

Distr. GENERAL

CBD/CP/SEC/AHTEG/2017/1/3\* 27 October 2017

**ENGLISH ONLY** 

AD HOC TECHNICAL EXPERT GROUP ON SOCIO-ECONOMIC CONSIDERATIONS Ljubljana, 9-13 October 2017

# REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SOCIO-ECONOMIC CONSIDERATIONS

#### INTRODUCTION

- 1. At its eighth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopted <u>decision CP-VIII/13</u> extending the mandate of the Ad Hoc Technical Expert Group (AHTEG) on Socio-economic Considerations to allow it to meet face-to-face to work on the guidelines envisaged under the outcomes of the operational objective 1.7 of the Strategic Plan for the Cartagena Protocol on Biosafety.<sup>1</sup>
- 2. Accordingly, the meeting of the AHTEG on Socio-economic Considerations was held in Ljubljana from 9 to 13 October 2017. It was attended by 23 experts from the following Parties: Austria; Belarus; Bolivia (Plurinational State of); Brazil; China; Dominican Republic; European Union; France; Germany; Honduras; Hungary; India; Mauritania; Mexico; Niger; Nigeria; Norway; Philippines; Republic of Korea; Republic of Moldova; Slovenia; South Africa; and Thailand. It was also attended by five experts from the following observer countries and organizations: Canada; Third World Network; Global Industry Coalition; GENØK Centre for Biosafety; and International Indigenous Forum on Biodiversity. The list of participants is contained in annex I.

#### ITEM 1. OPENING OF THE MEETING

- 3. The meeting was opened by the Co-Chairs, Mr. Andreas Heissenberger (Austria) and Ms. Ranjini Warrier (India) at 9:30 a.m. on Monday, 9 October 2017. Welcoming the participants, Ms. Warrier recalled the work and mandate of the AHTEG as set out in decisions of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.
- 4. Ms. Tanja Bolte, Director-General of the Environment Directorate at the Ministry of the Environment and Spatial Planning of Slovenia, made opening remarks, welcoming the participants to Slovenia. She stressed that the expertise of the participants was of great significance to developing guidance on the process for assessing socio-economic considerations. She wished the experts fruitful discussions.
- 5. A representative of the Secretariat addressed the Group on behalf of Ms. Cristiana Paşca Palmer, Executive Secretary of the Convention on Biological Diversity. She encouraged experts to seek to build bridges and jointly develop an outcome that responded to the ambitious objective of the meeting for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its ninth meeting and which will help countries seeking guidance in this area. She expressed her gratitude to the Government of Slovenia for hosting the meeting and thanked the Governments of Finland, France and

<sup>\*</sup> Reissued for technical reasons on 23 January 2018.

<sup>&</sup>lt;sup>1</sup> http://bch.cbd.int/protocol/issues/cpb\_stplan\_txt.shtml.

the Netherlands as well as the European Union for their generous financial support, which had enabled the participation of experts from developing countries and from an indigenous peoples and local communities' organization.

# ITEM 2. ORGANIZATIONAL MATTERS

# 2.1 Adoption of the agenda

6. The provisional agenda for the meeting (<u>CBD/CP/SEC/AHTEG/2017/1/1</u>) was adopted without amendment.

# 2.2 Organization of work

7. The proposed organization of work as contained in the annex to the annotated provisional agenda (CBD/CP/SEC/AHTEG/2017/1/1/Add.1) was also adopted without amendment.

# ITEM 3. GUIDANCE ON THE ASSESSMENT OF SOCIO-ECONOMIC CONSIDERATIONS IN THE CONTEXT OF ARTICLE 26 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

- 8. Under this item, the Co-Chairs introduced the text entitled "Draft guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" (CBD/CP/SEC/AHTEG/2017/1/2, annex). The Co-Chairs provided further information on the development of the text, which they had prepared to facilitate the discussions of the AHTEG. They explained that the document was based on previous outcomes of the work of the AHTEG, in particular the "Revised Framework for Conceptual Clarity", which had been noted by the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-VIII/13 and also taking into account information provided during the online discussion of the AHTEG. They also explained that submissions made in response to notification 2017-39<sup>4</sup> as well as other existing guidance documents made available on the Portal on socio-economic considerations had been considered in drafting the Co-Chairs' text.<sup>5</sup>
- 9. Mr. Heissenberger further indicated the Co-Chairs had chosen to follow a process-based approach in the document, i.e. to focus on how an assessment could be performed, rather than focusing on parameters to be assessed, as the latter highly depended on regional and national circumstances.
- 10. The AHTEG considered the Co-Chairs' text and agreed that the process-based approach in the Co-Chairs' text was a constructive way forward.
- 11. The AHTEG elaborated the assessment process contained in the document and revised the sections on "introduction and objective" as well as the "principles for the assessment of socio-economic considerations."
- 12. During the deliberations, some experts proposed including language on the precautionary approach in the Co-Chairs' text. While agreeing on the importance of the issue, other members did not agree to include that language, as they felt that the precautionary principle addresses decision-making while the Guidance focuses on the process for conducting a socio-economic assessment.
- 13. Furthermore, an expert did not support the inclusion of the examples in the list of areas that can be encompassed by the assessment.<sup>6</sup>
- 14. Following extensive deliberations, the AHTEG agreed on the draft "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety", as contained in annex II below.

The online discussion is available at: <a href="http://bch.cbd.int/onlineconferences/portal">http://bch.cbd.int/onlineconferences/portal</a> art26/ahteg discussion/

<sup>&</sup>lt;sup>2</sup> <u>UNEP/CBD/BS/COP-MOP/8/13</u>.

<sup>&</sup>lt;sup>4</sup> The submissions are available at: http://bch.cbd.int/protocol/cpb\_art26\_submissions/AHTEG2.shtml

<sup>&</sup>lt;sup>5</sup> http://bch.cbd.int/onlineconferences/portal\_art26/ahteg/

<sup>&</sup>lt;sup>6</sup> Contained in step 1 (Scoping) of Stage B (Assessment and evaluation) of the assessment process (see annex II below).

- 15. The AHTEG recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:
- (a) Consider the report of the meeting, including the draft "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety", as contained in annex II;
- (b) Invite Parties and other Governments to make use, if applicable, of the "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety".
- 16. The AHTEG noted that further work was needed to supplement the "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety", in particular on the application of methodologies and examples of application of socio-economic considerations, and recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:
- (a) Invite Parties, other Governments and organizations to submit examples of methodologies and applications of socio-economic considerations in the light of the elements of the "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" and request the Executive Secretary to compile the information submitted;
- (b) Consider the utility of extending the mandate of the AHTEG to supplement the "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" making use of the information submitted.

# ITEM 4. OTHER MATTERS

17. The Co-Chairs asked the participants if they had any other matters they wished to raise that were relevant to the agenda of the meeting. No other matters were raised.

# ITEM 5. ADOPTION OF THE REPORT

18. The participants adopted the report of the meeting as orally amended.

#### ITEM 6. CLOSURE OF THE MEETING

19. Following brief closing remarks by the representatives of the Government of Slovenia and the Secretariat, the Co-Chairs declared the meeting closed at 3 p.m. on Friday, 13 October 2017.

#### Annex I

#### LIST OF PARTICIPANTS

#### **PARTIES**

#### Austria

1. Mr. Andreas Heissenberger Environment Agency Austria Spittelauer Lände 5

Vienna A-1090, Austria Tel.: +43 1 31304 3032 Fax: +43 1 31304 3700

Email: andreas.heissenberger@umweltbundesamt.at

#### Belarus

2. Ms. Galina Mozgova

Head of the National Co-ordination

**Biosafety Centre** 

Institute of Genetics and Cytology

National Academy of Sciences of Belarus

27 Akademicheskaya Minsk 220072, Belarus Tel.: +375172840297 Fax: +375172841917

Email: g.mozgova@yandex.ru g.mozgova@igc.by

# **Bolivia (Plurinational State of)**

3. Ms. Georgina Catacora Vargas

Viceministerio de Medio Ambiente, Biodiversidad, Cambios Climáticos y de Gestión y Desarrollo Forestal

Ministerio de Medio Ambiente y Agua Calle Strongest No. 1878, La Paz, Bolivia Tel. +591-2-2146382/85 - Int. 685

Email: g.catacora@gmail.com

# **Brazil**

4. Ms. Fernanda Antinolfi Lovato

Fiscal Federal Agropecuário, D. Sc. Department of Plant Health Protection

Ministry of Agriculture, Livestock and Food Supply

Esplanada dos Ministérios, Bloco "D", Anexo B,

Brasilia DF 70043-900, Brazil

Tel.: +61 3218-2330

Email: fernanda.lovato@agricultura.gov.br

#### China

5. Mr. Jintao Zhan

Associate Professor

College of Economics and Management

Nanjing Agricultural University

Nanjing, China

Tel.: (86 25) 84396687

Email: jintao.zhan@njau.edu.cn

# **Dominican Republic**

6. Mr. Genaro Antonio Reynoso Castillo

Director

Centro de Tecnología Agrícola

Instituto Dominicano de Investigaciones

Agropecuarias y Forestales

1, Calle Primera No. 8, Las Pradesas

Santo Domingo, Dominican Republic

Tel.: +809 564 4401

Email: greynoso@idiaf.org.do

genaro.555@gmail.com

antonio55@yahoo.com

#### **European Union**

7. Mr. Pablo Pindado

Policy Officer - Biotechnology DG SANTE - Unit 3: Biotechnology

European Commission

Avenue de Beaulieu 5

Brussels B-1049, Belgium

Tel.: + 32 2 296 8753

Email: pablo.pindado-carrion@ec.europa.eu

#### France

8. Mr. Martin Remondet

Chargé de mission

Comité Économique, Éthique et Social

Haut Conseil des biotechnologies

3, place de Fontenoy Paris 75007, France

Tel.: +33 1 44 49 84 70

Email: martin.remondet@hautconseildesbiotechnologies.fr

# Germany

9. Ms. Nicola Consmüller

Agricultural Economist

Department of Genetic Engineering,

Unit Coexistence

GMO Monitoring and Database Management

Federal Office of Consumer Protection and Food

Safety

Mauerstrasse 39-42

Berlin D-10117, Germany

Tel.: 49 30 18445 6402

Email: nicola.consmueller@bvl.bund.de

#### **Honduras**

10. Mr. Carlos Alberto Almendares Ordóñez

Jefe de Departamento de Certificación de Semillas Departamento de Certificación de Semillas, Servicio Nacional de Sanidad Agropecuaria (SENASA)

Secretaría de Agricultura y Ganadería Colonial El Hogar, 5ta. Calle, casa No. 2908

Tegucigalpa, Honduras Tel.: +504 33942546

Email: calmendares81@yahoo.com

# Hungary

11. Ms. Rita Andorkó

GMO expert

Department of Nature Conservation, Biodiversity and Gene Conservation Unit

Ministry of Agriculture Kossuth Lajos ter 11 Budapest 1055, Hungary

Tel.: +36-1-795-3726 Fax: +36-1-795-0069

Email: <u>rita.andorko@fm.gov.hu</u> <u>andorko.rita@gmail.com</u>

#### India

12. Ms. Ranjini Warrier

Former Adviser

Ministry of Environment, Forests and Climate

Change

Indira Paryavaran Bhavan, Jor Bagh Road

New Delhi 110003

India

Email: ranjiniw@yahoo.com

#### Mauritania

13. Mr. Ossama AbdelKawy

Conseiller Scientifique

Ministère de l'Environnement et du

Développement Durable

B.P. 170, Nouakchott, Mauritania

Tel.: +201111561456

Email: abdkawy@yahoo.com,

elkawyo@gmail.com

#### Mexico

14. Ms. Natalhie Beatriz Campos Reales Pineda

Directora de Políticas y Normatividad Secretaría Ejecutiva CIBIOGEM

Comisión Intersecretarial de Bioseguridad de los

Organismos Genéticamente Modificados

San Borja 938, Del Valle, Benito Juárez

México D.F. 03100, Mexico

Email: ncampos@conacyt.mx, becnat@yahoo.com

# Niger

15. Mr. Mahaman Gado Zaki

Point Focal National de Biosécurité Direction Générale des Eaux et Forêts Ministère de l'Environnement et du Développement Durable

Tel.: +227 96 11 04 15 Fax: +227 20 72 37 63

Email: mahamane\_gado@yahoo.fr

# Nigeria

16. Mr. Abisabo Adamu

Acting Head, Planning, Research and Statistics National Biosafety Management Agency

Nigeria National Park Service Airport Expressway, P.M.B 0258 Garki Abuja, FET, Nigeria

Tel.: +2348068135250

Email: anohogye@yahoo.com

# **Norway**

17. Mr. Casper Linnestad

Senior Adviser

Ministry of Climate and Environment P.O. Box 8013 DEP. Kongens GT.20

Oslo N-0030, Norway Tel.: +47 22 24 58 95

Email: <a href="mailto:casper.linnestad@kld.dep.no">casper.linnestad@kld.dep.no</a>

# **Philippines**

18. Mr. Leonardo A. Gonzales

President

STRIVE Foundation

One Tepeyac Place, Governor San Luis Road

Putho-tuntungin

Los Baños Laguna, Philippines

Tel.: +6349 536 9242 Fax: +6349 536 5535

Email: lag@strivefoundation.com

# Republic of Korea

19. Mr. Hong-Tak Lim

Research Professor

Korea Advanced Institute of Science

and Technology Republic of Korea Tel.: +82 10 3326 4478

Fax: +82 42 350 6339 Email: htlim@kaist.ac.kr

# Republic of Moldova

20. Ms. Angela Lozan

Head of the Biosafety Office Ministry of Environment 9, Cosmonautilo Str. Chisinau MD-2005

Republic of Moldova Tel.: +373 22 226874 Fax: +373 22 226874

Email: angelalozan@yahoo.com

#### Slovenia

21. Mr. Martin Batič

Head of Biotechnology Unit

Ministry of Environment and Spatial Planning

Dunajska 48 Ljubljana 1000

Slovenia

Tel.: +386 1 478 74 02 Fax: +386 1 478 74 25 Email: martin.batic@gov.si

#### **South Africa**

22. Mr. Ben David Durham

Chief Director Bio-innovation

Department of Science and Technology

Private Bag X 894, Pretoria Pretoria 0001 Gauteng 0001

South Africa

Tel.: +27 83 653 4422 Fax: +24 86 681 0018

Email: ben.durham@dst.gov.za

#### **Thailand**

23. Ms. Praopan Tongsom

Former Director

**Biological Diversity Division** 

Office of Natural Resources and Environmental

Policy and Planning

60/1 Soi Phibun Wattana 7, Phayathai, Rama 4

Bangkok 10400, Thailand Email: ga\_prao@hotmail.com

#### **NON-PARTIES**

# Canada

24. Ms. Catherine Walter

Senior Trade Policy Analyst Technical Trade Policy Division, Market and Industry Services Branch Agriculture and Agri-Food Canada 930 Carling Avenue Ottawa, ON K1A 0C5

Canada

Tel.: 613-773-0771

Email: catherine.walter@canada.ca

#### **ORGANIZATIONS**

#### GenØk - Centre for Biosafety

25. Ms. Rosa Binimelis

Society, Ecology and Ethics Research

Department

GenØk - Centre for Biosafety

P.O. Box. 6418 Tromsø 9294 Norway

Email: rosa.binimelis.adell@genok.no

rosa.b.adell@uit.no

# **Global Industry Coalition**

26. Mr. Eric Sachs

Global Industry Coalition c/o CropLife International 1156 15th Street NW, Suite 400 Washington, DC 20005

United States of America

Email: eric.s.sachs@gmail.com

# International Indigenous Forum on Biodiversity

27. Ms. June Batang-ay Tebtebba Foundation

No 1 Roman Ayson Road

Baguio City 2600

Philippines

Email: june@tebtebba.org

# **Third World Network**

28. Ms. Li Ching Lim

Researcher

Third World Network

B-05-03, 3 Two Square, No. 2, Jalan 19/1

Petaling Jaya, Kuala Lumpur 46300

Malaysia

Tel.: +603 7955 5220 Fax: +603 7955 3220

Email: ching@twnetwork.org,

twnet@po.jaring.my

Web: www.twnside.org.sg

# SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY

29. Mr. Peter Deupmann

Legal Officer

Secretariat of the Convention on

Biological Diversity

413, Saint-Jacques Street W., Suite 600

Montreal, Quebec H2Y 1N9

Canada

Tel: +1 514 764 6365

Email: peter.deupmann@cbd.int

30. Ms. Kathryn Garforth

Legal and Policy Officer

Secretariat of the Convention on

**Biological Diversity** 

413, Saint-Jacques Street W., Suite 600

Montreal, Quebec H2Y 1N9

Canada

Tel.: +1 514 287 7030

Email: kathryn.garforth@cbd.int

31. Ms. Paola Scarone

Programme Assistant

Secretariat of the Convention on

**Biological Diversity** 

413, Saint-Jacques Street W., Suite 600

Montreal, Quebec H2Y 1N9

Canada

Tel.: +514 287-8702

Email: paola.scarone@cbd.int

#### Annex II

# GUIDANCE ON THE ASSESSMENT OF SOCIO-ECONOMIC CONSIDERATIONS IN THE CONTEXT OF ARTICLE 26 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

# Introduction and objective

Article 26, paragraph 1, of the Cartagena Protocol on Biosafety states: "The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

Parties have a right to take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, although Article 26 does not impose an obligation on Parties to do so.

This document is aimed at providing guidance on the process for assessing socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous peoples and local communities. The document also provides an operational definition and lists important principles for the process of assessing socio-economic effects.

# **Operational definition**

Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on national or regional circumstances and on national measures to implement the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as ecological and health-related aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol.

# Principles for the assessment of socio-economic considerations

If a Party chooses to take socio-economic considerations into account, then there are certain aspects of an assessment of socio-economic effects which should be considered:

- 1. Taking socio-economic considerations into account in decision-making on the import of living modified organisms must be consistent with relevant international obligations, which include, inter alia, trade agreements, environmental agreements and human rights agreements.
- 2. Taking socio-economic considerations into account in decision-making on the import of living modified organisms should be consistent with existing national regulatory frameworks and policies.
- 3. In taking into account socio-economic considerations, Parties should consider their local and national circumstances, priorities and needs as well as, if applicable, regional circumstances, priorities and needs. Such circumstances, priorities and needs could include different cultural practices and religious beliefs and practices as well as indigenous, traditional and local knowledge and practices, in particular those related to the value of biological diversity to indigenous peoples and local communities.
- 4. The assessment process of socio-economic considerations should be science-based and evidence-based and lead to defendable results.
- 5. Lack of knowledge, scientific consensus or information on socio-economic effects should not necessarily be interpreted as indicating a particular positive or negative effect, or an absence of an effect.
- 6. The assessment of socio-economic considerations and the risk assessment may be conducted concurrently, consecutively or in an integrated manner, as applicable. Planning and conducting a risk assessment and an assessment of socio-economic considerations may be complementary and both may contribute to the decision-making process.

- 7. Article 23 of the Protocol creates obligations regarding public awareness, education and participation. Public participation and consultation, and access to information, may form part of the process of taking socio-economic considerations into account.
- 8. Where required by national regulatory frameworks, the assessment of socio-economic considerations should involve indigenous peoples and local communities, including obtaining their free, prior and informed consent for participation in the assessment, and their views on any potential introduction of the living modified organism into their territories, taking into account customary laws and community protocols.
- 9. The results of any assessment of socio-economic considerations associated with a decision on the import of living modified organisms may be subject to a review in the light of new relevant information or knowledge or a change in national policy or protection goals.

# The overall assessment process

The principles identified above apply throughout the assessment process. The assessment of socio-economic considerations should follow, like any other impact assessment, a systematic approach. This approach could include the following:

Stage A: Preparation for assessment

Stage B: Assessment and evaluation

Step 1: Scoping

Step 2: Assessment

Step 3: Evaluation of results and drawing conclusions

Stage C: Review and monitoring

The stages and steps, which set out an iterative process, are elaborated below.

Stage A: Preparation for assessment

This stage is meant to take stock of existing information and instruments and identify the actors to be involved in the assessment process. This stage is led by regulators and may include the involvement of stakeholders that may be engaged through consultative processes. The following activities may be carried out in the preparatory stage:

- (a) Identifying relevant national legal and policy instruments, as well as responsibilities, protection goals and socio-economic objectives, taking into account regional and international policy and legal instruments;
- (b) Deriving nationally relevant protection goals from regional and international instruments, in particular those provided in the Cartagena Protocol on Biosafety and the Convention on Biological Diversity, where national protection goals are absent;
  - (c) Identifying how national protection goals relate to socio-economic objectives;
- (d) Determining what information is needed to carry out the assessment as a basis for identifying what information is available and what information is missing;
- (e) Identifying relevant actors to be involved in the assessment, including outlining information flows between different actors and determining mechanisms for public participation, paying due regard to applicable requirements concerning free, prior and informed consent.

Stage B: Assessment and evaluation

Step 1: Scoping

This step is aimed at framing and defining the boundaries of the assessment based on the elements identified in Stage A. Scoping is led by regulators.

Based on a problem statement, possible socio-economic effects can be identified for consideration in the assessment. The assessment can encompass the following areas, as appropriate:

- Economic: e.g. effects on income;
- Social: e.g. effects on food security;
- Ecological: e.g. effects on ecosystem functions;
- Cultural/traditional/religious/ethical: e.g. effects on seed saving and exchange practices;
- Human health-related: e.g. effects on nutritional status.

In determining the boundaries of the assessment, the following could also be considered:

- Uses of the living modified organism (e.g. intended, expected);
- Alternatives to address the stated problem;
- Time scale:
- Geographical scale;
- Level of assessment (e.g. macro- or microeconomic, farm-scale, whole supply chain);
- Direct and/or indirect effects;
- Relevant stakeholders.

As the scope of the assessment highly depends on the national or regional circumstances and on national measures implementing the Protocol, it may vary considerably, but should in any case be determined at the beginning of the assessment in order to ensure the credibility and transparency of the process.

# Step 2: Assessment

In this step, the possible effects identified in the scoping step are assessed. The assessment may be led by regulators, or by assessors or by a combination of both and may include the involvement of stakeholders that may be engaged through consultative processes. The assessment of socio-economic effects can be carried out *ex ante*, *ex post* or both.

#### i. Methodology and data

A wide array of methodological approaches is available to assess socio-economic effects, including both quantitative and qualitative methods, as well as participatory approaches. Each method has strengths and limitations; therefore, a combination of different methods may be used, as appropriate. Factors which may influence the choice of the assessment include:

- (a) Information needs of decision makers;
- (b) Data availability (e.g. baselines and data linked to the context of introduction and use of the living modified organism);
- (c) Data sources (e.g. those derived from reports, literature, statistics, surveys and consultations as well as traditional, indigenous and local knowledge);
  - (d) Available assessment capacities.

Methods chosen should be science-based and evidence-based, or be based on other accepted approaches where scientific methods are not applicable, subject to national practices and requirements. Assessment methods should be reliable and applied in a transparent and verifiable manner and may be based on a comparative approach.

#### ii. Aspects of the assessment

The assessment of socio-economic effects may cover the following aspects:

- Relation between the impact of the living modified organism and the socio-economic effects;
- Beneficial or adverse nature of the effects;
- Likelihood of effects to occur;
- Intensity or magnitude of the effects;

- Possible downstream and cumulative effects;
- Reversibility of the effects;
- Mitigation of the effects;
- Effects on different communities and groups, in particular vulnerable or marginalized groups and indigenous peoples and local communities;
- Anticipated onset and duration of the effects (e.g. sustainability and persistence).

Step 3: Evaluation of results and drawing conclusions

The evaluation of results is meant to analyse the assessment outcomes in an integrated manner, taking into account the context of the introduction of the living modified organism. Based on the evaluation, conclusions are drawn which can be used in decision-making. This step is led by regulators.

The evaluation of assessment outcomes may be based on the following:

- Significance of evaluated effects;
- Distribution of effects among stakeholders;
- Limitations of the applied methods;
- Uncertainties:
- Comparison with available alternatives to the living modified organism;
- Validity of claimed benefits and harms.

Based on the evaluation, conclusions are drawn which can be used in decision-making. In the evaluation process, needs for additional information may be identified, and they have to be clearly stated in the final report.

The evaluation results could be presented to stakeholders for feedback. Feedback received from stakeholders should be included in the final report.

The final report should be submitted to decision makers for consideration.

#### Stage C: Review and monitoring

Review refers to the re-evaluation of the assessment outcomes in the light of new relevant information or knowledge, or a change in national policy or protection goals. Review is led by regulators.

Monitoring refers to the process of observing socio-economic effects of the living modified organism concerned over time. Monitoring may be led by assessors, regulators or a combination of both, according to the national regulatory framework. If monitoring is conducted, the findings may feed into a review process.