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WORKSHOP ON CAPACITY-BUILDING FOR RESEARCH AND INFORMATION EXCHANGE ON SOCIO-ECONOMIC IMPACTS OF LIVING MODIFIED ORGANISMS
New Delhi, India, 14-16 November 2011

SYNTHESIS OF INFORMATION ON NATIONAL EXPERIENCES WITH SOCIO-ECONOMIC CONSIDERATIONS IN DECISION-MAKING ON LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

I. INTRODUCTION

1. In decision BS-V/3, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to convene a regionally-balanced workshop on capacity-building for research and information exchange on socio-economic impacts of living modified organisms (LMOs). One of the objectives of the workshop is the exchange and analysis of information on the use of socio-economic considerations in the context of Article 26 of the Protocol.

2. This document synthesizes information on national experiences with socio-economic considerations in decision-making on LMOs contained in the submissions made by Parties and the contributions to the online discussion groups on socio-economic considerations[1] and the Regional Online Real-time Conferences on Socio-economic Considerations in Decision-making concerning Living Modified Organisms[2] organized by the Secretariat through the Biosafety Clearing-House. Section II of the document addresses information regarding countries with actual experience incorporating socio-economic considerations in their decision-making. Section III synthesizes information on countries that have provisions for including socio-economic considerations in decision-making but where these provisions have not been put into practice.

II. INFORMATION REGARDING COUNTRIES WITH EXPERIENCE INCORPORATING SOCIO-ECONOMIC CONSIDERATIONS IN THEIR DECISION-MAKING ON LIVING MODIFIED ORGANISMS

3. The first part of this section synthesizes information regarding countries that have conducted *ex ante* assessments of socio-economic impacts and incorporated such assessments into decision-making on LMOs. It includes information on countries that may not have formal rules for including socio-economic

[1] http://bch.cbd.int/protocol/cpb_art26/discussiongroups_se.shtml.
[2] http://bch.cbd.int/protocol/cpb_art26/realtime_se.shtml.

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considerations in decision-making but nonetheless have some relevant experience. Information is provided on the following Parties: Belgium, Bolivia, France, India, Malaysia, Norway, South Africa; and the following non-Parties: Argentina and the United States of America. Part B synthesises information on socio-economic considerations raised after a decision has been taken on an LMO (*ex post* assessments). It focuses on provisions on the co-existence of different forms of agriculture. Information is provided on the following Parties: the European Union (EU), Austria, Belgium, Czech Republic, Germany and Spain.

A. Ex ante *assessments in decision-making*

(i) Belgium

4. In the online discussion groups and the real-time online conference for the Western Europe and Others Group (WEOG) and Central and Eastern Europe (CEE), the representative of Belgium noted that the country has not adopted any legislative or procedural instrument to include socio-economic assessments in its decision-making procedures on LMOs but does have experience with socio-economic considerations in decisions on field trials of two types of genetically modified (GM) trees.

5. In response to an application in 2004 regarding apple trees, the Minister for Public Health and Environment established a provisional committee to give an opinion on ethical and socio-economic considerations in addition to the biosafety concerns considered by the Belgian Biosafety Advisory Council. The opinion of the provisional committee was unfavourable, and the application for the field trial was refused.

6. More recently, the Belgian Biosafety Advisory Council recommended the approval of field trials of GM poplar trees for use as biofuels in transportation. The Ministers for Health and Environment denied the request, based on, among other things, public concerns and doubts about the benefit to society and the sustainability of the GM poplars. The applicant appealed the decision and the State Council ruled in its favour of the applicant, considering that the arguments for the refusal were insufficiently justified and should have been based only on risk concerns, according to the legislation derived from EU law.

(ii) Bolivia

7. In the discussion groups and the Latin America and the Caribbean (LAC) real-time conference, the representative of Bolivia described her country's biosafety regulation and approach to socio-economic considerations in decision-making related to LMOs. She outlined the following legal framework by which socio-economic considerations related to LMOs are currently governed in Bolivia:

(a) The New Political Constitution of the State (2009) has specific clauses on genetically modified organisms (GMOs) and provides guidelines for realising the social and economic rights of the Bolivian people, with particular emphasis on the rights of indigenous and peasant communities regarding the conservation and use of natural resources and their social, spiritual and cultural values.

(b) The Law on the Rights of Mother Earth (2010), which is rooted in the recognition of the strong and intertwined nature-society relationship. It sets clear rights to and duties for the protection of nature, recognizing its importance for sustainable rural and indigenous livelihoods.

(c) The Law of Productive Revolution Community Agriculture (2011) whose primary objective is to regulate the strengthening of food sovereignty in balance with Mother Earth.

8. The representative of Bolivia noted that the country's goals for the introduction or development of technologies, including LMOs, are strengthening well-being and food sovereignty, especially for indigenous and native communities and other vulnerable or marginalized groups. From Bolivia's

perspective, socio-economic considerations are necessary so that social and economic factors that could affect the conservation and sustainable use of biodiversity are taken into account when making decisions.

9. According to the representative, the main challenge for Bolivia in taking socio-economic considerations into account is the lack of capacity among technical and decision-making staff. Other major obstacles are gaps in knowledge on the subject of socio-economics and underestimating the social and cultural factors that may be affected by the introduction of LMOs. It was noted that in some sectors, there is a tendency to assume that relevant socio-economic considerations are only a matter of pure economics based on quantitative analysis (especially in relation to changes in production costs and international market opportunities.) The information generated usually does not provide details on the social aspects nor on the interactions between ecological and social issues. In Bolivia's view, the protection goals should go beyond economic indicators.

10. She indicated that Bolivia is currently in the process of strengthening its national mechanism for effective inclusion of socio-economic considerations in biosafety decision-making to address both social and economic aspects as well as the technology package associated with the LMOs. This is being done through methodological pluralism (including quantitative, qualitative and participatory research) from the perspective of sustainability (based on precautionary and long-term approaches).

11. During biosafety decision-making, Bolivia conducts consultations through: i) public hearings (usually performed at the seat of government); ii) participation of representatives of social groups and civil society in the activities of the Biosafety Committee; and iii) regional workshops conducted by the national competent authority (the Vice-Ministry of Environment).

12. The representative of Bolivia provided three examples of the inclusion of socio-economic considerations in decisions on LMOs in the country. In the first example, in 2000, field trials on a GM potato tolerant to nematodes were not approved due to the organism's potential adverse socio-ecological effects given that Bolivia is part of the centre of origin and genetic diversification of potato. An important factor in this decision was the concerns raised by social groups, mainly peasants and indigenous people. They submitted to the competent authorities their opposition to the introduction of GM potato due to its potential adverse effects on their main source of food and on the conservation of local varieties for agricultural and cultural purposes. The other main factors considered included the potential for gene flow caused by humans and the importance of the conservation of local biodiversity and wilderness in the ethno-cultural dynamics, especially among the highland groups.

13. In 2004, the country received an application regarding glyphosate-tolerant soybeans. During the risk assessment process, the analysis focused on issues concerning agricultural economics (including cost reduction and productivity). Other considerations were not included on the grounds that Bolivia is not a centre of origin of soybeans. However, *ex post* assessments have indicated that the economic assessment was lacking as the country is now experiencing impacts such as changes in production systems and a reduction in the diversity of locally available food, loss of differentiated markets as a result of physical contamination from GM soy and increased investment in conventional herbicides in some regions.

14. In the third example, in 2005, field trials of GM maize tolerant to armyworm (*Spodoptera frugiperda*) and the herbicide ammonium glufosinate were not approved for environmental and socio-economic reasons. Given that Bolivia is an important centre for genetic diversification of maize, the decision process considered the high probability of genetic contamination of local maize varieties which are a staple food with multiple local and cultural uses. Although the introduction of GM maize was banned in 2005, native communities complained to the competent authority about the illegal introduction of GM maize seeds from neighbouring countries in 2009.

15. The representative of Bolivia indicated the following main lessons learned in these processes:

(a) The needs of indigenous and local communities are central in decision-making related to the conservation and sustainable use of biological diversity particularly in countries, such as Bolivia, that are centres of origin and genetic diversity of important species;

(b) The impact assessments related to the introduction of LMOs need to consider potential impacts on sustainable livelihoods, with particular emphasis on indigenous and local communities;

(c) Attention should be given to illegal introductions since they pose particular monitoring challenges. Appropriate approaches to assess their impacts need to be developed.

(iii) France

16. In the WEOG and CEE real-time conference, a representative of France described how socio-economic considerations are included in the country's biosafety regulatory system. In the fall of 2007, France held a "*Grenelle de l'environnement*" – a nationwide forum for discussions on sustainable development. One of its conclusions was that the societal interests in the cultivation, import and consumption of genetically modified organisms should be evaluated as is done for the environmental risks. The idea was to establish a body to evaluate sustainable development criteria, i.e. environmental, social and economic criteria. Improved involvement of socio-economic stakeholders and civil society was also requested.

17. In response, France enacted a new law on genetically modified organisms (Law 2008-595 of 25 June 2008). The new law creates a right to produce and consume with or without genetically modified organisms, which raises several questions regarding co-existence between production methods, information and transparency for citizens. Socio-economic evaluations are one of the means to answer these questions by balancing the benefits of different production methods with the constraints and costs they could produce.

18. The new law established the High Council on Biotechnology (*Haut Conseil des Biotechnologies*, HCB). The HCB includes two committees: the Scientific Committee and the Economic, Ethics and Social Committee (*Comité économique, éthique et social*, CEES). The Scientific Committee provides a scientific evaluation of health and environmental risks. The CEES provides advice to the government on economic, ethical and social aspects of GMOs, including during the evaluation of dossiers for field trials and placing on the market of GMOs submitted under EU directive 2001/18/EC and dossiers for GM food and feed products submitted under EU regulation 1829/2003. Guidance for different types of dossiers, e.g. GMO importation, cultivation and field trials, is available to proponents.

19. The representative of France indicated that the HCB tries to ensure consistency by publishing the guidelines and questions it plans to address. The main factors that the HCB currently considers include: impact on agricultural practices (especially the use of pest control products), cultivated biodiversity, farm size, labour, organic and non-GM production and the interests of consumers. Guidelines for dossiers on GMOs for import state that the HCB considers socio-economic conditions in the producing country when "fundamental values" are at stake (e.g. human rights, safety of the populations, work conditions, etc.)

20. It was stated that these factors are sometimes difficult to take into account as they are the result of an analysis of the limited socio-economic data that is available and of a debate between stakeholders with different opinions. French authorities consider inputs from stakeholders as a crucial part of the evaluation. The goal of the CEES is to make explicit to the government the stakes of cultivation or import of a specific GMO. It thus gathers information on both positive and negative impacts from various stakeholders and tries to weigh them with the scientific data where possible. It is then the task of the French government to take a decision on the basis of the information and analysis provided by the HCB.

21. In the online discussion groups and the WEOG and CEE real-time conference, a representative from Austria provided additional information on the French system.[3] He stated that the HCB is linked to five ministries but describes itself as independent from political power. The government, elected officials, industrial boards and non-governmental organizations (NGOs) can file inquiries with the HCB and the HCB can also launch proceedings by itself. He described the CEES as consisting of three experts (a lawyer, an economist and a sociologist) and 24 stakeholders (including elected officials, representatives from professional organizations, unions and consumer, environmental, and health protection organizations). The CEES takes up its role after the Scientific Committee has issued its opinion. The opinions of the two committees are then transferred to the government.

22. The representative of Austria mentioned the following as some of the challenges faced by the Committee as described by Christine Noiville, CEES Chair, at a conference in the Netherlands in 2009:

- Convergence from the diversity of viewpoints present in the Committee;
- Absence of guidance on what to assess and by what methods; and
- Lack of data and access to data: there is no basis in the EU law to require notifiers to conduct socio-economic assessments. HCB has asked all EU competent authorities to request notifiers to provide socio-economic data and a briefing document.

23. The representative of Austria noted that the opinions of the CEES indicate that the Committee does not only assess socio-economic aspects but also interprets the results and conclusions of the Scientific Committee against this backdrop – providing a kind of synopsis of health and environmental risks and benefits as well as socio-economic impacts. For the hybrid maize MON89034xNK603 for instance, CEES acknowledged "few advantages" in case of maize monoculture and higher infestation rates. The CEES found too many disadvantages for conventional and GM-free agriculture and, in light of the uncertainties associated with the scientific aspects, advised against growing the crop. In another case, when reconsidering the French ban on maize MON810, the CEES identified a number of concerns:

- Risks of an increase of the area treated with insecticides;
- High seed price considered a problem if infestation frequency is low;
- Uncertainties regarding possible negative impacts on bees and livestock breeding; and
- Possible economic impacts on certain branches of agricultural production.

(iv) Honduras

24. During the Latin America and Caribbean real-time conference, a representative of Honduras indicated that his country has not included provisions on socio-economic considerations in its regulation but its decisions take into account the views of indigenous peoples on whether to allow the entry of LMOs into their communities.

(v) India

25. During the online discussion groups, the representative from the International Food Policy Research Institute (IFPRI), an intergovernmental organization, stated that India's current rules from 1998 do not formally require inclusion of socio-economic considerations in decision-making. He noted that studies have been commissioned for some applications but how these studies influenced decision-making is unclear. During the Asia-Pacific real-time conference, a representative of India indicated that the country has a mechanism to conduct socio-economic assessments. He indicated that one of the criteria used in the assessment is the economic benefits of the LMO.

[3] The information was drawn from a report prepared for the government of Austria by the representative: Spök, A. *Assessing Socio-Economic Impacts of GMOs: Issues to Consider for Policy Development*. Final Report. Forschungsberichte der Sektion IV 2/2010, Vienna. http://bmg.gv.at/cms/home/attachments/5/0/0/CH1050/CMS1291038713992/assessing_socio-economic_impacts_of_gmos,_band_2_20101.pdf.

(vi) Malaysia

26. In the Asia-Pacific real-time conference, the representative from Malaysia indicated that section 35 of the country's Biosafety Act 2007 provides as follows: "The Board or Minister shall not be prevented from taking a decision, as appropriate, under Part III or Part IV, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms or products of such organisms on human, plant and animal health, the environment and biological diversity and may also take into account socio-economic considerations." (Part III refers to the approval process for release and import and Part IV to the notification process for export, contained use and import for contained use).

27. He also pointed to the country's Biosafety (Approval and Notification) Regulations 2010, section 25 of which addresses socio-economic considerations and reads as follows:

> "The Board or the Minister, in taking into account socio-economic considerations pursuant to section 35 of the Act, may consider –
>
> "(a) the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms;
>
> "(b) the effects to the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms."

28. The representative from Third World Network (TWN), a Malaysia-based NGO, noted that the Biosafety Act also creates a Genetic Modification Advisory Committee (GMAC), whose function is "to provide scientific, technical and other relevant advice to the Minister or the Board" (section 6(2)). Members of GMAC are to consist of experts from various science-based and other relevant disciplines (section 6(5)). The inclusion of "other relevant advice" and "other relevant disciplines" in the function and membership of GMAC is understood to facilitate the inclusion of socio-economic considerations. The Act also provides that the highest decision-making body, the National Biosafety Board, shall have "not more than four other persons who have the knowledge or experience or both in any of the disciplines or matters relevant to this Act" (section 4(2)). This again was crafted to be wide enough to include persons who have knowledge or experience in socio-economic issues.

29. The representative from Malaysia identified two goals that the country wishes to achieve by taking socio-economic considerations into account in decision-making on LMOs:

- To ensure that they do not miss out on the benefits of LMOs; and
- To ensure that in their eagerness to benefit from LMOs, they don't lose what they already have due to contamination, etc.

30. He indicated that there has been little experience in implementing socio-economic considerations in decision-making on LMOs. However, when the country received applications to carry out field trials for limited release of a transgenic mosquito and a transgenic yeast, the need to consider both positive and negative socio-economic considerations became more apparent. The representative from TWN noted that in the assessment of the LM mosquitoes, the National Biosafety Board stated that it took socio-economic considerations into account, including the number of deaths and the cost of medication due to dengue. No details on how the Board made the socio-economic assessment were provided to the public.

31. The representative from TWN also commented that during the evaluation of the dossiers for some GM maize intended for direct use as food or feed, or for processing in Malaysia, there was discussion on the need to assess the potential socio-economic implications of the GM maize grain coming

into the country, as Malaysia also has local maize varieties and there were concerns regarding the possibility of contamination and the impacts this could have on smallholder farmers.

32. She also pointed to the country's National Policy on Biological Diversity 1998, which includes biosafety issues and foresaw the need for "an Environmental Impact Assessment procedure for biotechnology research and activities, including assessment on safety and social impacts". She noted past efforts to raise the issue of socio-economic considerations, including dialogues conducted by the Ministry of Natural Resources and Environment with relevant stakeholders looking at religious views on biotechnology and biosafety.

(vii) Norway

33. In the online discussion groups and the WEOG and CEE real-time conference, representatives of Norway outlined how socio-economic assessments have been integrated into the country's decision-making process on LMOs. Norway established a requirement to consider socio-economic impacts of LMOs when it adopted its Gene Technology Act in 1993. Under the legislation, the national decision-making process regarding deliberate release of LMOs into the environment must include an assessment of not only risks to health and the environment but also the criteria of benefit to society, contribution to sustainable development and ethical considerations.

34. They indicated that there has been a clear decision in Norway that socio-economic considerations are independent assessment criteria when taking a national decision on an LMO. Section 1 of the Gene Technology Act states the broad goal of the legislation as being "to ensure that production and use of GMOs and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment".

35. Further details on the above criteria were set out in regulations relating to impact assessment pursuant to the Gene Technology Act (latest revision from 2005). Appendix 4 of the regulations contains guidelines for assessing the criteria of benefit to society, sustainability and ethical considerations. The list of elements in Appendix 4 is not exhaustive and not all elements may be relevant in all cases. Examples of the guiding elements in Appendix 4 include the following:

(a) Impacts on biodiversity and ecosystem functioning, which include issues such as:

- Gene-flow (horizontal and vertical) and subsequent effects;
- Non-target effects (mammals, birds, invertebrates etc.);
- Increase of secondary pests;
- Change in agricultural practices leading to effects on biodiversity and ecosystem services (e.g. pesticide use);

(b) Impacts on ecological limits, which include impacts on the:

- Efficiency and extent of energy use;
- Efficiency of the use of other natural resources;
- Proportions of the use of renewable and non-renewable resources;
- Emissions of global and transboundary pollutants as well as greenhouse gas emissions;

(c) Impact on the distribution of benefits and burdens between generations;

(d) Demand or need for the product, including if it would solve or help to solve a social problem (e.g. employment) and if the product would tend to create problems for existing production;

(e) Possible adverse effects on local and indigenous peoples, people who live in highly traditional cultures, or weaker groups. Special account should be taken of the right to self-determination. This may be especially relevant in megadiverse countries and countries that are part of centres of origin and genetic diversity.

36. The representatives of Norway noted that the documentation from the applicant is important but should always be evaluated together with existing local or national knowledge, for example, regarding the local agricultural system, existing monitoring programmes and the basic local knowledge about the crop in question and possible impacts on the environment.

37. They remarked that the Norwegian legislation is broader in scope than Article 26 of the Biosafety Protocol and is also probably broader than just socio-economic considerations. They felt that EU directive 2001/18/EC contains openings to consider both ethical concerns (Article 29) and socio-economic concerns (Articles 7d and 31). They further noted that both positive and negative impacts are considered in the socio-economic assessment and the criteria are applied not only to GMOs for cultivation in Norway but also to GMOs produced in other countries for import into Norway.

38. They explained that the country continues to develop methods and guidelines for applicants to follow in submitting information regarding benefit to society, sustainability and ethics. Opinions of the Norwegian Biotechnology Advisory Board (NBAB) have also contributed to the understanding of the impact assessment criteria. In 2010, the Norwegian Directorate for Nature Management co-operated with NBAB in organizing an ad hoc group on assessing sustainable development impacts of insect resistant LMOs. The ad hoc group discussed environmental, economic and societal considerations and considered how these should or could be assessed. The report from the group is scheduled for completion in 2011.

39. One of the challenges the country has faced in implementing its requirements for socio-economic assessments is a lack of information. It was pointed out that although Norway is not an EU member state, it receives the same dossiers submitted to the EU authorities. They described how this poses a major challenge to Norway's ability to assess the criteria of benefit to society, sustainability and ethics because information on socio-economic impacts is not required by the EU rules. A 2009 report to the Norwegian Directorate for Nature Management by Rosendal and Myhr[4] identified that information on sustainability and benefit to society is lacking in the documentation contained in LMO applications. The Norwegian representatives indicated that the authorities will continue to work towards a solution to this challenge.

40. A representative from Austria noted that in the Norwegian system, socio-economic information is weighed against health and environmental risks and associated uncertainties and irreversibility. The unfavourable opinions of the NBAB frequently mention a lack of both benefits to society and positive contributions to sustainable development, though health and environmental risks still seem to be the most important factors.

(viii) South Africa

41. In the English-language Africa real-time conference, an observer from the University of Pretoria noted that South Africa requires a socio-economic impact study in addition to a risk assessment when considering applications for GM commodity imports and general release. This requirement has only been added recently in order to implement Article 26 of the Protocol. The provision requires applicants to "Specify what, if any, positive or negative socio-economic impacts the GM plant will have on communities in the proposed region of release". He indicated that there are currently no guidelines on what exactly needs to be included. Furthermore, socio-economic studies submitted to date have been quite comprehensive and broader than the biodiversity focus.

[4] http://www.dirnat.no/content/582/Societal-Utility-and-Sustainable-Development.

42. In the online discussion groups, the representative from the *Gesellschaft für Internationale Zusammenarbeit* (GIZ) noted that South Africa had rejected an application for a variety of genetically modified wine yeast on the basis of socio-economic considerations.

(ix) Argentina

43. In the discussion groups, the representative of Argentina indicated that environmental and food safety assessments form the basis of the country's decisions on the agricultural use of LMOs. He noted, however, that Argentina's regulation also entails an assessment of the potential commercial impacts from the release of a GMO. Initially, the scope of the latter analysis mostly covered the potential hampering of Argentina's international trade; for example, impacts that could arise from a situation of "asymmetric authorizations" with trade partners. This was and continues to be a relevant socio-economic issue for Argentina, as a great proportion of their economy relies on exports of primary agricultural commodities.

44. He stated that the international situation and domestic experience have evolved during the last decade and, therefore, the current administration has updated the practice. The most important features of the current practice are:

- Most of the potential issues considered in the analysis would arise directly from human factors (regulations, choices, etc.) rather than from any impacts of GMOs on biodiversity. Although some methodological or empirical aspects of the Argentine experience may be useful, it cannot be presented as a paradigm of paragraph 1 of Article 26 of the Protocol.

- The analysis is completely separate from the environmental and food safety assessments. It has different goals, is performed within the context of different disciplines in a different timeframe, is reviewed by a dedicated staff and is handled in a separate dossier.

- The scope of the analysis has recently been broadened to include consideration of both the potential negative and positive impacts along the production and commercialization chain. The benefits cannot just be alleged; the applicant must provide information supporting the claimed benefits in such a way that it can be critically analysed by technical experts.

- Although the initial information is provided by the applicant, other governmental sources (e.g. on trade intelligence) as well as representatives of the production chain also provide information and points of view to help analyse, validate and fill any gaps in the initial information package.

- The study is mainly economic; however, this concept is not restricted to profitability or net returns to farmers through monetary gains. The analysis must also cover other issues like impacts on labour, food security, sustainability of production practices, public health, distributional aspects or intellectual property, as well as non-economic factors. For instance, a genetically pest-protected crop would likely reduce the farmer's costs (and ultimately, the cost of food for the consumer, in Argentina and abroad), and this may be considered in the economic aspects. However, the reduction in the use of chemical insecticides (and their broad negative effects on non-target organisms) is also taken into account as a potential benefit of the technology for the environment and, potentially, public health.

- Potential benefits are not the leading criteria of the analysis, they are only considered as a counterweight to potential commercial pitfalls. Argentina's view is that there should not be a requirement for one technology to show advantages over others before being allowed on the market.

(x) United States of America

45. In the online discussion groups, some participants indicated that socio-economic considerations in decision-making on LMOs have been raised in litigation over decisions in the United States on genetically modified alfalfa and sugar beets. The representative from the University of Washington noted that in both instances, the courts have held that the government failed to fully assess the environmental, human health and socio-economic impacts of the LMOs and required the relevant agencies to do so.

46. The representative from the Centre for Science in the Public Interest pointed to the country's National Environmental Policy Act (NEPA) – a procedural statute that requires government agencies to conduct an environmental assessment of the action they are taking. This assessment can take the form of either an Environmental Assessment (EA) and a Finding of No Significant Impact (FONSI) or an Environmental Impact Study (EIS). The latter is very involved and can take several years to complete.

47. In an EA or EIS, the government does not limit itself to the potential environmental risks of an action. It also assesses the benefits of the action as well as some of its economic impacts and impacts on humans. For example, the United States Department of Agriculture (USDA) recently completed an EIS for herbicide-tolerant alfalfa that looked not just at potential environmental risks but also the benefits to farmers, the potential impact on organic and conventional alfalfa growers, the seed supply for different varieties of alfalfa and other issues.

48. Under NEPA, if the EIS identifies impacts from the agency's decision, then the applicant can propose actions to mitigate those impacts. Because NEPA is a procedural statute, however, the assessment done under it does not factor into the government agency's decision to approve the action before it. Therefore, while the USDA assessed the impact of genetically modified alfalfa in an EIS, it made its decision on whether to approve the alfalfa for commercial planting based on whether it was a "plant pest" according to its regulations and statute.

B. Ex post *assessments, including co-existence*

(i) European Union

49. A number of participants in the discussion groups as well as the WEOG and CEE real-time conference described the situation in the EU. Decisions on the placing on the market of LMOs for import or cultivation are taken at the EU-level rather than by the individual EU member states. The current EU directive governing decision-making on GMOs for intentional release into the environment does not include provisions allowing the incorporation of socio-economic considerations in decision-making. It does, however, provide the possibility to take "other legitimate factors" into account when deciding on the authorization of a GMO. So far, there is no practical example indicating which factors could be taken into account and what data need to be provided. There is a common understanding that these "other legitimate factors" include possible socio-economic effects, among other things.

50. Once a genetically modified organism has been approved by the EU, the member States can apply co-existence rules to regulate the actual planting of genetically modified crops. A European Commission recommendation of July 2010 on co-existence of genetically modified crops with conventional and organic crops gives flexibility to the member States to define co-existence measures to avoid the unintended presence of genetically modified organisms. According to the recommendation, the "objective of co-existence measures in areas where GMOs are cultivated is to avoid unintended presence

of GMOs in other products, preventing the potential economic loss and impact of the admixture of GM and non-GM crops (including organic crops)." [5]

51. The recommendation confirms the role of the European Co-existence Bureau (ECoB), which is based in the Joint Research Centre of the European Commission, to develop together with member states best agricultural practices for co-existence as well as to provide technical guidelines on related issues. The ECoB has produced the first EU-level consensus on best agricultural practices for co-existence in maize production. The document is not legally binding.

52. There are also ongoing discussions in the European Union to amend the directive for the intentional release of genetically modified organisms into the environment to include other aspects as part of decision-making to restrict or prohibit the cultivation of such organisms. No final approach has been adopted, however.

(ii) Austria

53. Information from Austria stated that the legislative and executive power with regard to co-existence rules rests with the country's nine federal provinces (Bundesländer), all of which have adopted co-existence legislation. A representative of Austria in the WEOG and CEE real-time conference added that the legislation foresees a number of additional requirements for cultivating genetically modified crops.[6]

(iii) Belgium

54. According to the representative of Belgium in the WEOG and CEE real-time conference, co-existence rules have been developed separately by the country's Flemish and Walloon regions, which are competent for most agricultural matters. Required separation distances between genetically modified and non- genetically-modified maize fields, for example, are very different in the co-existence rules of the two regions. The two regions are presently trying to develop co-existence agreements to govern their border areas.

(iv) Czech Republic

55. The submission from the European Union indicated that genetically modified maize (MON 810 resistant to European corn borer) and genetically modified potatoes (Amflora potatoes with an altered amylopectin content) have been grown in the Czech Republic since 2005 and 2010, respectively. The cultivation is regulated through co-existence rules and the Czech Republic follows the European Commission Recommendation on co-existence of genetically modified crops with conventional and organic crops. The co-existence guidelines in the Czech Republic include specific approaches to the cultivation of genetically modified maize and genetically modified potatoes. Measures for other genetically modified crops will be included in the guidelines after the crops are approved at the European Union level.

56. The submission indicated that the aim of the co-existence guidelines is to minimise the potential economic losses connected with the increased use of genetically modified crops. The Ministry of Agriculture has defined ten basic principles for the cultivation of genetically modified crops:

[5] Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in convention and organic crops, 2010/C 200/01 at recital 4.

[6] The legislation may be accessed in German at http://www.bmg.gv.at/home/Schwerpunkte/Gentechnik/Rechtsvorschriften_in_Oesterreich/Gentechnik_Vorsorgegesetze_der_Laender.

(a) Notify the Ministry of Agriculture before sowing/planting genetically modified crops;;

(b) Notify the neighbouring farmers before sowing/planting genetically modified crop;

(c) Keep the prescribed isolation distance between genetically modified crop and the fields with the same non-genetically-modified species and/or surround the plantings of genetically modified organisms with a buffer strip of the same conventional crop;

(d) Keep the prescribed isolation distance between genetically modified crop and the fields with the same species crop grown organically;

(e) Notify the Ministry of Agriculture after sowing/planting genetically modified crop;

(f) Notify the neighbouring farmers after sowing/planting genetically modified crop;

(g) Inform the Ministry of the Environment about the location of genetically modified crop cultivation;

(h) Mark the locality of GM crop cultivation;

(i) Label the genetically modified crop product;

(j) Keep records and store data on growing and further use of GM crop and its products.

(v) Germany

57. The representative of GIZ in the WEOG and CEE real-time conference stated that Germany has a federal sub-law regulation (Rules on Good Agricultural Practise amended by the *Gentechnik-Pflanzenerzeugungs-Verordnung* of April 2008) establishing the framework for co-existence rules with regard to GM maize cultivation (e.g. 150m distance to conventional maize and 300m distance to organic maize). As a federal country, Germany gives some autonomy to its states in matters of agriculture and environment. Some of the states have used this autonomy to set up additional co-existence rules based on the federal framework.

(vi) Spain

58. The representative of Spain in the WEOG and CEE real-time conference stated that the country does not have experience with socio-economic considerations in decision-making since no provision has been included in the Biosafety Legislation. Spain does, however, include co-existence measures in a case-by-case analysis as a condition for authorizing the environmental release of an LMO. This is done taking into account the crop, the ecosystem and regional economic activities.

III. INFORMATION REGARDING COUNTRIES THAT HAVE PROVISIONS FOR INCLUDING SOCIO-ECONOMIC CONSIDERATIONS IN DECISION-MAKING BUT WHERE THESE PROVISIONS HAVE NOT BEEN PUT INTO PRACTICE

59. The section synthesises information regarding countries that have provisions in their regulatory frameworks for including socio-economic considerations in biosafety decision-making but where these provisions have not been used. Information is provided on the following Parties: Austria, Brazil, Colombia, Egypt, Liberia, Mexico, Niger, Panama, Sudan, Togo and Zimbabwe; and the following non-Party: Uruguay.

(i) Austria

60. A representative of Austria in the online discussion groups pointed to a provision in the Austrian law on genetically modified organisms allowing decision makers to ban the marketing of products considered 'socially unsustainable' (*sozial unverträglich*) – referring to social, economic and ethical aspects. The meaning of this provision has never been clarified and it may conflict with EU legislation. In no case has an explicit reference to this provision been made, which could thus be considered void. In case of an EU policy change, e.g., allowing for national assessments of socio-economic impacts of genetically modified organisms, this provision could become an interesting reference.

61. The information submitted by Austria indicated that the country's main concerns with regard to possible socio-economic impacts of living modified organisms are linked to the country's agricultural structure in which the average farm size is small and includes a high proportion of organic farming. The country is of the view that cultivation of living modified organisms might lead to higher production costs for organic farmers and other farmers who produce products free of living modified organisms due to higher control costs and precautionary measures to avoid contamination. These higher costs may jeopardize the efforts by farmers to choose a production system that does not use living modified organisms.

(ii) Brazil

62. During the online discussion groups, the representative from IFPRI reported that Brazil's Biosafety Law No. 11.105 approved in 2005 considers two distinct bodies for the regulation of GMOs. The first is the National Biosafety Technical Commission (CTNBio), a technical body and one of the competent national authorities. The second is the National Biosafety Council (CNBS), an independent body formed by ministers and designated experts. CTNBio approves new genetically modified organisms by assessing impacts on human and animal health and the environment. The CNBS decides on commercial deployment if any social or economic issues are raised during the evaluation process.

(iii) Colombia

63. The representative of Colombia in the real-time conference for Latin America and Caribbean reported that socio-economic issues are not included in the country's current regulatory framework for assessments of living modified organisms and any information on these issues is only provided on a voluntary basis. She did note, however, that for the development of any project, work or activity in the collective territories of black or indigenous communities, the prior informed consent of these communities must be obtained through a consultation mechanism. Furthermore, there is an express prohibition against planting genetically modified corn in their territories.

(iv) Egypt

64. The representative of Egypt in the English-language Africa real-time conference stated that the draft Egyptian National Biosafety law integrates socio-economic considerations into the risk assessment procedures and hence into decision-making. Risk assessment must be conducted "in a transparent and scientifically sound manner" and should also "identify risks which are uncertain or unknown (e.g., due to a lack of appropriate data)". Risk assessment must take place in the potential receiving environment and it covers six major topics including "human activities in that environment".

65. In Egypt, the overseeing structure (the National Committee for Consideration of GMO Applications) is empowered to call on specialists with relevant expertise to participate in discussions on specific applications and to hold public hearings on its own initiative or upon requests from the public, where socio-economic elements (including religious, national security, etc.) could be raised. Presentations during such hearings have to be evidence-based but no set criteria are required beforehand.

66. He pointed to two goals that the country wishes to achieve by taking socio-economic considerations into account in decision-making on living modified organisms:

(a) Ensuring the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities;

(b) Reducing, mitigating and, as much as possible, preventing all potential adverse effects of living modified organisms, including potential adverse effects on rural livelihoods, public health and food sovereignty, taking into account the specific context of national consumer habits, patterns and practices.

(v) Liberia

67. In the English-language Africa real-time conference, the representative of Liberia cited the following provisions on decision-making from his country's draft Biosafety Act:

> "No approval shall be given unless it is considered and duly determined by the Competent Authority that the import, transit, contained use, release or placing on the market of the genetically modified organism or the product of the genetically modified organism:
>
> (a) Shall benefit Liberia without causing significant risk to human health, biological diversity and in general the environment;
>
> (b) Shall contribute to sustainable development;
>
> (c) Shall not have adverse socio-economic impacts; and
>
> (d) Shall accord with the ethical values and concerns of communities and does not undermine community knowledge and technologies."

68. He also quoted the relevant liability provision:

> "Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism or product thereof to economic, social or culture conditions, including negative impact on the livelihood or indigenous knowledge systems or technologies of a community or communities or damage or destruction arising from incidence of public disorder triggered by the genetically modified organism or product

thereof, disruption or damage to production or agriculture systems, reduction in yields, soil contamination, damage to biodiversity, damage to the economy of an area or community, and any other consequential damage."

69. He listed three goals that Liberia seeks to achieve through socio-economic considerations in its biosafety requirements:

(a) Protection of human health from possible adverse effect of living modified organisms;

(b) Ensuring sustainable livelihoods of local and vulnerable communities from potential adverse effects; and

(c) Maintaining traditional knowledge, cultural values and norms which have significantly contributed to biodiversity.

(vi) Mexico

70. In the online discussion groups, a representative of the observer organization *Unión de Científicos Comprometidos con la Sociedad* described how the system for decision-making on LMOs is structured following the enactment in 2005 of the Law on Biosafety of GMOs (*Ley de Bioseguridad de Organismos Genéticamente Modificados*, LBOGM). Under the law, the Interministerial Commission on Biosafety of Genetically Modified Organisms (*Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados*, CIBIOGEM) is the highest decision-making body on LMOs in Mexico. CIBIOGEM consists of the Ministers of Agriculture, Ecology, Health, and Treasury and the Director General of the National Council of Science and Technology (CONACYT).

71. Two other entities are also mandated by the law: a Scientific Consulting Council whose conclusions are binding on CIBIOGEM, and a Stakeholder Consulting Council whose conclusions are non-binding. The LBOGM also mandates CIBIOGEM to stimulate the development of national, scientific and technical capabilities and research on biosafety and biotechnology. Such research includes: a) risk evaluation of LMOs for introduction into the environment, biodiversity, health and socio-economic considerations; and b) evaluating and testing the information provided by the LMO industry. It is also mandated that native maize landraces should have special protection as Mexico is the centre of origin and genetic diversity of maize and because of its status as the basic staple food for Mexicans.

72. He indicated that under the law, the process for decision-making takes into account socio-economic considerations, as well as biodiversity, human health and the ecosystem. A representative of Mexico the LAC real-time conference commented that while socio-economic considerations are included in the country's biosafety law, they have not been implemented in practice.

73. Another representative of Mexico in the LAC real-time conference noted that CIBIOGEM had recently opened two calls for proposals for research on the topics of "Economic, social and cultural impacts from the possible introduction of corn and other genetically modified species to Mexico" and "Cost-benefit analysis of the potential use of genetically modified maize in Mexico". He elaborated that the cost-benefit analysis required is a comprehensive analysis in the sense that the interest is not only in accounting matters such as input costs, but it also seeks to quantify potential costs and benefits to all stakeholders involved or affected in society. He felt that the results of this research could serve as a good basis for considering the potential inclusion of socio-economic considerations in decision-making.

(vii) Niger

74. During the informal real-time discussion among French-language participants from Africa,[7] the representative of Niger indicated that his country has a national biosafety framework that takes socio-economic considerations into account. This framework was harmonized with the West African Economic and Monetary Union (UEMOA) legal framework as the introduction of Bt cotton has had multiple impacts on the environment and society.

75. He noted that the UEMOA legal framework was developed in order to prepare member countries for the eventual impacts of living modified organisms. He stated that the impacts might be positive or negative; hence the need for efficient and appropriate regulations.

(viii) Panama

76. During the LAC real-time conference, the representative from the Panamanian Authority for Food Safety (*Autoridad Panameña de Seguridad de Alimentos*) stated that his country is currently working on strengthening the National Biosafety Commission. The structure of the Commission allows the participation of civil society in the public consultation process, however, in practice, this consultation still needs to be effectively implemented, particularly with regard to socio-economic considerations.

(ix) Sudan

77. During the English-language Africa real-time conference, the representative of Sudan stated that his country's biosafety law has an article for socio-economic considerations in the risk assessment of GMOs. He provided a translation of the relevant definitions from the law:

> "Risk assessment" means the evaluation of direct and indirect risks, in the short, medium or long term, to human health, biodiversity or the environment, including social and economic conditions, or ethical values resulting from importation, exportation, restricted use, and release or marketing of genetically modified organism or a product of a genetically modified organism;
>
> "Socio-economic impact" means the direct or indirect effects of a genetically modified organism or a product of a genetically modified organism on the economy or the social conditions.

78. He provided examples of possible socio-economic considerations under Sudan's law: impact on the maintenance of farmers' varieties and local landraces due to domination by genetically modified varieties; farmers' ability to cover the cost of genetically modified seeds every year; and effects on incomes due to technologies where less labour is needed (e.g. herbicide tolerance).

(x) Togo

79. During the informal discussion among French-language participants from Africa, the representative from the Togolese Initiative for Sustainable Development (*Initiative Togolaise pour le Developpement Durable*) stated that Togo had incorporated socio-economic considerations in its national biosafety framework and law. He cited some relevant provisions from the national biosafety policy:

- develop and make operational assessment mechanisms and management for biosafety, taking into account environmental, health, social, economic and cultural concerns;

[7] An insufficient number of participants were present for the French-language Africa real-time conference to take place. An informal discussion was held among those who were present and the relevant information has been included here.

- the competent authority must ensure risk assessment, protection of human health, preservation of biodiversity, maintenance of the balance of the socio-economic environment and the conservation of cultural norms.

80. He indicated that Togo does not have experience in the implementation of socio-economic considerations regarding biosafety; however, a general assessment was made during the process of developing the national biosafety framework. It showed that the use of biotechnology is currently limited to traditional biotechnology: plant and animal production, fisheries, the food industry and human health.

81. He stated that, in general, by taking socio-economic considerations into account, Togo seeks to ensure that the production, introduction and use of LMOs is conducted in an ethical and socially and culturally justifiable manner in accordance with the principles of sustainable development and without adverse effects on the environment and health. Specific goals are to:

- preserve biodiversity;
- respect, preserve and maintain the knowledge, innovations and practices of local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity;
- promote the application of traditional knowledge;
- ensure equitable benefit-sharing; and
- protect human health.

(xi) Zimbabwe

82. During the Africa English-language real-time conference, the representative from Zimbabwe noted that his country has specific provisions in its policy and legal framework for socio-economic issues to be taken into account in biosafety decision-making. He stated that Zimbabwe's goals concern sustainable development, for example, how development can come with minimal negative impacts on households, communities, the environment and the national economy. The key considerations are: market access, food security, sustainable livelihoods, freedom of choice, equity and sustainable agriculture.

(xii) Uruguay

83. The representative from the Action Network on Pesticides and Alternatives for Latin America (*Red de Acción en Plaguicidas y sus Alternativas para América Latina*) stated in the LAC real-time conference that Uruguay has conducted public consultations on the approval of new GM crops and socio-economic impacts have been included in these consultations. She noted that this does not mean that the views have been taken into account and publicity for the consultations has been very limited. In addition, some government entities in the Biosafety Cabinet have argued against the approval of these new crops but the crops have nevertheless been approved and the contrary opinions were not taken into account.
