

Article

Inclusion and Implementation of Socio-Economic Considerations in GMO Regulations: Needs and Recommendations

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Abstract: Socio-economic considerations are included in the regulatory frameworks on genetically modified organisms (GMOs) of many countries. This is a reflection of an increasing interest in and recognition of the necessity to consider a broader range of issues when conducting a GMO risk assessment. At the same time, there are discussions about how socio-economic considerations can be identified and how their assessment can be carried out. To provide an understanding of the advances achieved so far, we describe the state of the art of existing biosafety institutional frameworks, legislation and policies with provisions on socio-economic considerations. We analyse the scope of the socio-economic considerations that have been included, the methodological options taken and the role of participatory processes and stakeholders involvement in the GMO-related decision-making. Since many of the countries that have legislation for assessing socio-economic considerations lack implementation experience, we provide an analysis of how implementation has evolved in Norway with the intention to illustrate that the inclusion of socio-economic considerations might be based on a learning process. Norway was the first country to include broader issues in its GMO assessment process, and is at present one of the countries with the most experience on implementation of these issues. Finally, we emphasise that there is a great need for training on how to perform assessments of socio-economic considerations, as well as reflection on possible ways for inclusion of participatory processes.

Keywords: socio-economics; GMOs; sustainability; regulation; impact assessment

1. Introduction

There is an increasing international consensus that decision-makers need to consider a broader range of issues, beyond the environmental and health-related aspects, when assessing the use of agricultural biotechnologies [1–4]. A broader assessment represents a way to emphasise social responsibility towards present and future generations [4], and to acknowledge environmental and socio-economic aspects while taking into account the possible costs of both regulatory action and inaction [5]. In the regulatory or academic documents there is at present no general definition of what the “socio-economic considerations” that should be assessed are. According to the Interorganizational committee on principles and guidelines for social impact assessment in the US [6], social aspects consider “the consequences to human populations of any public or private actions that alter the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society. The term also includes cultural impacts involving changes to the norms, values, and beliefs that guide and

rationalize their cognition of themselves and their society". As regards to the dimensions or aspects included as "socio-economic considerations", the AdHoc Technical Group on Socio-Economic Considerations (AHTEG-Sec) of the Convention of Biological Diversity, recognised that there is no single agreed definition but considered that the scope of the term includes five dimensions: (a) economic; (b) social; (c) ecological; (d) cultural/traditional/religious/ethical; and (e) human-health related [7].

This inclusion of a broader range of issues is being called for in international frameworks (e.g., article 26 of the Cartagena Protocol on Biosafety), European (e.g., [8–10]) and African fora (e.g., African Biosafety Model Law), as well as in an increasing number of national regulations on GMOs. For instance, the Norwegian Gene Technology Act (1993) is the pioneering example. It emphasizes the need to consider the social utility and contribution to sustainability of GMOs, as well as their direct and indirect impacts on agricultural practice and the socio-technological context. At the European level, the aim to take socio-economic considerations into account when making decisions on GMOs has initiated several activities. These activities includes for instance, the organisation of workshops on socio-economic considerations (e.g., the International workshop on socio-economic impacts of GMOs organised by JRC and FAO in November 2011; the European Environmental Agency workshop "Framing socio-economic assessment in GMO & chemicals regulation" in December 2012), the creation in 2013 of a working-group including Member States' experts to address methodological frameworks for the assessment of socio-economic considerations of GMOs, as well as by the establishment of the European Socio-Economic Bureau at the Joint Research Center, the publication of national reports (see, e.g., [11–13]), and the organisation of workshops on socio-economic considerations (e.g., the International workshop on socio-economic impacts of GMOs organised by JRC and FAO in November 2011; the European Environmental Agency workshop "Framing socio-economic assessment in GMO & chemicals regulation" in December 2012). Finally, in March 2015 a new directive on GMOs was approved (Directive (EU) 2015/412), allowing a Member State (or region) to adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, based on compelling grounds such as those related to socio-economic impacts, avoidance of GMOs presence in other products, agricultural policy objectives or public policy (article 1.3).

At the international level, the sixth meeting of the Conference of the Parties serving as the meeting of the Parties (COP-MOP) to the Cartagena Protocol on Biosafety also recognized the need, expressed by several Parties, for further guidance when choosing to take into account socio-economic considerations (decision BS-VI/13 (<http://bch.cbd.int/protocol/decisions/?decisionID=13246>)), and recalled operational objective 1.7 of the Strategic Plan of the Cartagena Protocol on Biosafety for the period 2011–2020. The objective 1.7 aims: *"To, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of living modified organisms"*. For this purpose, the Secretariat of the Convention on Biological Diversity (CBD) launched several on-line discussions and appointed an Ad Hoc Technical Expert Group (AHTEG-Sec). This work will be continued following agreement reached at COP-MOP 7 to reconvene the group of experts to further develop clarity on the issue and to develop an outline for guidance on the implementation of socio-economic considerations in biosafety decision-making [14].

An increasing number of countries are aiming to include an assessment of a broader range of issues. However, the need for robust methodologies or frameworks (including criteria, indicators and comparators) able to capture ex-ante and ex-post socio-economic considerations related to GMO cultivation, for gaining grounded empirical knowledge, and for appropriate systems for data collection has been recognised [5,8,15–17]). These gaps have driven, and are at the same time a result of, a rather contentious debate among biosafety policy-makers and scholars on the desirability of including such considerations. There are also disagreements on what socio-economic considerations should be taken into account, both in the regulatory and the research fields (see [18–21] for a review of the debates on article 26 of the Cartagena Protocol). Contentions have emerged around the scope, methods and disciplines involved, timing of consideration, baselines and comparators, criteria and indicators, "endpoints" or targets, the role of public participation and the precautionary principle, and

the relationship with other fields of knowledge and with other dimensions of risk assessment (mainly environmental and health-related issues) [12,16,22]. Some of the implications by the selection of specific approaches in national regulatory frameworks have been reviewed in Spök [12] and Falck-Zepeda [22]. In these two reviews, the number of countries reported was restricted to 12 and 18 countries or regions respectively, and only a small selection of topics were analysed in detail. An overview commissioned by the CBD Secretariat [23], which, using a descriptive approach, compiled information from a greater number of countries (33). The present paper analyses the inclusion of socio-economic considerations in 34 countries. Compared to Spök [12] and Falck-Zepeda [22], our literature study include information on the implementation experience, a description of the protection goals and considerations taken into account, a description of the methodological approaches in each country and the role of public participation in the GMO regulation related to SEC.

The objective of this paper is to describe and analyse the state of the art of existing biosafety institutional frameworks, legislation and policies with provisions on socio-economic considerations. The aim is to recognise the advances achieved so far internationally and to reflect on the main challenges and lessons learnt based on a deeper analysis of a selected case (Norway).

2. Methodology and Information Sources

The present study reviews information regarding the inclusion of socio-economic considerations for commercial approvals in biosafety decision-making in 34 countries. Countries that have not included socio-economic considerations are not included in the study. This concerns also countries that have ratified the Cartagena Protocol but that at present do not have any national biosafety legal framework that includes socio-economic considerations. The primary sources of information were the laws, regulations and national policy frameworks, as well as other national official reports, if any. Most of the information was retrieved using the Biosafety Clearing House established by the Cartagena Protocol of Biosafety or the National Clearing Houses established by the national Focal Points of the Protocol, or directly through the official websites for non-signatory countries of the Protocol (e.g., Argentina).

Additionally, the CBD Secretariat has compiled a series of summaries and reports [23], as well as national surveys in order to assess how socio-economic considerations are taken into account [24]. These documents have also been reviewed to gather information relative to the state of the art of the implementation experience of socio-economic considerations in decision-making, as well as on capacity-building needs. Additionally, a literature review on the implementation of socio-economic considerations in biosafety decision-making has been conducted. This literature review of policy reports and academic papers allowed the identification of key contentious issues [14,16,19,22], most of them also identified by Parties of the CBD as aspects that could contribute to the development of conceptual clarity on socio-economic considerations [7]: (a) how socio-economic considerations are defined (including the definition of socio-economic considerations in the analysed regulatory frameworks, the scope (protection goals, criteria for inclusion and potential impacts taken into account)); (b) the methodological options (relation between the health and environmental risks and the socio-economic impact assessment, definition of baselines, factors affecting the methodological approaches, role of socio-economic expertise in the decision-making, data availability and the inclusion of participatory approaches) and (c) the role of participatory processes and stakeholders involvement in the GMO-related decision-making. The results section of the paper is structured following these categories. With the aim to analyse the practical implementation of socio-economic impact assessments we then describe the case of Norway. It was the first country to integrate a broader range of issues in its biosafety regulatory framework.

The regulatory documents were analysed in their original language when it was English, French, Italian or Spanish, and English translations were used for all other languages. Detailed information on the documents analysed can be found in Table A1. The first legislation integrating socio-economic

considerations is the Norwegian Gene Technology Act from 1993 while the last reviewed regulations are from 2013. The retrieval of the regulations was performed in September 2014.

All the regulatory documents are analysed and classified per type and topics included, and the classifications we have used are explained below in more detail.

Type of regulatory framework. This classification differentiates between laws, regulations and guidelines. The classification of the different sources can be found in Table A1. We also recorded the existence of specific biosafety legislation *versus* a generic one covering also GMO-related issues.

Implementation experience. For signatory countries of the Cartagena Protocol, we analysed the experience in adopting socio-economic considerations in decision-making on GMOs using the Second National Reports on the implementation of the Cartagena Protocol. These reports are based on the declarations made by the national authorities (see http://bch.cbd.int/protocol/cpb_natreports.shtml). The national surveys conducted by the CBD Secretariat in 2014 were also used as information sources [24]. For the case of Argentina (non-signatory), information we retrieved was from the Ministry of Agriculture webpage.

Definition approach. The description of socio-economic considerations were coded and classified in prescriptive *versus* descriptive approaches. The prescriptive approach defines socio-economic considerations while the descriptive approach identify first a series of protection goals and then list, in a non-exhaustive manner, potential impacts. Moreover, we recorded if the socioeconomic dimension included the environment.

Protection goals and socio-economic considerations. We extracted and classified the information on protection goals and socio-economic considerations using a mix of top-down and bottom-up approaches. We coded and labeled the protection goals and socio-economic consideration expressed in the laws, regulations and guidelines. Then, the list of protection goals and socio-economic considerations was simplified by merging of closely related labels, and classified by using the five dimensions identified by the AHTEG-Sec [7].

Methodological approaches. We coded the methodological approaches that are described in the information sources using the same terminology as in the AHTEG-Sec document [7] and by Falck-Zepeda and Zambrano [21]. We left the list open, so that other methodologies could also be registered.

Indicators. Indicators are a measure of the progress/harm of specific actions in a time frame. In some cases (e.g., Norway) the framework establishes guiding questions instead of indicators. We registered and classified the indicators using the five dimensions defined in the AHTEG-Sec report [7].

Baseline. As in environmental risk assessment, baselines also need to be defined for socio-economic assessment in order to establish which impacts are considered acceptable, desirable or avoidable are discussed [13]. We established three options for the use as comparator: conventional agriculture, organic agriculture and others.

Conditions for approval. In some cases, normative frameworks establish socio-economic considerations as a condition for approval. In these cases, we chose to take a bottom-up approach, coding the different issues expressed in the analysed frameworks trying to maintain the original wording and, when possible, merging similar concepts.

Inclusion of risks and benefits. This aspect analyses if the assessment considers only risk (and cost) aspects (as it is done in the environmental and health risk assessment) or if it includes also benefits.

Direct and indirect impacts. Direct impacts include impacts that arise as a result of the modifications to the crop itself while indirect effects are those arising from the effects of the GM crops management (e.g., co-technologies such as herbicides used with herbicide-resistant crops).

Relation between the socio-economic impact assessment and the environmental and health risk assessment. The CBD document prepared for the AHTEG-Sec points out that countries can follow different options when choosing to perform socio-economic assessment for biosafety decision-making [23]. We classified the documents according to the options described in the CBD document: “Three general routes were observed: (i) address socio-economic considerations in the risk assessment; (ii) have an independent

socio-economic considerations assessment; and (iii) evaluate socio-economic considerations through public participation in the decision-making process” [23].

Level of analysis. This aspect analyses whether the regulatory system will require a specific assessment for each submission or if it considers other possibilities such as that the assessment needs to be based on the trait or trait-crop level.

Socio-economic expertise in decision and advisory bodies. This aspect analyses which bodies that are in charge of conducting the socio-economic assessment and decision-making, and if these bodies (both for national authorities and advisory committees) have experts with “social sciences” background. We did not include experts in related areas of expertise such as “agriculture” or “biodiversity”, neither representatives of Ministries nor other official institutions selected by their affiliation.

Inclusion of the precautionary principle. We classified the countries depending on if they had included the precautionary principle as a basis for taking decisions in their biosafety frameworks.

Participatory approaches. We took into account three aspects when analysing the role of public participation in the GMO assessments: public awareness and educational aspects, the access to information (if final assessments are published or made available to the public upon request), and if public participation are integrated in the decision-making process.

We carried out the coding and analysis of the data using the computer assisted mixed method (quantitative and qualitative) data analysis software Dedoose. The coding process was done by one of the authors. In case of doubts, the coding and classification was discussed with the second author. The two authors have performed the analysis of the data.

3. Results and Discussion: Inclusion of Socio-Economic Considerations in National Biosafety Decision-Making

3.1. Basis for Inclusion of Socio-Economic Considerations

In total, there are at present 34 countries that have included socio-economic considerations in their national biosafety legal frameworks. The geographical distribution of the countries can be found in Figure 1.



Figure 1. Geographical distribution of analysed biosafety frameworks and regulations.

Of the total, 14 were African countries (Burkina Faso, Cameroon, Ethiopia, Ghana, Kenya, Mali, Madagascar, Mauritius, Namibia, Senegal, South Africa, Togo, Zambia, Zimbabwe), followed by 9 Latin American countries (Argentina, Brazil, Colombia, Costa Rica, Cuba, Mexico, Panama, Uruguay,

Venezuela). For Asia-Pacific, 6 Asian countries were included (Cambodia, Indonesia, Malaysia, Pakistan, Philippines, Tajikistan) plus New Zealand. Finally, the laws of 4 European countries were analysed (France, Italy, Latvia and Norway). Besides these countries, Spök [12] identifies also the following countries as incorporating socio-economic considerations: Bangladesh, Bhutan, China, Honduras, India, Lebanon and Syrian Arabic Republic. We did not find specific legislation referring to socio-economic considerations in these countries except in the case of the Syrian Arabic Republic, which was not included since the regulatory framework was only found in Arabic. The cases of Belize, Nigeria and Uganda were also initially analysed, as they all include socio-economic considerations in their biosafety policies. However, as they do not have approved biosafety legislation yet but only policy frameworks, they were not included in the final results.

The great majority of the 34 analysed countries have created new legislation for addressing biosafety, with the exception of Madagascar, Costa Rica and Venezuela. In the case of Madagascar the legislation is a generic one concerning environmental impact assessment for all kind of activities (and GMOs are included as requiring this type of assessment). Similarly, in the case of Costa Rica, the phytosanitary protection regulation includes provisions on GMOs. In Venezuela, GMOs are regulated under the Environmental Assessment Law and the Law on Genetic Diversity.

According to what the countries themselves have declared, 18 of the analysed countries do not have experience in the implementation of socio-economic considerations, while 15 of them have at least some experience in their implementation (See Figure 2). Information on implementation experience could not be found for Uruguay.

	Africa														Asia-Pacific						Europe				Latin-America									
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Yes																																		
No																																		
N/A																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black. Costa Rica has been classified as a GM crop-producing country despite the limited GM cultivated area. Countries in the EU that have taken measures to block cultivation in their territory have been classified as countries with no GMO approval.

Figure 2. Implementation experience of socio-economic considerations (SEC) in genetically modified organisms (GMO) decision-making.

3.2. Definition of Socio-Economic Considerations in the Legislation of Analysed Countries

3.2.1. Implementation Is Based on Either a Prescriptive or a Descriptive Approach

There are significant differences between countries with regard to how they have defined socio-economic considerations. For example, Mali and Ethiopia have prescriptive approaches, defining socio-economic considerations as “any direct or indirect adverse effect that results from a transaction on the social or cultural conditions, the livelihood or indigenous knowledge systems or technologies of a local community, including on the economy of the country”. A very similar definition is used by Zambia and Togo, by describing socio-economic impacts as “any direct or indirect effect to the economy, social or cultural practices, livelihoods, indigenous knowledge systems or indigenous technologies as a result of the import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism”. Both definitions are very similar to the definition proposed in the African Model Law on Biosafety. The African Model Law on Biosafety was proposed by the African negotiators of the Cartagena Protocol on Biosafety aiming to develop a model to provide guidance for

the development of domestic biosafety laws. The objective of the African Model Law on Biosafety is “to contribute to ensuring an adequate level of safety for the protection of biological diversity, human and animal health, socio-economic conditions and ethical values in the making, safe transfer, handling and use of genetically modified organisms and products of genetically modified organisms resulting from modern biotechnology”. However, most of the other countries use a descriptive approach, identifying first a series of protection goals and then listing potential impacts and the main dimensions to assess (see Tables 1 and 2). This type of approach has been also used in policy reports such as the one published by the COGEM (Netherlands Commission on Genetic Modification), which states: *“It includes concepts like the benefit to society, the contribution to economy and well-being, health (human rights and labor conditions), food supply (food security and fair trade), cultural heritage, freedom of choose, security (environmental and food), biodiversity and environmental quality”* [11]. The level of detail also varies widely among the different regulatory frameworks; some countries’ legislation only mention the need to assess socio-economic aspects (without specifying which type of impacts the legislation is referring to) (see, e.g., Brazil, Cuba, Kenya, Mexico and Uruguay), while others have a comprehensive check-list with the different aspects that may/should be taken into account (see, e.g., Norway).

3.2.2. Scope of the Socio-Economic Considerations Included in the Analysed Legislation: Protection Goals and Considerations Taken into Account

Most of the regulations that were analysed define first protection goals (21 of the total 34 countries), which would form the basis for the socio-economic dimensions that should be taken into account when conducting the assessments. As when conducting an environmental or health assessment, the first step for a socio-economic assessment is to establish the context for the assessment by identifying components of the socio-economy that are valued by civil society and/or protected by relevant laws or policies. This exercise establishes the so-called policy protection goals: components that should be protected and taken into account to support regulatory decision-making. These protection goals (or assessment endpoints) can vary between jurisdictions, but their overall aim is to minimise harm. A thorough problem definition is thereby an essential prerequisite for the operational definition of these protection goals [25].

These protection goals are then reflected in how the countries define socio-economic considerations in their biosafety decision-making. In regards to what dimensions are to be included as socio-economic considerations, Figure 3 shows that most countries do not restrict the definition of socio-economic considerations exclusively to social and/or economic aspects, but includes also cultural/ethical aspects, ecologically-related and health aspects not covered by the environmental and health risk analysis. For instance, in the case of the ecological-related dimension, 16 countries define protection goals (see Figure 3).

Both countries with GM approvals for commercial purposes and those countries without approvals have included a variety of protection goals in their regulatory frameworks. Figure 3 illustrates that the number of social, cultural, health- and ecological-related dimension is equally distributed, while the focus on the economic dimensions is stronger for the countries that have approved GM crops.

In Figure 4 the socio-economic considerations that have been taken into account in biosafety decision-making are presented. Figure 4 also differentiates between countries that have approved GM crops (in gray) and countries without GMOs approvals (in black), showing that both types of countries consider socio-economic effects in all five dimensions. Argentina is the only country that has limited the aspects to focus only on the assessment of the economic dimension (see Figure 3).

	Africa										Asia-Pacific					Europe			Latin-America																		
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela			
Social dimension																																					
Aesthetic aspects																																					
Changes in land use																																					
Changes in the usefulness of species																																					
Changes in communities' use rights on sustainable use of biodiversity																																					
Distribution of benefits with future generations																																					
Equity issues																																					
Food sovereignty																																					
Fulfillment of basic needs																																					
Gender impacts																																					
Impacts on non-GM crops/coexistence																																					
Intellectual property rights and patents																																					
Livelihood of communities																																					
National policies on research and technology																																					
Social conflicts																																					
Sustainable development policies																																					
Working conditions (linked to companies)																																					
Social aspects (in general)																																					
Economic dimension																																					
Access and costs for GM technology																																					
Agronomic advantages and risks or disadvantages																																					
Changes in agricultural production systems																																					
Changes in agricultural productivity																																					
Changes in export trends																																					
Changes in the economic value of traditional species																																					
Changes in the industrialisation trends																																					
Changes in traditional markets																																					
Crop loss																																					
Economic conditions of the country/ communities																																					
Economic conditions for small-income farmers																																					
Employment loss/gain																																					
Impact on "quality-labeled" products																																					
Impacts on small business development																																					
Impacts on sustainable/organic agriculture																																					
Patrimony losses																																					
Poverty alleviation/ wealth creation																																					
Trade and market opportunities																																					
Economic aspects (in general)																																					
Cultural/ethical/religious dimension																																					
Cultural aspects and practices																																					
Erosion of indigenous technologies and knowledge																																					
Ethical and moral considerations																																					
Impacts on traditional crops and products																																					
Religious considerations																																					
Ecological-related dimension																																					
Genetic diversity loss																																					
Agrodiversity loss																																					
Farmers' varieties loss																																					
Traditional varieties loss																																					
Loss of ecosystem services																																					
Development of weed resistance in farming systems																																					
Changes in energy use patterns																																					
Changes in herbicide use																																					
Greenhouse gases emissions																																					
Soil contamination / erosion																																					
Health dimension																																					
Food production and security, nutrition																																					
Public health impacts																																					
Health-related impacts (in general)																																					

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 4. SEC taken into account in biosafety decision-making.

3.3. Methodological Approaches and Use of Criteria and Indicators for Assessing Socio-Economic Considerations

Many of the regulatory frameworks that were analysed do not describe methodological approaches to use for the assessment of socio-economic considerations. In some cases, there is only an indication of the methods to use: for instance in Argentina, Burkina Faso, Cameroon and Senegal it is explicitly noted that the assessment of socio-economic considerations should be based on cost-benefit principles.

Most of the frameworks do not identify indicators or guiding questions beyond the parameters described in Figure 4, and there is no suggestion for how to integrate divergent results. Moreover, only a very restricted number of countries indicate the baselines or the comparators that should be used for conducting assessments, although the choice of appropriate baselines is crucial for the results of an assessment. However, some of the countries establish socio-economic considerations as a condition for approval, mainly linked to the contribution of the GM crop for benefits that are in the public interest as well its contribution to sustainable development in the country (see Figure 5).

	Africa										Asia-Pacific					Europe		Latin-America																
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Conditions for approval																																		
Benefits the public interest																																		
Contributes to public welfare																																		
Contributes to sustainable development																																		
Does not damage public health or biodiversity																																		
Does not damage socio-economy of the country																																		
Does not impact non-GM crops																																		
Does not impact organic /sustainable agriculture																																		
It is not a crop or livestock important to national food security																																		
Protects cultural values																																		
Respects local ecosystems																																		
Respects (existing) agricultural systems																																		
Respects communities' knowledge and technologies																																		
Respects ethical rules																																		
Responds to the communities' concerns																																		
Responds to the ethical and religious values																																		
There is evidence of insurance cover																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 5. Conditions for GM cultivation approval related to SEC.

3.3.1. Differences with Regard to Inclusion of Risks and Benefits as Well as Direct and Indirect Effects

Less than 40% of the analysed countries focus only on risks, while the majority of countries explicitly state that they take into account both risks or costs and benefits within socio-economic considerations in decision-making. Normally benefits are assessed in relation to risks and/or costs, or the assessment requires some indication of that the GMO contributes with a solution to a social need or utility (see Figure 6).

	Africa										Asia-Pacific					Europe			Latin-America															
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Risks																																		
Benefits																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 6. Inclusion of risks and benefits in the analysed biosafety regulatory frameworks.

Of the 34 analysed countries, 15 explicitly state in their legislative framework that socio-economic impact assessment should include indirect aspects, while the rest of the countries do not specify the type of socio-economic risks or considerations they are taking into account (see Figure 7).

	Africa												Asia-Pacific					Europe			Latin-America													
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Direct and indirect																																		
Not specified																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 7. Inclusion of indirect impacts in the analysed biosafety regulatory frameworks.

3.3.2. Relation between the Socio-Economic Impact Assessment and the Environmental and Health Risk Assessment

None of the countries we have analysed evaluate socio economic considerations only based on what the CBD documents identify as option (iii): evaluate socio-economic considerations through public participation. Only the first two options were found: (a) Socio-economic considerations were assessed in the general risk assessment procedure (option (i); or (b) Socio-economic considerations were evaluated through an independent assessment (option (ii) (sometimes consecutive to the environmental and health risk assessment, others in a parallel but separate process).

Figure 8 summarises the different options taken by the national frameworks that were analysed.

	Africa										Asia-Pacific					Europe			Latin-America														
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay
Independent SEC assessment																																	
SEC assessment integrated in RA																																	

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 8. Relation between socio-economic considerations (SEC) assessment and the environmental and health risk analysis.

Table 1 shows that in nine of the analysed countries, socio-economic considerations are defined as part of the environmental dimension. In these cases, the socio-economic assessment is conducted

together with the environmental risk assessment. Exceptions are Mexico and Pakistan. Although these two countries consider socio-economic considerations as part of the environment (see Table 1), they do establish a distinct and non-integrated assessment for socio-economic and environmental aspects (see Figure 8).

Table 1. Definitions of “environment” included in SEC frameworks.

Region	Country	Definition of Environment	Article or Section
Africa	Cameroon	<i>Environment: (a) all the natural or artificial elements and the bio-geochemic equilibriums in which they are involved, as well as the economic, social and cultural factors which foster the existence, transformation and development of the environment, living organisms and human activities; (b) natural abiotic resources such as the surrounding air, surface waters, underground water, soils, land surface, wildlife and plants, and the interactions between the elements which all form an integral part of the cultural heritage and specificities of the landscape under Cameroon’s jurisdiction</i>	Law N° 2003/006 of 21 April 2003, chapter II, sect 5(21)
	Ethiopia	<i>...the environmental rights provided under Articles 44 and 92 of the Constitution of the Federal Democratic Republic of Ethiopia require that human and animal health, environmental well-being and, in general, the socio-economic conditions of the country be protected from risks that may arise from modified organisms</i>	Proclamation 665/2009 on Biosafety, preamble
	Namibia	<i>“Environment” means the complex of natural and anthropogenic factors and elements that are mutually interrelated and affect the ecological equilibrium and the quality of life, and includes: (a) the natural environment being land, water, air, all organic and inorganic material and all living organisms; and (b) the human environment being the landscape and natural, cultural, historical, aesthetic, economic and social heritage and values</i>	Biosafety Act (Act No.7 of 2006), chapter 1, definitions
	Zambia	<i>“environment” means the aggregate of surrounding objects, conditions and influences that affect the life and habits of human beings or any other organism or collection of organisms;</i>	Biosafety Act (Act 10) of 2007, part 1, art. 1
	Zimbabwe	<i>“environment” means the aggregate of surrounding objects, conditions and influences that affect the life and habits of human beings or any other organism or collection of organisms;</i>	National Biotechnology Authority Act of 2007, part 1, art. 2
Asia-Pacific	Pakistan	<i>Environment: An ecosystem or habitat, including humans and animals, which is likely to come in contact with a released organism</i>	National Biosafety Guidelines 2005, app. 12
	New Zealand	<i>environment includes: (a) ecosystems and their constituent parts, including people and communities; and (b) all natural and physical resources; and (c) amenity values; and (d) the social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) or which are affected by those matters</i>	Hazardous Substances and New Organisms Act 1996, interpretation
Latin-America	Mexico	<i>Environment: The set of natural and artificial elements or those induced by man allowing the existence and development of human beings and other living organisms that interact in a determined space and time, outside the facility areas, or outside the realms where genetically modified organisms are used in a confined manner</i>	Law on Biosafety of GMOs 2005, art. 3(XIX)
	Venezuela	<i>Environmental Impact Assessment: Study oriented to predict and assess the impact of developing an activity on components of the natural and social environment and to propose preventive, mitigation and corrective measures in order to verify compliance with environmental provisions contained in current legislation in the country and to identify environmental parameters there under may be established for each program or project (own translation)</i>	Normas sobre Evaluación Ambiental de Actividades Susceptibles de Degradar el Ambiente título I, art 3

3.3.3. Variation in the Level of Assessment and Specifications When Assessing Socio-Economic Considerations

The majority of frameworks do not specify the level of analysis to be taken into account in the case of socio-economic assessment. Risk assessment is conducted as a response to market applications on a case-by-case basis. Assessments are conducted at the event-level in most of the cases, and only in some cases, the legislation specifies that if there is sufficient reason to believe that a GM crop is safe, there is a possibility to conduct a simplified risk assessment (implying an initial assessment at the trait level). This is the case in Kenya, for instance. In Norway, socio-economic considerations are considered on a case-by-case basis. In addition, guiding questions that are trait-specific have been developed, focusing on herbicide tolerant and insect resistant plants [26,27].

3.3.4. Socio-Economic Expertise in Decision and Advisory Bodies

Only in two of the analysed countries, Argentina and France, is there a specific body that is designated in the legislation as being in charge of conducting the socio-economic assessment. In the

case of Argentina, the Direction for Agricultural Markets, under the Ministry of Agriculture, issues a report on productive and commercial impacts, which complements the assessments for health safety and environmental risks. In the case of France, the High Council for Biotechnologies comprises two committees, a scientific committee and another that is in charge of providing recommendations for economic, ethical and social considerations. In the other cases, it is the national competent authority or committee in charge of GMOs that takes socio-economic considerations into account. In fact, many of these countries have at least one member of the committee or national authority that is appointed based on his or her social science expertise. This is the case in France, Kenya, Namibia, Philippines, Tajikistan and Zimbabwe.

In other countries, experts on socio-economic considerations are members of the advisory committees; this is the case, for instance, in Ghana and Norway. In 12 of the analysed countries, there is no information on the background of the members of the committee or the body providing socio-economic assessment advice.

The decision-making process varies greatly among the different national regulatory frameworks. In general, there are two institutional arrangements for making the final decision: (i) it is taken by the National Authority, which deals directly with the risk assessment or is advised by a technical body; (ii) the final decision is taken by the Minister responsible (Minister of Agriculture, Minister of Environment or Minister of Science and Technology), on the advice of the technical bodies and/or National Authority. The selection of the members of the national authorities and advisory committees also varies greatly among countries, with members appointed by the responsible ministers, government or the President.

3.3.5. Other Aspects Related to Socio-Economic Assessment: Inclusion of Precautionary Approaches in GMO Regulation

The majority of the countries reviewed refer to the precautionary principle or approach as a basis for taking decisions, although precaution is not taken as a guiding principle in eight of the countries (see Figure 9).

	Africa														Asia-Pacific						Europe			Latin-America										
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Yes																																		
No																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 9. Use of the precautionary principle as a guiding principle.

Only in Indonesia, Togo and Zambia it is explicitly stated that the precautionary principle can also be applied to socio-economic considerations. In the case of Costa Rica, the precautionary principle is linked to the co-existence between GM and organic farming and, in France it also covers consumers' freedom to choose between GM and non-GM products. In the cases of Burkina Faso and Cameroon the precautionary principle is introduced in the context of evaluating alternatives to GM crops, as part of the risk assessment. In the cases of Brazil, Colombia, Ghana and Venezuela, the application of the precautionary principle is restricted to the environmental risk assessment (including biodiversity risks).

There are different definitions used when referring to the use of the precautionary principle or approach. While in some countries the emphasis is placed on the right to use preventive measures in case of suspicion of serious threat or irreversible damage, even in the absence of scientific proof or evidence (Cameroon, Burkina Faso, Mali or Senegal); in other countries the focus is not placed

on preventive measures but on the information used for taking decisions by using the formulation in Table A1 III (on risk assessment) of the Cartagena Protocol of Biosafety: “Provided that lack of scientific knowledge due to insufficient relevant scientific information or scientific consensus should not be interpreted as indicating a particular level of risk, or absence of risk, or an acceptable risk” (e.g., Mexico). In one case, the Philippines, the two approaches coexist in the same regulatory piece. In other cases, the legislation establishes some limits to or nuances in the application of the precautionary principle. For example, in the case of Senegal, it establishes the precautionary principle as a guiding principle and adds: “The authorities must take into account the general principles applicable to all risk management: the principle of proportionality, the principle of non-discrimination, the principle of consistency of the measures and the examination of benefits and costs resulting from the approval, as well as the development/evolution of scientific knowledge” (own translation, Loi 2009/27 portant sur la Biosécurité, cap IV, art. 4).

In some cases, the precautionary principle is applied together with the prevention principle that instigates the application of anticipatory measures to prevent negative impacts. In the case of Togo, for instance, it is explicitly stated that both principles should be applied to potential damaging impacts on human and animal health, biodiversity, the socio-economic domain and cultural values (Loi de Biosécurité, art. 6).

3.4. Participatory Approaches in GMO Regulation

A participatory approach in GMO socio-economic assessment may serve different purposes, ranging from informing and raising public awareness on the technology to be introduced, to the inclusion and representation of divergent societal opinions so as to increase transparency and legitimacy in the decision-making process. *Public awareness and education* are aspects raised by one-third of the analysed biosafety regulatory frameworks (e.g., Burkina Faso, Cambodia, Colombia, Ghana, Kenya, Latvia, Namibia, Pakistan, Philippines, Senegal, Tajikistan and Togo). Most of these countries promote public awareness, aiming to improve the understanding of biosafety issues by providing information on national policies and on the risks and benefits of modern biotechnology. Some of the means described for doing so are the publication of guidance documents and other materials for the general public and through public lectures, seminars and workshops. Moreover, the Togo Biosafety Law establishes a fee for importers of GM products, which is channeled to fund public education and awareness activities (art. 91). This is also the case of the Philippines where the fee is used for building “the capacity of environmental and developmental non-government organizations, people’s organizations, professional organizations, including industry and other concerned entities to assist in this capacity-building program shall be enhanced” (Executive order 514/2006, 8.1(d)).

Most of the analysed countries have regulated *access to information*, by providing for public access to information on biosafety in general (for instance, by implementing National Biosafety Clearing Houses), and information on applications for GM crops approvals as well on approved cultivation of GM crops. In some countries, the information on applications is available to the public upon request (e.g., Ghana, Kenya, Mali and Senegal), while some fee is also applied in one of the countries (e.g., Kenya). Latvia, Italy and France have also implemented a public register of GM fields, which should be made available to the public. Moreover, the great majority of the analysed countries publish the final assessments so that the public can consult them. Only in the case of Namibia is the assessment facilitated upon request of interested parties (see Figure 10).

	Africa														Asia-Pacific					Europe			Latin-America											
	Burkina Faso	Cameroon	Ethiopia	Ghana	Kenya	Madagascar	Mali	Mauritius	Namibia	Senegal	South Africa	Togo	Zambia	Zimbabwe	Cambodia	Indonesia	Malaysia	New Zealand	Pakistan	Philippines	Tajikistan	France	Italy	Latvia	Norway	Argentina	Brazil	Colombia	Costa Rica	Cuba	Mexico	Panama	Uruguay	Venezuela
Yes																																		
Upon request																																		
Not known																																		

Countries that have approved GM crops for cultivation are marked in gray, while countries without approvals are colored black.

Figure 10. Use of the precautionary principle as a guiding principle.

Public participation in the decision-making process is crucial for facilitating transparency and accountability, and for strengthening public support for the decisions taken regarding GMOs [28,29]. In 31 of the 34 analysed countries, public participation is integrated into decision-making on GMOs, although the role it plays in this process varies widely, as do the detailed provisions to make participation effective. Information is lacking for the case of Argentina, Cuba and Pakistan. However, important gaps exist on how these provisions are implemented, as well as with regard to the weight that the public has in the final decision. Moreover, it was not possible to establish the role that public participation plays specifically in the assessment of socio-economic considerations.

3.5. The Norwegian Approach for Assessing Broader Issues

3.5.1. Basis for the Inclusion and Implementation Experience

The Norwegian Gene Technology Act of 1993 regulates the production and use of GMOs. For a GMO to be approved in Norway, the Act requires that the production and use of GMOs take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on human and animal health and the environment. Section 10, second paragraph, of the Act lays down that GMOs may only be approved when there is no risk of adverse effects on human or animal health or the environment, and that considerable weight is to be given to whether the GMO will be of benefit to society and is likely to promote sustainable development.

In Norway the government appointed Biotechnology Advisory Board is responsible for making a broad assessment of GMOs, and has a special responsibility for assessing sustainability, social benefit and ethical factors. The Board is an independent body consisting of 15 members appointed by the Norwegian government. Each member has a background and/or education to ensure that the member is competent to discuss questions regarding the use of modern biotechnology. The Board gives advice to the Norwegian Environment Agency.

3.5.2. Implementation of the Socio-Economic Aspects

In 2000, the Board published a report on how to operationalise the concepts of sustainable development, social benefit and ethical and social considerations in the Gene Technology Act [30]. Parts of this report were included in the appendix of the Regulations on Impact Assessment pursuant to the Gene Technology Act (2005). The assessment in Norway is carried out by a case-by-case approach and covers both direct and indirect well as delayed effects. The precautionary principle is only linked to the risk assessment on health and the environment. The scope of the Regulations on Impact Assessment is to govern the whole process from content to processing of the impact assessments for GMOs to the investigations that need to be carried out during and after deliberate release, and provides scopes and definitions. The socio-economic considerations covers both potential beneficial factors (favourable) as well as risks or costs (non-favourable).

There has been an increased stringency and robustness as well as greater scope and depth of detail in the assessment of GMOs by the Board [31], which can also be found in the revisions carried out in 2006 and 2009 of the report from 2000. Rosendal has performed an analysis of a total of 50 cases from the period between 1994 to 2005, and she found that between 1993 and 2002, the main aspects that were emphasised by the Board developed from only considering societal concerns related to pesticide use to include benefits to the community/public utility, opportunities to reuse seed for farmers, ethics, and sustainable development. In the period between 2003 and 2005, these issues were extended to also include access to seeds for food security, effects on global agriculture structures, and North-South issues of equity.

With the aim of achieving further operationalisation of the provisions related to societal utility considerations and contribution to sustainable development, the Norwegian Environmental Agency did in 2009 requested two researchers in the field for a report on how and to what extent marketing applications for GMOs fulfill the criteria of sustainable development and societal utility in the Norwegian Gene Technology Act [17,31,32]. The authors, Rosendal and Myhr, identified four objectives for this report: (a) elaborate how the Norwegian authorities can use the procedures implemented in the EU system; (b) discuss how the concepts of sustainable development and societal utility can be applied in a broader sense; (c) evaluate the information provided in two given GMO marketing applications, with a focus on the adequacy of the supplemented information; and (d) develop recommendations concerning the assessment of sustainable development and societal utility.

In the two GMO marketing applications that were analysed (see Table 2), the authors of the report found that the information supplied by the applicants was found to be of high relevance when assessing impact on global impact and ecological limits, while no information was found related to basic human needs, distribution between generations, distribution between rich and poor countries, and economic growth. The checklist used for the analysis of two marketing applications is found in appendix 4 of the impact assessment pursuant to the Norwegian Gene Technology Act.

Table 2. Available and lacking information for conducting assessment of societal utility and contribution to sustainable development, following the Norwegian Gene Technology Act (adapted from Myhr and Rosendal [17]).

Checklist in Appendix 4 of the Regulations on Impact Assessment Pursuant to the Gene Technology Act.	Available Information Found in Applications That Can be Used for Answering Questions in the Checklist.	Information Lacking in Applications that Concerns the Questions in the Checklist
Global impacts	Persistence, invasiveness, possible population and fitness changes introduced in the GMPPotential for gene transfer	Changes in biogeochemical processesChanges due to cultivation patternsEffects on water and energy balanceLatency/cumulative effects
Ecological limits	Interaction between GMP and target organismsInteractions between GMO and non-target organisms	Impacts on socio-ecological relationships
Basic human needs	Benefits for healthToxicity and allergenicity	Latency/cumulative effectsFood security issues
Distribution between generations	Not found	Latency/cumulative effectsInfluence by scientific innovationsTrade-off between utility and risk
Distribution between rich and poorer countries	Not found	Adequacy for meeting problems in poor countries and especially for small-scale farmers
Economic growth	Not found	Latency/cumulative effectsTrade off between short term economic growth <i>versus</i> potential long term adverse effects

When assessing the adequacy of the supplemented information, the authors encountered problems due to confidentiality restrictions. Furthermore, a substantial number of the supplied references pointed back to the applicants' own research departments and therefore lacked peer-review. For wider concerns that include any potential effects on socio-ecological relationships, the assessed applications provided little or no relevant information to be used by Norwegian administrative staff to process

applications. The authors also assessed whether the two applications to market GMOs fulfilled the criteria of societal utility. Societal utility is closely linked to these four criteria, but is a complicated concept that may require many points to be considered. These would include, for example, an assessment of whether the technology is beneficial to small or large farms, whether the technology is likely to have any effect on employment, food security, landscape aesthetics, or human and animal health and welfare, and an assessment of who will benefit from the technology. The authors conclude that the applicants had carried out little research to identify how GM crops might contribute to sustainability and societal utility around the world [17].

3.5.3. Methodological Approaches and Use of Criteria and Indicators

The Norwegian Environment Agency did in 2010/2011 asked the Board to carry out a project aimed at translating the concepts of sustainable development, social benefit and ethics in the Gene Technology Act. Insect-resistant genetically modified plants (2011) and herbicide-resistant plants (2013) were chosen as case studies. The Agency's intention was to develop guidelines that could be used by administrative staff to process applications for approval of such GMOs pursuant to the Gene Technology Act. In both projects, scientists from different scientific disciplines and institutions in Norway contributed as ad-hoc experts. The parameters that were elaborated by the project included environmental, societal and economical issues (see Table 3). Questions that could be asked were elaborated in further detail in the reports [26,27].

Table 3. Parameters and questions to applicants included in the guidelines elaborated by the Norwegian Biotechnology Advisory Board for conducting SEC assessments. Adapted from the Norwegian Biotechnology Advisory Board [26,27].

Parameter	Questions to Applicants
Environment/Ecology	On the GM plant: characterization, gene flow, interaction between plant and the environment, preservation of biodiversity, comparison with control plants
	On the herbicide/Bt toxin: characterization, effects of altered use, development of resistance
	Soil, water, energy and climate
Society/Economy	The right to sufficient, safe and healthy food (food safety, security and quality)
	Animal health and welfare (feed quality)
	Living conditions and profitability for the farmers who cultivate GM plants, in the short term (less than 5 years) and in the long term (more than 20 years) Health and safety, contracts and framework conditions, employment, developments of costs and incomes, agronomic factors, the right to seed, ownership rights <i>etc.</i>
	Plant genetic resources for food and agriculture
	Independent risk research
	Freedom to choose agricultural system in the future

When assessing applications for import and use of GMOs in Norway, the Board now uses the points described in Table 3, and in most cases on GM crops they find there is a lack of information with regard to these broader issues and asks the applicants to answer the questions as elaborated in the reports. The reason behind the increased stringency in the Norwegian assessment of broader issues can hence be due to that this has been a learning process both for the Board and the Agency. The assessments done by Board are made public and are published on their homepage.

3.5.4. Participatory Approaches

Norway has regulated access to information, by providing for public access to information on applications for GM crops approvals. Besides the Board, it is possible both for individuals and for both research/academic institutions and non-governmental organizations to contribute with inputs as comments and statements during the assessment period. It is the Norwegian Environment Agency that makes this information, most often summaries of applications, available through homepage and by using mailing lists. The Board does also have access to the inputs provided through the public access. One problem for public participation is that there is not possible to have access to the whole applications due to confidentiality closures [16].

4. Discussion: Opportunities for and Challenges to the Inclusion of Socio-Economic Considerations

The review of the literature and the analysis of the national legislative frameworks show that there is a high interest in the inclusion and implementation of socio-economic considerations in national biosafety regulations. There are differences in approaches and policy goals, resulting, e.g., in a high diversity in the choice of indicators and parameters to be assessed. The case study of Norway points out that the inclusion and implementation of socio-economic considerations may be based on a learning process.

4.1. Methodological Issues and Approaches Taken

The review reveals that there are significant differences in how socio-economic considerations are integrated into and assessed in the studied national normative frameworks. The main differences are related to the status of the regulations and approach used (prescriptive *versus* descriptive formulations of what socio-economic considerations refer to, the inclusion of only risks *versus* assessments integrating both risks and benefits, or assessments taking only into account direct effects *versus* the ones that also integrate the assessment of the co-technologies used in conjunction with the GM crop).

At the same time, the research has made explicit that the inclusion of socio-economic considerations responds to a diversity of national policy goals, which can partially explain the differences in framing, criteria and indicators between the different countries. The research has also revealed the importance of identification of protection goals in framing of the socio-economic assessment in order to achieve an efficient and transparent assessment. The case study on Norway also illustrates that making the protection goals explicit and consequently developing a framework with corresponding questions [26,27] can, besides increasing the efficiency, also help in gaining credibility. This credibility is achieved by providing transparency and being open for public scrutiny of both the specific questions used in the assessment and their value-based background (e.g., protection goals).

A second interesting feature is the wide inclusion of health and environmental-related considerations as part of the socio-economic assessment, and the integration of socio-economic aspects in the definition of “environment” in a significant number of the analysed countries, blurring the separation between these dimensions that is traditionally demarcated by the risk assessment. This is also found in the Norwegian case where the environment is considered in a much broader context to include aspects as preservation of biodiversity, and impacts on soil, water, energy and climate. The inclusion of environmental aspects may vary and be further developed or removed with experience both in Norway and in other countries.

4.2. Need for More Empirical Data

There is a need for empirical research for providing data that can be used for assessing socio-economic considerations. As illustrated in the Norwegian case, the information in applications is provided for answering issues of relevance for environmental and health risk assessment, hence only some of the information can be used for assessing socio-economic considerations [17]. Another challenge is that data from one area may not be directly applicable in another country, or even in

another area of the same country with different socio-economic characteristics, requiring a reflection on the significance of the data and the framework and methods used in the context assessment of an GMO application [16,18].

4.3. Values and Public Participation

Natural scientists from research institutions and representatives of the biotechnology industry have often dominated the debates concerning risk issues, framing them as purely technical issues [33], while leaving aside holistic arguments (see, e.g., Walls *et al.* [34] as an example of how the latter type of arguments (e.g., concern for the implication for landscape and culture embedded in the agricultural system or for the growing dominance of multinational corporations in the life sciences) were marginalised in New Zealand's debate on GMOs. Jensen *et al.* [35] have applied the concept of a "risk window" to illustrate that risk assessments frame the world through a "risk window" that only makes visible what has been predefined as a relevant risk. The size and structure of this window is determined by value judgments about what is considered relevant as adverse effects identified in the process by stakeholders. This is because stakeholders use different conceptual frameworks in their identification of the values deemed to be important in risk governance of GM crops [36]. The difficulty in making transparent normative values can be illustrated by for example the discussion about the appropriate comparators that could serve as baselines for assessing the impacts of GM crop introduction.

It may be expected that stakeholders will also use different conceptual frameworks for how to approach and for acknowledging empirical research and data on socio-economic considerations. It is therefore important that normative values (or policy goals) are made explicit and that debates on values includes public participation. Further work needs to be conducted on how to interweave expert and stakeholder inputs and forms of values and knowledge. One example is provided by the Norwegian case, where members of the Board, scientists and stakeholders were involved in the identification of parameters and questions to be included in the guidelines for conducting assessment of sustainability [26,27].

4.4. The Precautionary Principle

The precautionary principle/approach is often linked to the regulation of environmental risks in general. When it comes to biosafety legislation 14 of the 34 countries analysed connect the principle to environmental risks. However, precaution is explicitly applied to socio-economic considerations in only 3 of the total 34 countries examined, extending the traditional implementation of the principle to the wider governance of science, innovation and trade [33]. The link between the environmental application of the precautionary principle and the socio-economic assessment is in fact strengthened by the European Environmental Agency working definition of the precautionary principle [37], which establishes that an appropriate implementation of the precautionary principle should involve a well-conceived socio-economic assessment, aiming at more responsible and socially relevant innovations by addressing the limitations associated with current decision-making by broadening the issues assessed, integrating public concerns and providing an assessment of alternative options [5].

5. Conclusions: Needs and Recommendations

The review has pointed out that there are challenges related to achieving an effective and systematic implementation of socio-economic considerations in biosafety regulations. For instance, very few of the analysed regulations establish robust methodologies during the processes of framing, data gathering, assessment and decision-making related to socio-economic considerations. In addition, there are uncertainties associated with socio-economics since the respective scientific evidence and data remain insufficient, inconclusive or uncertain. There is therefore a need for both more empirical data and for competence in on how to perform assessments of socio-economic considerations. The

case study of Norway shows that one of the outcomes by experience is a greater scope and depth of detail in the assessment of GMOs.

It is necessary to make explicit the normative values during the assessment of socio-economic consideration and in the decision-making phases. The implementation of socio-economic assessments, in most of the cases, would result in contradictory or divergent results (not only between different socio-economic aspects but also between socio-economic assessment and the environmental and health risk assessment), according to the framing used, the different assessment endpoints, or to the applied methods. Thus, it is difficult to arrive at unanimous overall conclusions, creating a more demanding need for transparency, openness and accuracy in the communication of this process.

There is also a need to characterize the different roles played by stakeholders in the analysed regulatory frameworks at different phases of the assessment: e.g., at the beginning of the process so as to frame the issues, during the assessments so as to provide data or at the end of the process for reviewing conclusions and providing opinions, as well as on the possible means of participation and/or consultation.

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Author Contributions: Rosa Binimelis did the search of legislative documents, and performed the coding and classification of the data using the programme Dedoose. Both authors performed the analysis of the data. Rosa Binimelis led the drafting of the paper, with Anne Ingeborg Myhr leading the section on the Norwegian case and contributing to the manuscript with text and comments, supporting references and feedback throughout an iterative process involving several rounds. All authors have read and approved the final manuscript.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix

Table A1. Consulted laws, regulations or guidelines.

Country	Analysed Documents	Type of Document
Argentina	Resolución SAGYP n° 510/2011 of 17th August 2011	Regulation
	Resolución SAGYP n° 763/2011 of 17th August 2011	Regulation
Brazil	Law No. 11105, 24th March 2005	Law
	Decree No. 5,591, 22nd November 2005 (revised version 18th January 2006)	Regulation
Burkina Faso	Loi N° 005-2006/AN du 4 Mai 2006 portant regime de securit en matiere de biotechnologie	Law
	Law on Biosafety promulgated on 15th February 2008 (unofficial translation)	Law
Cambodia	Sub-decree on Mechanisms and Procedures for Implementing the Law on Biosafety (unofficial translation)	Regulation
Cameroon	Law N° 2003/006 of 21 April 2003 to lay down safety regulations governing modern biotechnology in Cameroon	Law
Colombia	Decreto n° 4525 de 6 de diciembre de 2005 por el cual se reglamenta la Ley 740 de 2002	Regulation
	Reglamento a la Ley de Protección Fitosanitaria (N° 26921-MAG), 2008	Regulation
Costa Rica	Reglamento para el Desarrollo, Promoción y Fomento de la Actividad Agropecuaria Orgánica (Decreto 35242-MAG-H-MEIC), 2008	Regulation
Cuba	Reglamento para el otorgamiento de la autorización de seguridad biológica (Resolución 180 2007)	Regulation
Ethiopia	Proclamation 665/2009 on Biosafety	Law
	Directive No. 01/ 2009 issued to determine the contents of applications for undertaking transactions involving modified organisms	Regulation
	Directive No. 02/ 2009 issued to determine Risk Assessment Parameters for modified organisms	Regulation
France	LOI n° 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés (NOR: DEVX0771876L; version consolidée au 19 juin 2014)	Law
	Code de l’environnement	Law

Table A1. Cont.

Country	Analysed Documents	Type of Document
Ghana	Biosafety Act (No. 831), 2011	Law
	Biosafety (Management of Biotechnology) Regulations, 2007 (Legislative Instrument 1887)	Regulation
Indonesia	Regulation of the Government of the Republic Indonesia Number 21 on Biosafety of Genetically Engineered Product, 2005	Regulation
Italy	Decreto Legislativo 8 luglio 2003, n. 224. Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati	Regulation
	Decreto Legislativo 21 marzo 2005, n. 70. "Disposizioni sanzionatorie per le violazioni dei regolamenti (CE) numeri 1829/2003 e 1830/2003, relativi agli alimenti ed ai mangimi geneticamente modificati	Regulation
Kenya	Biosafety Act No. 2, 2009 (revised version 2012)	Law
Latvia	Law On Circulation of Genetically Modified Organisms, 2007 (text consolidated by Valsts valodas centrs (State Language Centre), 2013)	Law
	By-law of the Supervision Council for Genetically Modified Organisms (text consolidated by Valsts valodas centrs (State Language Centre), 2013)	Law
	Regulation No. 453 adopted 19 May 2009. Regulations Regarding the State Fee for Preparation of the Risk Assessment's Opinion of Genetically Modified Organisms	Regulation
	Regulation No. 457, adopted 26 May 2009. Regulations Regarding the Procedures for the Release into the Environment or Placing on the Market of Genetically Modified Organisms, the Procedures for Monitoring and Issuance of a Permit, as well as the Procedures for Providing Information Regarding Circulation of Genetically Modified Organisms and Public Involvement in the Decision Taking Process	Regulation
	Regulation No. 1078, adopted 22 December 2008. Methodology for the Risk Assessment of Genetically Modified Organisms	Regulation
Madagascar	Decret N° 99-954 du 15 decembre 1999 modifié par le décret n° 2004-167 du 03 février 2004 relatif à la mise en compatibilité des investissements avec l'environnement (MECIE)	Regulation
Malaysia	Biosafety Act, 28th 28 August 2007	Law
	Biosafety (Approval and Notification) Regulations 2010	Regulation
Mali	Loi n°08-042/AN – RM du 1er decembre 2008 relative à la sécurité en Biotechnologie en République du Mali	Law
Mauritius	The Genetically Modified Organisms Act 2004; Act No. 3 of 2004	Law
	Ley de Bioseguridad de Organismos Genéticamente Modificados, de 18 de marzo de 2005	Law
México	Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados, de 19 de marzo de 2008	Regulation
Namibia	Biosafety Act (Act No.7 of 2006), 30th December 2006	Law
New Zealand	Hazardous Substances and New Organisms Act, 10th June 1996 (reprint as at 1st January 2014)	Law
	Biosecurity Law Reform Act No 73 of 17th September 2012	Law
Norway	Act relating to the production and use of genetically modified organisms (Gene Technology Act) Act of 2 April 1993 No. 38 with subsequent amendments, most recently by Act of 17 June 2005 No. 79	Law
	Regulations relating to impact assessment pursuant to the Gene Technology Act laid down by Royal Decree of 16 December 2005 and annexes 1 to 4	Regulation
	Sustainability, Benefit to the Community and Ethics in the Assessment of Genetically Modified Organisms: Implementation of the Concepts set out in Sections 1 and 10 of the Norwegian Gene Technology Act. Opinion by the Norwegian Biotechnology Advisory Board.	Guidelines
Pakistan	Pakistan Biosafety Rules, of 26th April 2005	Law
	National Biosafety Guidelines 2005, Notification No. F:2 (7)95-Bio	Guidelines
Panama	Ley 48 de 2002 que crea la Comisión Nacional de Bioseguridad para los Organismos Modificados Genéticamente y dicta otras disposiciones	Law
	Decreto-Ley 11 de 2006 que crea la autoridad panameña de seguridad de alimentos y dicta otras disposiciones	Law
Philippines	Executive Order No. 514 establishing the national biosafety framework, prescribing guidelines for its implementation, strengthening the national committee on biosafety of The Philippines, and for other purposes	Regulation

Table A1. Cont.

Country	Analysed Documents	Type of Document
Senegal	Loi n° 2009-27 du 8 juillet 2009 portant sur la Biosécurité	Law
	Décret n° 2009-1408 du 23 décembre 2009 portant missions, organisation et fonctionnement du Comité National de Biosécurité (CNB)	Regulation
	Décret n° 2009-1409 du 23 décembre 2009 portant missions, organisation et fonctionnement de l'Autorité Nationale de Biosécurité (ANB)	Regulation
South Africa	Genetically Modified Organisms Act 1997 (Act No. 15, 1997)	Law
	Genetically Modified Organisms Amendment (Act No. 23 of 2006)	Law
Tajikistan	Law on Biological Safety	Law
	National Biosafety Framework of the Republic of Tajikistan. Safarov N., Novikova T., Idrisova A. et al. Dushanbe: National Biodiversity and Biosafety Center. 2004. - P.66	Guidelines
Togo	Loi n° 2009-001 sur la prévention des risques biotechnologiques	Law
Uruguay	Decreto N° 353/008, 2008	Regulation
Venezuela	Ley de Gestión de la Diversidad Biológica, de 1 de diciembre de 2008	Law
	Normas sobre Evaluación Ambiental de Actividades Susceptibles de Degradar el Ambiente	Regulation
	Decreto n° 4334, mediante el cual se dispone que la Comisión Nacional de Bioseguridad, como organismo técnico-científico, asesorará al Ejecutivo Nacional en las actividades que en él se señalan. Decreto No. 1.257, de 13 de marzo de 1996	Regulation
Zambia	Biosafety Act (Act 10) of 24th April 2007	Law
Zimbabwe	National Biotechnology Authority Act [Chapter 14:31], Act 3/2006	Law

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