness and innovation ability). This, in turn, can affect the distribution of costs and benefits amongst the different actors along the supply chain, as well as their market power (e.g. ability to influence the price of a commercialised item).

Worldwide, countries have different domestic regulations concerning the trade and labelling of GM products, which can affect international trade patterns in agricultural products and the competitiveness of partner countries and their corresponding sectors. The stringency of GMO regulations of large food importers such as Europe is reported to affect the strategies of developing countries (e.g. Argentina and selected African countries) concerning GMO production and regulations (Paarlberg, 2010; Adenle, 2011; Laursen, 2013).

The handling of GM materials and products along the supply chain can also have social or legal effects owing to political and trade differences regarding GMOs, such as disputes regarding market access and trade interests (World Trade Organization; for an example, see Punt & Wesseler, 2016), shifts in the market power of different actors, and the response from retail sector based on (perceived) consumer acceptance (Tung, 2014).

3.5. Food Security and Consumer Level Impacts

In countries with suboptimal agriculture and limited access to resources, GM crops can improve food security (Qaim & Kouser, 2013). Most of the world's hungry people live in developing countries, where one report estimated the prevalence of undernourishment as 14% (FAO, IFAD & WFP, 2013). The same report defined food security as:

a situation that exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences, for an active and healthy life.

It identified four dimensions of food security:

1. **Availability** of sufficient quantities of food of appropriate quality, supplied through domestic production or imports (including food aid);
2. **Access** by individuals to adequate resources for acquiring appropriate foods for a nutritious diet;
3. **Utilisation** of food through an adequate diet, clean water, sanitation and health care to reach a state of nutritional well-being, where all physiological needs are met; and,
4. **Stability** in the availability of, and access to, food regardless of sudden shocks (e.g. an economic or climatic crisis) or cyclical events (e.g. seasonal food scarcity).

Thus, food security is a multi-dimensional concept and all four dimensions must be fulfilled simultaneously (Ruane & Sonnino, 2011). Therefore, GM crops alone are unlikely to solve all food security problems. They can, however, contribute to a wider approach to food security (Dibden *et al.,* 2013). GM crops can improve food availability by utilising traits such as insect and/or herbicide resistance, as well as drought and/or salinity tolerance, to decrease yield losses from pest insects, weed infestations or adverse climate conditions. GM crops can also improve food access (e.g. by increasing income for farmers) and improve food utilisation (e.g. biofortified crops with increased nutritional value).

As indicated in Section 3.2., farmers can choose whether or not to cultivate GM crops or instead to adopt an organic farming system. This same range of choices extends to consumers, for whom a wide variety of food preferences can be influenced by national, cultural and individual characteristics (age, gender, highest attained educational level), and values (cultural, religious and ethical influences). Consumer choice for GM or non-GM products is determined by the availability, acceptance and pricing of GM versus non-GM products.

Several countries have mandatory or voluntary GM-related labelling schemes (GMO or GMO-free) with different tolerance levels (i.e. the permitted threshold under which GMOs can be present in the final product without impacting the product's "non-GMO" status[5]). Most organic certification scheme require their products to be GMO-free, as this is one of the main principles of organic agriculture (USDA, 2013). Socio-economic impacts at the consumer level relate to the costs of labelling or banning products and the willingness to pay to acquire or avoid specific products. The effect of price

[5]Tolerance levels for unintended adventitious or technically unavoidable low level presence of GMOs in food and feed are set because a zero tolerance level is almost impossible to achieve in an international trade setting. Most countries have a threshold value of 0.9% per ingredient for authorised GMOs.

premiums for non-GM products have been evaluated in different GM-related labelling schemes, including their effect on consumer welfare (Lusk *et al.,* 2005; Costa-Font *et al.,* 2010; Aerni *et al.,* 2011; Oh & Ezezika, 2014). As indicated by Garcia-Yi *et al.* (2014):

> *Potential buyers can indicate their willingness to pay (WTP) for these products, and changes in social welfare can be calculated based on the differences between the WTP and actual or expected prices (price premiums). If there is a moratorium or ban on GM products, option values can be calculated based on a (hypothetical) WTP to preserve or maintain this situation. Social welfare can be estimated by the difference between the WTP and the opportunity costs of forgoing economic growth associated with the commercialization of GM products.*

4. USING SECS WITHIN REGULATORY FRAMEWORKS

This section discusses the main aspects and challenges of using SECs within regulatory frameworks, beginning with methods to measure and compare SECs. SECs will then be discussed from a legal and regulatory perspective by identifying the challenges of implementing them and harmonising the different biosafety regulations.

4.1. Measuring Socio-economic Impacts

Numerous methods are available to calculate SECs (e.g. the list reported by Falck-Zepeda & Zambrano, 2011); however, there is no standard methodology for measuring socio-economic impacts. Every analysis is case-specific and each method has specific strengths and weaknesses.

SECs related to economic, social, environmental, cultural and health-related impacts can sometimes be expressed in monetary or other quantifiable terms (e.g. the number of employees, working hours, hourly pay rate, revenue in currency per tonne), but others, such as those related to innovative ability or competitiveness, are more challenging to quantify. SECs can be quantitative or qualitative, absolute or relative. Social effects can be expressed quantitatively (e.g. the number of unemployed people, the number of people living in poverty or on social security benefits), but social exclusion or justice, for example, are more difficult to quantify.

Although there are many potential SECs, those used within a regulatory assessment framework should preferably have at least one measurable indicator (either quantitative or qualitative) and a plausible causal mechanism by which GM crop cultivation might affect the indicator (i.e. a direct relation or link between the indicator and GM crop cultivation). A scientifically sound method of assessing the impact of GM crop cultivation on the indicator is also needed to ensure transparency, traceability and reproducibility (Kathage *et al.,* 2015). The following sub-sections discuss the most important aspects of measuring SECs.

4.1.1. *Ex post* or *ex ante*?

Socio-economic assessments can be done *ex post* or *ex ante*:

- ***Ex post* assessment.** This is done to evaluate a technology after it has been introduced, based on data from the actual case, within a specific country/region and over a specified time period. Information gathering is based on input and output data for production and information from surveys. One example is a study of Bt cotton in South Africa that highlighted the impact that institutions can have on the type and level of benefits that technology may bring to farmers (Gouse *et al.,* 2005; Gouse, 2009). The study found that the successful introduction and adoption of Bt cotton by smallholder cotton farmers on the Makhathini Flats in South Africa were halted due to institutional failure.
- ***Ex ante* assessment.** This is done by countries when there is a need to evaluate a technology before deciding whether it can be authorised for introduction. As no data is already available specific to the SECs of the technology in the country, data has to be identified from identical or comparable cases and/or assumptions based on baseline data and extrapolation. One example is a series of studies by Kikulwe and colleagues (cited by Falck-Zepeda & Gouse, 2017) on GM banana in Uganda, where low adoption levels due to negative perceptions about GM technology in general were identified as a potential risk and was addressed by increased communication efforts by the developer.
- In general, an *ex ante* assessment has more uncertainties and limitations compared with an *ex post* study; therefore, it is even more important that the assessment is clearly defined in terms of scope, methods and assumptions made.

4.1.2. Data availability and quality

It is important to first define the scope of a socio-economic analysis: What exactly is to be investigated? For instance, is it an investigation of the impact of a GM crop on farm gross income, or on local food security, or on farm workers' health? Once the research question has been defined, the type of data needed can be quickly identified: this can be primary data (input/output, crop-specific) or secondary data (welfare economics). It is important to remember that data sets may not always be available or accessible and might therefore need to be collected or generated by the researchers.

Next, it is important to evaluate the data quality (Falck-Zepeda & Gouse, 2017). This is influenced by factors such as specificity, significance, sample size, accuracy and reliability, experimental design and randomisation, and statistical analysis. Data on GM crop adoption and distribution should preferably be distinguished by the typology of farms and farming systems to overcome potential bias (Table 3).

Table 3. Potential sources of bias in the socio-economic assessment of GM crops (adapted from Falck-Zepeda & Gouse, 2017)

Source of bias	Description
Selection	Can occur when individuals, groups or data are selected for analysis such that proper randomisation is not achieved: the obtained sample is therefore not representative of the intended population. An example is when adopters and non-adopters have different characteristics (other than adopting/not adopting the technology) that affect the indicator and are not controlled for. Another example is when adopters within government programmes or programmes initiated by seed companies cannot be considered 'real adopters' because the decision to adopt was not made by them.
Measurement	Can occur when the act of sampling influences the measurement. This can result from factors such as a too small sample size or too few samples taken from a population.
Estimation	Can occur when the impact is over- or underestimated, for example in farmer surveys.
Simultaneity	Can occur when the explanatory variable is determined jointly with the dependent variable. An example is when input decisions may be related but their connectivity is not addressed (i.e. the use of specific herbicides with herbicide-tolerant crops).
Sampling	Can occur when samples are collected in such a way that some members of the intended population are less likely to be included than others, such as sampling of only higher profit-generating or larger farms.

In measuring farm-level effects (such as adoption rates), obtaining accurate and sufficient data on the adoption and distribution of GM seed by type/size of farmers (large or small scale, commercial or subsidence) may be challenging if accurate records of seed sales and users are unavailable. Similar issues concern the accuracy of farmer survey recall data and administration of on-farm activities, which may be impaired because of illiteracy, for example. Although it may not be possible to solve these issues or to adjust for them, it is important to acknowledge and make explicit potential uncertainties and limitations of the data set.

When investigating socio-economic impacts over a specified period, the data continuity is important. Single-year and single-location studies have limited value because climatic conditions and the production practices of individual farmers may unduly influence pest pressure or weed persistence and thus the assessment. Multi-year/multi-location studies are preferable to increase the representativeness and accuracy of the results. However, data continuity may also pose a challenge. Inevitably, climate conditions and pest pressure over the years may vary (within a certain range). Other, less predictable factors can also hamper data continuity, such as extreme erratic weather or damage from animals; farmers discontinuing GM crops because of external conditions such as off-farm employment; changes in government support or subsidies; and seed availability. Finally, gradual climate change may lead to the loss of a group of farmers (e.g. GM crop adopters) after a number of seasons. These factors are not directly associated with the effect of the crop itself but may influence data continuity and the results of the assessment.

4.1.3. Uncertainties and limitations

SEC measurements inevitably suffer from uncertainties and limitations. Uncertainties can relate to the objectivity and accuracy of data, for example, how independent are the data, who collected or provided them, and how objective and accurate are data from farmer surveys or interviews (e.g. when asking about the [perceived] drawbacks or benefits of adopting GM crops or the motivations for certain decisions in farm management)? Uncertainties relate not only to the data but also to the method chosen for quantification.

It is theoretically possible to quantify almost every SEC by scoring the responses related to experiences with GM crops. However, quantification should never be a target in itself because quantitative analysis is often partial and does not present a complete picture. In addition, quantitative assessment is only as good as the input data. Therefore, the risk of quantifying qualitative data is that it gives the illusion of hard data.

For these reasons, uncertainty and sensitivity analyses are extremely important, along with an explicit analysis of the limitations, when assessing SECs. The use of averages in multi-year, multi-location studies can easily mask effects on individual stakeholders, whereas specific effects might be overestimated or underestimated in smaller studies. Hence, the limitations of all studies should be made explicit when drawing conclusions.

Once the effects have been identified and measured, their position within the overall context of the study must be determined. To arrive at a conclusion, the measured effects need to be compared with the baseline (see Box 4). In an analysis of GM crops, the **impact** is usually calculated as the value indicator under the impact scenario (i.e. with GM cultivation) minus the value indicator under the baseline scenario (i.e. without GM cultivation) (Kathage *et al.,* 2015).

Box 4. Baseline

A baseline (or reference) is the minimum or starting point used for comparative analyses, usually comprising an initial set of critical observations or data used for comparison or as a control. It is therefore critical for assessing the impact of an intervention. A comparable alternative (counterfactual) rather than a baseline (actual) approach can also be used for comparisons.

In conclusion, measuring and comparing SECs can be difficult because of a lack of (accessible) data and the effort needed to transform data into a form that is useful for analysis. There may also be data asymmetries: data on benefits (health/environmental impacts) are often scarcer (and more uncertain) than data on costs. Finally, the use of both qualitative and quantitative information may cause problems in comparing impacts.

4.2. Implementing SECs in Regulatory Frameworks

An effective regulatory system should: (1) have adequate legal authority and clear safety standards for decision-making procedures; and (2) operate in a cost- and time-efficient manner (Jaffe, 2004). As discussed in Section 2, Article 26 of the CPB (see Box 1) allows for the inclusion of SECs in biosafety approval processes. Moreover, the openness of the CPB to different interpretations provides possibilities and flexibility, as well as challenges, in implementing SECs at the national and international levels. These relate to the meaning of SECs and how they can be used in an overall assessment framework for GM crop applications.

The importance of clearly defining the questions "when", "how" and "under what decision-making rules" that developers or decision-makers will consider in assessing the socio-economic issues for products undergoing regulatory review is widely recognised, not only for companies and other stakeholders but also from an international perspective (Jaffe, 2005; COGEM, 2009, Falck-Zepeda, 2009; Binimelis & Myhr, 2016; Racovita, 2017). Two types of challenges using SECs in regulatory decision-making can be identified: procedural and technical challenges (see Tables 4 and 5).

From a procedural perspective, the CPB does not indicate the rationale for including SECs in Parties reaching a decision on specific GMOs. Therefore, depending upon interpretation by individual Parties, this can lead to the question of whether SECs can constitute a legitimate reason to object or ban GM crops that are deemed safe[6].

Several technical challenges relate to the inclusion of SECs in biosafety decision-making. This review describes several categories of SECs that can be split into numerous sub-categories and indicators. A clear definition of scope, method and data requirements is needed to effectively include SECs in regulatory decision-making (Table 5).

For the purposes of regulatory decision-making, the assessment of SECs requires a mechanism for identifying positive and negative socio-economic impacts. This, in turn, requires a workable framework to ensure that socio-economic impact assessments add valuable insights and arguments to decision-making and do not constitute an obstacle to the safe development and transfer of biotechnology products to end users. Therefore, it is important that socio-economic assessments are conducted within a regulatory framework that is accessible, transparent, reproducible, flexible, predictable and science-based.

[6]Biosafety regulations predominantly require an assessment of risk, or safety, to underpin decision-making. The inclusion of SECs into this procedure is highly debated because it not only brings up the question of whether SECs might be used to ban GM crops, but also how this relates to comparable conventional crops that are not subject to such a safety assessment nor a socio-economic analysis.

Table 4. Procedural choices for the inclusion of SECs in biosafety decision-making (adapted from Falck-Zepeda & Zambrano, 2011; Falck-Zepeda *et al.*, 2016)

Attribute	Procedural choices
Goal	• Provide insight **OR** • Support decision-making
Status	• Voluntary **OR** • Mandatory **OR** • Absent
Applications	• All applications **OR** • (Confined) field trials ONLY **OR** • Market applications ONLY
When	• Concurrent but separate to the ERA* **OR** • Sequential (after the ERA) **OR** • Embedded within the ERA
How	• Case-by-case **OR** • Per crop trait (herbicide-tolerant, insect/virus-resistant or biofortified crops)
Who	• Policy makers **OR** • Experts **OR** • Applicants

*ERA: environmental risk assessment.

Table 5. Technical challenges with the inclusion of SECs in biosafety decision-making (adapted from Falck-Zepeda & Zambrano, 2011; Falck-Zepeda *et al.*, 2016)

Attribute	Technical challenges
Scope	• What questions are relevant for SECs in GM crop applications?
Method	• Which methodology is best suited for the purpose of the analysis?
Data	• Availability • Accessibility • Quality • Objectivity

4.3. Harmonisation of Regulatory Frameworks

There is no universal agreement or consensus on which factors constitute SECs or how they should be used in regulatory decision-making. As Article 26 of the CPB is open to interpretation, its implementation has resulted in the use of various terminologies and in different combinations of associated non-safety concerns. An overview of the status of national implementations of Article 26 of the CPB can be found in the working documents of the Ad Hoc Technical Expert Group on Socio-Economic Considerations of the Convention on Biological Diversity[7].

4.3.1. International differences

Article 26 of the CPB limits the scope of SECs to those impacts on biodiversity that are valued by indigenous and local communities, while national legislation in several countries has an expanded scope that includes a broader set of socio-economic issues. Some national laws simply include only the term **socio-economic** with an indication of its type or role, while others link the term to other aspects, such as culture, ethics and religion or even to aesthetic norms (Falck-Zepeda, 2009).

Measuring, objectifying or weighing several of these aspects in the overall decision-making process for GM crops will obviously be difficult. This may, in turn, lead to uncertainty for applicants and stakeholders (such as farmers) about whether new GM crops will be approved for market release. Eventually, this may justify avoiding certain markets and investment climates, potentially leading to opportunity costs.

International differences in procedural aspects of the implementation are also observed. For example, some countries have proposed that SECs should be included in all stages of the decision-making process and for all applications, whereas other countries have proposed their inclusion only in specific stages or for only some types of applications (Falck-Zepeda & Zambrano, 2011). With respect to how SECs, risk assessment and decision-making should interrelate or interact with one another, some jurisdictions require SECs to be incorporated into the risk assessment process, whereas others instead have a process that separates SECs from risk assessment but within decision-making. Other differences relate to which actors should assess SECs within the regulatory system, potentially leading to overlapping mandates between Ministries or expert committees.

4.3.2. Ongoing efforts to harmonise SEC implementation

Several Parties to the CPB have already begun to experience difficulties in defining and identifying SECs for their national context, as well as in integrating SECs into decisions in a manner consistent with international obligations such as World Trade Organization law. Faced with these implementation challenges, they have identified a need for further guidance when choosing to include SECs in their legislation.

International differences can also impair ongoing R&D and the introduction of new GM crops to the market. Otherwise, a well-structured, harmonised regulatory system confers benefits such as: cost efficiency; effectively shared technical capacity; harmonised compliance procedures; the creation of more competitive markets; facilitation of cross-border trade; and standardised, transparent processes to promote predictability in international trade. These benefits are of socio-economic importance

[7] www.cbd.int/doc/meetings/bs/bs-ahteg-sec-01/official/bs-ahteg-sec-01-02-en.pdf

to countries and regional economic communities. Owing to regional and national agroecological differences and concomitant regional and national regulations, international harmonisation of the inclusion of SECs in regulatory decision-making of GM crops requires insight, understanding and a willingness to cooperate from all involved Parties. Regulatory harmonisation requires a platform for consultation and a clear understanding of the benefits of an efficiently functioning system. Such a platform calls for peer-level (country-to-country) dialogues for confidence building and for partnerships that promote resource-sharing and exchange of experiences, data and best practices.

To develop a global overview, several activities and mechanisms were undertaken to compile, take stock of and review information on SECs. A scoping exercise on SECs was carried out by United Nations Environment (UNEP) – Global Environment Facility (GEF) and included a survey conducted in late 2009 in three UN languages: English, French and Spanish (Secretariat of the CBD, 2010). The survey highlighted a need for further work. Therefore, an Ad Hoc Technical Expert Group on SECs (overseen by the Secretariat of the Convention on Biological Diversity) was created which has since examined the outcomes of online discussion groups and a regional online conference in an attempt to provide conceptual clarity on SECs. These efforts, amongst others, have resulted in a descriptive approach to SECs (AHTEG-SEC, 2014). Continuing dialogue is aimed at agreement on identifying those SECs that can be included in regulatory decision-making in a standardised and structured way.

5. CONCLUSIONS & DISCUSSION

Worldwide, there is a growing adoption of GM crops; as a consequence, several socio-economic benefits for society and farmers have been reported, including farm profitability, decreased crop losses, increased income stability, ease of operation, savings on labour and pesticide use, time savings, and less exposure to toxic chemicals. Many SECs are not specific to GM crops and are applicable to other agricultural developments and changes. These include: access and affordability of planting materials and accompanying technologies; suitability of high-tech crop systems to smallholder farm operations and resource-poor farmers; intellectual property rights; the influence of large seed companies; balancing food distribution infrastructure versus production output; commercialisation of relevant products versus profit considerations; and a possible negative impact on trade with traditional trading partners.

Inherently, new market introduction has concomitant microeconomic and competitive benefits and drawbacks. Distribution of the benefits and costs amongst growers, consumers, food manufacturers, retailers and technology developers can make an assessment rather complex. Socio-economic impacts can be advantageous or disadvantageous, and sometimes both, so it is important to note that in most cases, both effects will occur and are not necessarily specific to GM crops. Socio-economic analyses focus on the resources used or gained by a specific GMO introduction compared with alternatives to determine the better option. However, it should be noted that not introducing (or even delaying) a technology or application can also have a socio-economic cost (Zimmerman & Qaim, 2005; Stein *et al.,* 2006; Wesseler, 2017). SECs are dependent on the type of GM crop, geographical location and type of user. Therefore, data and conclusions for a socio-economic assessment of a certain type of crop in one country cannot simply apply to the same crop in another country.

Worldwide, modern biotechnology and its regulation are subject to public and political debate. In addition to environmental risk assessments, socio-economic assessments can contribute to balanced decision-making regarding the market approval of GMOs and future investments in R&D and technology deployment. This calls for systematic and clearly outlined procedures and data/information gathering to guide policy formulation and decision-making on biotechnology applications.

To include all possible SECs in biosafety decision-making would take a tremendous effort and significant funding, which does not seem either feasible or practical within GMO regulatory decision-making. However, the importance of SECs in agricultural development is internationally acknowledged and becomes increasingly important when assessing not only the risks but also the potential benefits of GM crops.

Until countries have agreed on why and how SECs should be included in their decision-making processes for biotechnology applications, Binimelis & Myhr (2016) suggest taking a learning process approach as a starting point to establish a more solid knowledge basis. In a co-creative process, a pool of data can be established that provides better insight into the socio-economic impact of GM crops. Over time, this could result in a more structured approach for including specific SECs into regulatory decision-making.

Disclaimer: *The views expressed in this publication are those of the author and do not necessarily represent the official position of the Netherlands Commission on Genetic Modification (COGEM).*

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