

# PROBLEM FORMULATION AND OPTIONS ASSESSMENT HANDBOOK

A guide to the PFOA process and how to integrate it into environmental risk assessment (ERA) of genetically modified organisms (GMOs)



BY **KRISTEN C. NELSON AND MICHAEL J. BANKER**

A publication of the **GMO ERA Project**



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Problem Formulation and Options Assessment Handbook

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A full copy of this handbook is available in pdf format on the GMO ERA Project website: <http://www.gmoera.umn.edu>

Users of this handbook are encouraged to print copies, but we ask that you please notify us when you do, so we know who is using the handbook:

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# PREFACE

As genetically modified organisms (GMOs) and their products become increasingly available and widespread around the globe, countries everywhere are finding themselves pressed to make decisions about the status of GMOs within their borders. GMOs suggest possibilities for overcoming challenges faced by many countries, but unresolved concerns remain about the potential risks these technologies pose. For this reason, GMOs are the focus of international attention and controversy. Making decisions in the face of uncertainty is never an easy task; however, making decisions about a GMO is particularly challenging given the additional resources and expertise demanded for a review and the potential GMOs may hold to have broad, unintentional effects. There is widespread, international recognition of the need to improve the governance of GMOs, particularly the capacities of national governments everywhere to evaluate them (e.g., the Convention on Biodiversity, particularly in the Cartagena Protocol on Biosafety of Living Modified Organisms). Many organizations are collectively working to create these improvements.

The GMO ERA Project responded to the expressed need for the development of environmental risk assessment (ERA) methodologies well-suited for countries to use for GMOs. The GMO ERA Project is a pioneering initiative driven by public sector scientists, most of whom have strong expertise in environmental science, as well as biotechnology and socioeconomics. The project is identifying and developing scientific methodologies and tools that can be used for environmental risk assessment (ERA) and management of transgenic plants, in accordance with the Cartagena Protocol on Biosafety and other international agreements. ERA is a key component in the governance of GMOs. When a governing body is confronted with a technology having risk potential for the environment, some form of ERA is typically conducted to help decision-makers consider the range of possible benefits and harms posed by the technology. However, many traditional forms of ERA are not well-suited to evaluate GMOs. The aim of the GMO ERA Project is to provide improved ERA methodologies for all of the stages involved in the ERA of GMOs. One shortcoming the group has addressed is the inability of many traditional ERA processes to effectively involve societal perspectives and discussion in ERA in a practical way that interacts

with and informs the ERA throughout the entire process. The methodology that has emerged from the GMO ERA Project to deal with this deficiency is called Problem Formulation and Options Assessment (PFOA). It is the deadlock in the persisting controversy around GMOs that inspired the GMO ERA Project participants to develop this innovative component for ERA that would allow - if taken seriously - the ability to overcome this deadlock and actually move forward on legitimate ground in either direction, and this could be different in any country but based on a transparent and accountable process.

This handbook is a support tool for the PFOA methodology. The handbook has three primary purposes: 1) to introduce users to PFOA; 2) to guide users on integrating PFOA into a country's ERA procedures for GMOs; and 3) to examine considerations, techniques, and resources that can assist with a country-specific PFOA.

This handbook has been written for international use by the principal parties involved in the ERA of GMOs at a national level.

Many handbooks offer a step-by-step approach for how to do a particular methodology. However, the nature of the PFOA methodology has demanded that we take a slightly different approach in writing this handbook. There are definite steps involved in a PFOA, and we walk users through those, but beyond those steps there is not necessarily a "single" way to do a PFOA. The exact form of a PFOA will likely be different from country to country. The handbook provides users with a foundational framework for using the PFOA methodology more so than a strict set of procedures to follow. Thus, this Handbook is about putting into practice what in most cases will be a new or different methodology and gaining acceptance for it. Once the foundational framework for PFOA is in place, then specific users can customize it and make it more sophisticated according to their needs. We will be offering suggestions toward this end, as well.

We hope this handbook is successful in helping users effectively involve societal perspectives and discussions in the ERA of GMOs.



Kristen C. Nelson



Michael J. Banker

# ACKNOWLEDGEMENTS

The International Project on GMO Environmental Risk Assessment Methodologies (<http://www.gmoera.umn.edu>) is an initiative of public sector scientists associated with the IOBC Global Working Group on Transgenic Organisms in Integrated Pest Management and Biocontrol of the International Organization for Biological Control (IOBC).

We would like to thank the GMO ERA project participants and supporting institutions for the extensive inquiry and discussion that has resulted in numerous contributions for improved environmental risk assessment, particularly the development of the PFOA methodology. We extend a special thanks to Dr. David Andow and Dr. Angelika Hilbeck for their project direction and intellectual guidance and to Evelyn Underwood for her support in every aspect. The handbook content represents the creative ideas and discussion among the PFOA section members, chapter authors, and workshop participants in the GMO ERA project.

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- International Project on GMO Environmental Risk Assessment Methodologies (GMO ERA Project): [www.gmoera.umn.edu](http://www.gmoera.umn.edu)
- Swiss Agency for Development and Cooperation: [www.sdc.admin.ch](http://www.sdc.admin.ch)
- BiosafeTrain-project of East Africa: [www.biosafetrain.dk](http://www.biosafetrain.dk)
- Brazilian Agricultural Research Organization (Embrapa): [www.embrapa.br](http://www.embrapa.br)
- Vietnam Ministry of Agriculture and Rural Development (MARD): [www.mard.gov.vn](http://www.mard.gov.vn)
- University of Minnesota: [www.umn.edu](http://www.umn.edu)

The handbook gained much from those who provided a peer review, their collective insights clarified and expanded its contribution. Photographs were provided by many people, thank you for this visual memory of our collaboration. Finally, the hard work and dedication of Stephanie Grayzeck, Areca Treon, and Sarah Finley who assisted in the preparation of the report and kept the whole process moving forward, deserve a special thank you.



**ETH**

Eidgenössische Technische Hochschule Zürich  
Swiss Federal Institute of Technology Zurich



**Embrapa**



**UNIVERSITY  
OF MINNESOTA**



# ABOUT THE GMO ERA PROJECT

The International Project on GMO Environmental Risk  
Assessment Methodologies  
(GMO ERA Project)

## **ABOUT THE GMO ERA PROJECT**

The GMO ERA Project is a pioneering initiative driven by public sector scientists, most of whom have strong expertise in environmental science, as well as biotechnology and socioeconomics. The project is identifying and developing scientific methodologies and tools that can be used for environmental risk assessment (ERA) and management of transgenic plants, in accordance with the Cartagena Protocol on Biosafety and other international agreements.

## **WORK OF THE GMO ERA PROJECT**

The GMO ERA Project is working to develop comprehensive, transparent, scientific methodologies and processes for testing, monitoring, and regulating GMOs to ensure their safe and sustainable use. The work of the project is being completed in phases.

Phase I, completed in June 2005, produced, tested, and developed methodologies for scientific data collection and cooperative evaluation for use in the risk assessment of GMOs. One of those methodologies, PFOA, is the basis for this handbook.

A large part of the work in Phase I centered around three project case studies that took place in Kenya, Brazil, and Vietnam. Each of these three countries had expressed a need for further resources and capacity to assist with the ERA of GMOs, and they were chosen for their capability to become future resource points for neighboring countries in their regions. Each case study involved collaboration between international and local scientists, and focused on currently relevant crops for the case study countries. All three case studies have or will result in an internationally peer-reviewed book volume.

Phase II of the GMO ERA Project, which began in May 2005 and ended in October 2007, has focused on the systemization of methodologies developed in Phase I. A large part of this involved building the capacity of scientists and regulators in developing countries to independently carry out ERAs of GMOs using the GMO ERA Project methodologies for scientific data collection and evaluation. This includes formulating methodologies so that individual countries can tailor them to their specific needs. This handbook is one such means of achieving that end; it is a guided design and decision-making resource for formulating and implementing one project methodology, the PFOA process.

Additionally, Phase II also included an increased effort toward outreach to other countries and organizations that could benefit from or interact with the project about project methodologies. This involved creating broad-based partnerships and alliances, including engagement with private-sector scientists and civil society organizations.

Finally, during Phase II, project scientists continued collaborating with local scientists in the case study countries to develop the capacity of each case study country, specifically, to effectively utilize and implement project methodologies within the particular contexts of their country. As a result of this, there was an aim to build the capacity of project scientists and case study countries to become networked resource points for other countries in order to help expand the availability and usage of project methodologies to other parties that can benefit from them. Phase III will begin in 2007 and expand outreach efforts from the case study countries to other countries in their regions.

### **PARTNERS OF THE GMO ERA PROJECT**

To accomplish its objectives, the GMO ERA Project relies heavily on collaboration and support from an extensive network of partnerships and alliances. As was noted above, the project's work is being carried out by public sector scientists. These scientists make up the project's core group, currently consisting of over 350 scientists from over 60 countries with a broad range of expertise in areas including environmental science, ecology, agricultural science, biogenetics, risk analysis, and socioeconomics. The work of this core group is guided by a 20-person steering committee made up of core group members. There is also

a 25-person advisory board that includes representatives from international and national organizations who have the scientific and political expertise to critically advise the project and who can influence the adoption of the methodologies nationally and internationally.

In addition to these internal parties, there are also a number of key external partnerships and alliances. The GMO ERA Project is affiliated with the IOBC Global Working Group on Transgenic Organisms in IPM and Biocontrol. The project has partnerships in its case study regions with the Vietnam Ministry of Agricultural and Rural Development (MARD), the Brazilian Agricultural Research Corporation (Embrapa), and the BiosafeTrain Project in East Africa. Funding for the GMO ERA Project Phase I and Phase II has come from the Swiss Agency for Development and Cooperation (SDC). The project's work and findings have been or will be published by the Commonwealth Agriculture Bureau International (CABI). The Scientific and Technical Advisory Panel (STAP) of the Global Environmental Facility (GEF) has provided editorial and financial support with publications. The GMO ERA Project has also received additional financial, institutional, and administrative support from the Research and Projects Financing (Finep) and the National Council for Scientific and Technical Development (CNPq) in Brazil; the International Centre of Insect Physiology and Ecology (ICIPE) and the Kenya Agricultural Research Institute (KARI) in Kenya; and the Institute of Integrative Biology of the Swiss Federal Institute of Technology Zurich (ETH), the Swiss Federal Office of the Environment in Switzerland, and the University of Minnesota.



# 1

## INTRODUCTION

Chapter 1 provides an overview of the Problem Formulation and Options Assessment (PFOA) handbook. The chapter is divided into the following sections:

- A. Purpose of this Handbook**
- B. Audience for this Handbook**
- C. Content and structure of this Handbook**
- D. How to use this Handbook**

**IMPORTANT TERMS:** Problem Formulation and Options Assessment (PFOA); genetically modified organism (GMO); stakeholder; benefit; harm; deliberation; transparent

## A. PURPOSE OF THIS HANDBOOK

This handbook was developed to introduce readers to Problem Formulation and Options Assessment (PFOA) methodology and guide them through the process.

### Box 1.1: What is PFOA?

PFOA is a methodology for conducting deliberative formulations of problems and comparative assessments of future alternatives relative to the biosafety evaluation of GMOs.

The PFOA method was designed by a pioneering initiative driven by public sector scientists to develop tools to support environmental risk assessments (ERAs) of genetically modified organisms (GMOs) called the GMO ERA Project (Box 1.1, Box 1.2). PFOA is one of these tools, developed to conduct deliberative formulations of problems and comparative assessments of future alternatives relative to the biosafety evaluation of GMOs.

A PFOA process directly involves the people (i.e., stakeholders) in an assessment of the positive and negative impacts of a GMO. The process centers an ERA on the stakeholders to collaboratively identify and analyze both the benefits and harms of a GMO. A PFOA is transparent, inclusive of all appropriate stakeholders, and rationally informed by the best available science. It serves to strengthen an ERA by incorporating deliberation with scientific assessments.

### Box 1.2: What is a GMO?

A genetically modified organism (GMO), also known as a living modified organism (LMO), is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

The purpose of this handbook is to:

- Introduce and explain the substance, theory, and practice of the PFOA methodology
- Provide guidance about the integration of a PFOA into a country's ERA procedures for genetically modified organisms.
- Examine considerations, techniques, and resources that can assist in designing, implementing, and conducting a country-specific PFOA.

Recognizing that each country has particular contexts (e.g., ecosystems, laws and regulations, political infrastructures, cultures) and faces distinct challenges when trying to customize a PFOA process, this handbook was designed to accommodate and account for users around the world.

## B. AUDIENCE FOR THIS HANDBOOK

The primary audiences are the government agencies and personnel responsible for conducting ERAs of GMOs within a particular country. This includes those already committed to using the PFOA methodology in their ERAs and those who are considering doing so. This handbook aims to provide scientists, government regulators, and agency administrators with the necessary information and resources to design, implement, or conduct a PFOA.

While this handbook is not intended to be a training guide, per se, for how to participate in a PFOA process, parts of the handbook will provide information that could help participants, including scientists, farmers, industry representatives, environmental representatives, or various others, prepare for or train to participate in a PFOA process more effectively.

## C. CONTENT AND STRUCTURE OF THIS HANDBOOK

The PFOA handbook explains the substance, theory, and practice of the full PFOA process - from initial conception to completion and follow-up - and helps users integrate a PFOA into a country's ERA of GMOs. More specifically, the handbook:

- Discusses the context and background from which the PFOA methodology emerged.
- Synthesizes existing information about relevant concepts, issues, and processes underlying PFOA.
- Shows how PFOA provides a context in which the complex debates surrounding GMOs can occur.
- Guides users through major issues in designing, implementing, and conducting a PFOA.
- Directs users toward additional resources that will be useful in designing, implementing, and conducting a PFOA.

Based on this list, the handbook is organized into three main sections (Box 1.3).



Thomas Isler

**Box 1.3: Handbook Organization**

Section 1: Preface and Chapters 1-2  
*Overview of handbook & context for it*

Section 2: Chapters 3-4  
*Detailed explanation of PFOA methodology and key concepts*

Section 3: Chapters 5-6  
*Designing, implementing, and conducting a PFOA*

**Section 1: Preface and Chapters 1-2**

The Preface and Chapter 1 provide an overview of the handbook. Chapter 2 gives an overview of the context for PFOA and this handbook. Specifically, we look at GMOs and the debate surrounding them. We discuss some unique challenges created by GMOs and the need for improving international governance of them, particularly in the case of ERA procedures. Finally, we look at the work of the GMO ERA Project, from which the PFOA methodology emerged, as part of a collective response to the challenges and needs relating to GMOs.

**Section 2: Chapters 3-4**

In Chapter 3, the PFOA methodology is explained in detail from the specific steps involved in the process to the key concepts underlying it. Chapter 4 describes the findings derived from four workshops in Kenya, Brazil, Vietnam, and Malaysia, and how they refined the PFOA methodology.

**Section 3: Chapters 5-6**

Chapters 5 and 6 guide PFOA users from start to finish. Chapter 5 is about designing and implementing a PFOA into the ERA of GMOs according to a country's particular circumstances, needs, and goals. It explains objectives in the design and implementation of a PFOA and walks users through a series of questions that highlight major considerations in designing and implementing a PFOA. Chapter 6 is about the process of conducting a PFOA. Using a hypothetical scenario as an example, Chapter 6 explains and demonstrates what needs to be done before, during, and after a PFOA; this includes guidance about useful techniques and tools for every stage of the process.

Chapter 7 is a few final thoughts on PFOA and where future practitioners and scholars can contribute to strengthening the methodology. Finally, included at the end of the handbook, are a series of appendices.

**Appendix A** is a glossary of key terms.

**Appendix B** lists scholars and organizations that are associated with PFOA and the GMO ERA Project.

**Appendix C** lists associated works of the GMO ERA Project.

**Appendix D** discusses several trial runs of PFOA that have played a critical role in refining the methodology and de-

veloping this handbook. These are examples of the type of responses that may result from a deliberation.

**Appendix E** contains handouts and evaluation forms that are discussed in the handbook. Printable versions of these handouts are available on the GMO ERA website at <http://www.gmoera.umn.edu>.

**Appendix F** contains web based resources for the various techniques discussed in Chapter 6.

## D. HOW TO USE THIS HANDBOOK

The content and structure of this handbook were written based on the assumption that most readers have minimal knowledge of the PFOA methodology. However, the handbook can also act as a reference for those already familiar with a PFOA in order to assist, redesign, or further customize the process. Additionally, the handbook can help users pursue interests that go beyond its scope, as the handbook provides information about broader material in particular fields available elsewhere. The handbook can either be read straight through, or you might skip around to the parts most relevant to your needs. For those new to the PFOA or who are just starting out in creating a PFOA, it will probably be most helpful to go through the handbook chapter by chapter.

This handbook will be most helpful when used by a group that is going through the process of designing, implementing, and conducting a PFOA together. Each individual user will certainly gain knowledge about PFOA and benefit from personally reviewing the handbook, and we recommend doing so. However, when it comes to putting the handbook into practice, there are a lot of questions to be answered and decisions to be made, and these questions and decisions will usually require input from multiple people.

It is important to note that this handbook does not present the single, definitive way to conduct a PFOA. A PFOA needs to be designed, implemented, and conducted according to the specific needs and contexts of the country in which it will be used. Therefore, this handbook provides a foundational framework for using the PFOA methodology. This framework will help users to design, implement, and conduct a PFOA according to specific needs and contexts, and with this foundational framework, users can further customize or make a more sophisticated PFOA process as suits them.



Itamar Soares de Melo

*This Handbook does not present the single, definitive way to conduct a PFOA. A PFOA needs to be designed, implemented, and conducted according to the specific needs and contexts of the country.*





# IMPROVING GMO ERA AND GOVERNANCE

Chapter 2 introduces genetically modified organisms (GMOs) and environmental risk assessments (ERAs) and the GMO ERA project from which the PFOA methodology emerged. The chapter is divided into the following sections:

- A. Genetically Modified Organisms**
- B. The GMO debate**
- C. Unique challenges posed by GMOs**
- D. Improving GMO Governance**
- E. The Environmental Risk Assessment of GMOs**
- F. The GMO ERA Project and PFOA**

**IMPORTANT TERMS:** Genetically Modified Organisms (GMOs); environmental risk assessment (ERA); governance; Cartagena Protocol on Biosafety; GMO ERA Project; precautionary approach; uncertainty; transboundary movement; deliberative process; multi-stakeholder participation

**Box 2.1: What is a genetically modified organism?**

A genetically modified organism (GMO), also known as a living modified organism (LMO), is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

**Box 2.2: Common Traits of GMOs**

- herbicide tolerance
- insect tolerance
- virus tolerance
- fungal resistance
- enhanced nutritional value
- production of commercial products (e.g. pharmaceuticals)
- enhanced processing characteristics
- drought tolerance
- salinity tolerance
- aluminum tolerance
- changed appearance (color, fluorescence, etc.)
- growth hormones in animals

(Underwood 2007)

**A. GENETICALLY MODIFIED ORGANISMS (GMOs)**

Genetically modified organisms (GMOs) are organisms whose genetics have been technologically altered through the direct insertion of a selected gene or genes, usually originating from another type of organism, into the organism's genetic material. The intent behind most GMOs is to make a particular trait or characteristic either present or absent in an organism. For example, some genetically modified crop plants have greater resistance to certain types of pests than their non-genetically modified counterparts because the presence of a gene from a soil bacterium, *Bacillus thuringiensis*, enables the plants to produce a toxin that acts as a pesticide.

The modifications that exist in GMOs are artificially produced, not the direct product of natural breeding or mating. In natural processes, only genetic material from the same or similar species is combined, and then in a random manner. GMOs are created in a more controlled manner, and they can be the product of genetic material combined from organisms that are not in the same taxonomic kingdoms (i.e., genes from plants, animals, fungi, protozoa, and bacteria can be combined in a single organism).

In terms of their history, GMOs are a relatively recent invention. The first GMO was created in the early 1970s, (a genetically modified bacterium). Applications of GMO technology in crop plants began to emerge in the 1980s. Commercial usage of GMOs and the marketing of products made from GMOs didn't occur until around the mid-1990s. At present, there are a variety of commercially released GMOs and many potential future applications. Current and proposed GMO applications have ranged from increasing disease resistance to increasing nutrient content of crops to enhancing livestock yields to creating more environmentally friendly industrial processes. At present, genetically modified plants, animals, and microorganisms are primarily being used in the production of food, livestock feed, fiber, and pharmaceuticals. Notable examples include nutritionally enhanced rice, pest resistant cotton, fish with increased maturity rates, and microorganisms altered to help produce medicines. Research on GMOs continues and new GMOs are being developed regularly from almost every form of life. While much GMO research has thus far focused on agriculture and healthcare applications, there is no known limit to the future applications for which GMOs may be proposed.

## B. THE GMO DEBATE

Throughout their short history, GMOs have been the source of polarizing debates because of their complex nature and the uncertainties surrounding them.

On the one hand, GMOs may offer solutions that help countries overcome obstacles and meet specific societal needs (e.g. food security). Proponents argue that GMOs promise a variety of environmental, economic, and human health benefits. For example, GMO research relating to crop plants and livestock has focused on developing organisms with reduced susceptibilities to diseases and pests, increased yields, and reduced needs for resource and chemical inputs.

On the other hand, GMOs are a relatively new technology with much remaining to be learned about associated benefits and risks. Critics assert that there is too much uncertainty associated with GMOs. There are concerns that GMOs could ultimately have wide-ranging detrimental effects in areas such as biodiversity, ecosystem health, and even human health. For example, a GMO constructed with a gene that makes it resistant to a pest could form a hybrid with a wild relative and spread resistance across the population of the wild relative with unknown consequences for the ecosystem.

Intertwined in this debate is the fact that GMOs are a complex technology. Advanced understanding of GMOs is not widespread beyond specialists in relevant fields. The processes involved in creating GMOs are technically sophisticated. The issues surrounding GMOs are complicated. Within this complexity, GMO proponents and critics have both made claims that are not supported by the current scientific knowledge.

Given the uncertainty and complexity surrounding GMOs, acceptance and utilization throughout the world has thus far been mixed. In some countries, such as the United States, Argentina, Canada, and China, the promises of GMOs have led to the development and commercialization of some GMO crops. In other countries, such as in the European Union, the potential risks and uncertainties of GMOs have led to instances of public outcry and rejection of GMO crops and products, or to adopting a precautionary approach to GMO research and development. In many countries, especially developing countries, policy regarding GMOs remains unsettled. Some countries are early in the debate, others are in a polarized debate. Critics may argue that GMOs lead to



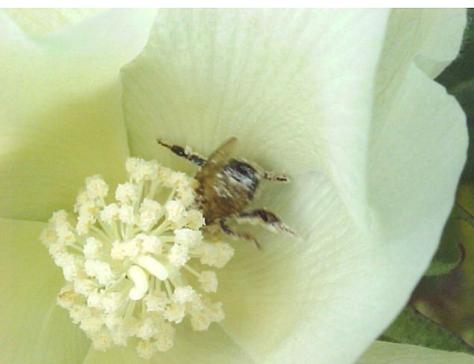
Nguyen Van Tuat

corporate dominance, threaten farmer's rights to save seed, reduce consumer choice, privatize seed, and represent an unethical patenting of life. Proponents argue for an innovative technology that could address global hunger, reduce the negative environmental and health consequences of current technology, and become an economic engine for countries.

### C. UNIQUE CHALLENGES POSED BY GMOs

GMOs pose some unique challenges to any country working to determine whether or how they will be allowed and managed within the country's borders:

- GMOs may potentially have widespread impacts.
- They are alive and therefore able to spread and evolve on their own accord.
- Every unique instance of proposed GMO technology should be considered individually.
- Evaluating GMOs requires particular scientific and institutional capacities.



Carmen Pires

GMOs may have broader, unintended effects on other people and environments. GMOs can be easily transferred within regions and across borders through trade or environmental processes, such as pollination. Once a GMO is introduced, a country's ability to control exposure and movement is limited. Thus, the effects of using GMOs may not be isolated to an intended area. One country's decision to allow and manage GMOs within its borders, even if only in one particular region, may unintentionally impact other regions within its borders or, of greater political significance, other countries. As the existence of GMOs becomes more pervasive, especially given the potential for transboundary movement, the capacities of countries to intentionally and autonomously decide whether or how GMOs will be allowed and managed within their borders could become diminished.

Each instance of GMO technology should be considered individually because every GMO poses its own unique benefits and harms to the ecological and societal contexts into which it is introduced. A GMO is the product of one or more distinct modifications to the genetic structure of a naturally-occurring species or subspecies. GMOs are usually similar in most respects to the species or subspecies from which they originate; however, the modifications in a GMO create potential for the organism to act differently than its naturally occurring counterpart in a particular environment.

Ecologically, these differences could manifest in patterns of survival and reproduction, interactions with other organisms, or roles in ecosystem function. Societally, these differences could manifest in any number of social, cultural, or economic systems. Furthermore, the consequences of these differences could be beneficial or harmful, benign or significant, contained or widespread. The only way to understand with reasonable certainty what the differences may be and what effect they may have is to specifically examine each proposed GMO within the particular contexts into which it is intended to be introduced.

Each country has the right and responsibility to design its own policies and regulatory systems to address GMOs; however, navigating the complexity and uncertainty surrounding GMOs requires that countries have particular capacities for conducting a reliable assessment of the technology. These include scientific capacities for conducting an environmental risk assessment (ERA) and institutional capacities for integrating socio-economic considerations into the overall decision-making process. Some countries already have the infrastructure in place to accommodate an assessment of GMOs that can effectively balance safety, competitiveness, and existing societal and ecological contexts. Other countries have faced difficulties in providing the infrastructure needed.

#### **D. IMPROVING GMO GOVERNANCE**

A need clearly exists for international attention toward ensuring effective governance of GMOs at both national and international levels. Several actions have been taken toward this end; probably of the broadest significance is the Cartagena Protocol on Biosafety (Box 2.3).

The Cartagena Protocol on Biosafety is an international agreement designed to help protect societies and the environment against potential risks and adverse effects that GMOs may pose. It was adopted by the Conference of the Parties to the Convention on Biological Diversity in January 2000, and as of October 2007 has been ratified by over 143 countries worldwide. The agreement aims to provide safeguards against the uncertainties associated with GMOs, and in doing so, it conforms to the precautionary approach guiding Principle 15 of the Rio Declaration on Environment and Development (1992).

#### **Box 2.3: What is the Cartagena Protocol on Biosafety?**

The Cartagena Protocol on Biosafety is an international agreement designed to help protect societies and the environment against potential risks and adverse effects that GMOs may pose. It was adopted by the Conference of the Parties to the Convention on Biological Diversity in January 2000, and as of September 2007 has been ratified by 142 countries worldwide.

Principle 15 states:

*“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”*

Overall, the Cartagena Protocol on Biosafety is part of an effort toward setting up guidelines, processes, and controls to ensure effective assessment and safe transfer, handling, and usage of GMOs. Of most significance to the purposes of this handbook is the guidance the Cartagena Protocol provides about assessing GMOs.

### **E. THE ENVIRONMENTAL RISK ASSESSMENT OF GMOs**

For governments to make adequately informed decisions about whether or how GMOs should be allowed and managed within a country’s borders, it is best to conduct environmental risk assessments (ERA). How risk assessment and risk management are defined depends on what framework you are adhering to, which could have significant implications in regards to what kind of decisions are made and by whom. The Codex Alimentarius (2005), a standard setting body on food safety for the Joint Food and Agriculture Organization of the United Nations and World Health Organization Food Standards Program, uses environmental risk analysis as an umbrella concept that includes: risk assessment, risk management, and risk communication. Each country may have a slightly different interpretation of how to organize these components.

The United States Environmental Protection Agency (US EPA) framework is one example (1998), other examples emphasize distinct points such as in the International Risk Governance Council report (IRGC 2005). For the US EPA (1998), risk assessment is, “a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.” Risk management is, “Selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results” (US EPA 1998). The US EPA excludes broader impacts from the risk assessment itself, which only covers impacts to human health and the environment. The US EPA (1998) risk analysis framework as described by Suter (2007) includes:



Angelika Hilbeck

- Planning: define the management goals and the scope and complexity of the required analysis process and decision
- Problem formulation:
  - characterize the GMO and the receiving environment
  - define environmental values objectively as assessment endpoints
  - develop risk hypotheses (conceptual models) of how the GMO could affect assessment endpoints
- Characterize exposure
- Characterize adverse effects
- Estimate risk as a combination of exposure and adverse effects
- Describe and interpret risk estimation results and associated uncertainty

In another interpretation, the key steps of environmental risk assessment in Annex III of the Cartagena Protocol on Safety, as described by Hill (2005), presents the following steps:

- Identify the characteristics of the GMO that may have adverse effects
- Evaluate the likelihood of these adverse effects being realized
- Evaluate the consequences if these adverse effects are realized
- Estimate the overall risk posed by the GMO based on likelihood and consequences
- Recommend whether or not the risks are acceptable or manageable and address uncertainty

Countries vary in their capacities and procedures for conducting an ERA, but various international efforts relating to improving governance of GMOs, such as the Cartagena Protocol on Biosafety, seem to suggest that an ERA of a GMO should minimally involve:

- Sufficient scientific information and expertise about the proposed GMO and its possible interactions with different environments.
- Thorough consideration of potential ecological effects of the GMO.
- Thorough consideration of potential societal effects of the GMO.



Pierre Silvie

- Direct input into the decision processes related to the GMO from the people to be most directly affected by any particular decision.
- Efficient processes for facilitating overall deliberation about the GMO.

The first and second points above are inherent to ERA. ERAs are traditionally a data-based process, conducted by scientists. Some of the scientists involved will have expertise about the technology in question and others will have expertise about the environments the technology could affect – in addition to any other expertise needed. The scientists evaluate the relative risk associated with the technology and the information derived is provided to decision-makers to consider as they make relevant policy determinations. However, many traditional ERAs do not generally move far beyond the few ecological effects in their studies.

There is a tendency in traditional ERA models to focus primarily on science and environmental issues. These issues are clearly essential to the effective governance of GMOs. In the case of GMOs, ERAs need to be responsive to broader societal issues. The complexity of issues and the prominence of uncertainties associated with GMOs influences their societal acceptance. Considerations of GMOs demand the inclusion of information about political, ethical, social, and economic issues.

*International efforts suggest that an ERA of a GMO will be more effective if broadened to focus not just on the ecological risks posed by a GMO but also on the critical societal needs that a GMO is being proposed to address.*

Several international efforts suggest that an ERA of a GMO will be more effective if broadened to focus not just on the ecological risks posed by a GMO but also on the critical societal needs that a GMO is being proposed to address. When a particular GMO is being considered for introduction in a country, it is being considered as a solution to some problem. Ideally, a societal problem will be addressed with the solution most suited to the problem. However, to do so demands a country understand the problem so that all of the possible alternative solutions can be considered. This requires social reflection and discussion.

A deliberative process involving multi-stakeholder participation is a method of integrating societal reflection and discussion into governance that is becoming increasingly common throughout the world; furthermore, it is viewed by many as the most robust means of doing so. A deliberative process is one involving careful consideration and evaluation of available options, and multi-stakeholder participation

means directly involving the voices of those people likely to be most affected by a particular decision. Integrating a deliberative multi-stakeholder process into ERA procedures for a GMO is a way to allow a relevant cross-section of society to cooperatively and comparatively evaluate the relevant critical needs and risks involved.

## F. THE GMO ERA PROJECT AND PFOA

This handbook and the methodology it focuses on emerged from the International Project on GMO Environmental Risk Assessment Methodologies (GMO ERA Project) (Appendix B). The GMO ERA Project, initiated in 2003, is a collaborative effort between public sector scientists from around the world. The project is working to address the needs pertaining to the ERA of GMOs, which have been suggested by the Cartagena Protocol and other international agreements, to ensure their safe and sustainable use. More information about the project can be found at <http://www.gmoera.umn.edu>.

Collectively, the GMO ERA Project is working to identify, develop, and make accessible comprehensive methodologies and tools for individual countries to conduct scientifically informed ERA of GMOs strengthened by multi-stakeholder deliberation (Appendix C). The methodologies and tools are aimed at enabling local scientists, regulators, stakeholders, and decision-makers to acquire the information necessary to effectively and transparently test, monitor, and regulate GMOs. The intent is to help expand ERA to address risk as well as the greater societal needs for which GMOs are being considered as a solution. This will better ensure a country's decisions are informed, benefits maximized, and costs minimized.

Problem Formulation and Options Assessment (PFOA) is one of the innovative methodologies developed by the GMO ERA Project. Above, we identified five components that an ERA for a GMO should minimally involve. The PFOA methodology contributes to the GMO ERA Project's framework for integrating the latter three:

- Thorough consideration of potential societal effects of the GMO;
- Direct input into the decision processes related to the GMO from the people to be most directly affected by a particular decision;
- Efficient processes for facilitating overall deliberation about the GMO.

*The GMO ERA Project is working to identify, develop, and make accessible comprehensive methodologies and tools for individual countries to conduct scientifically informed ERA of GMOs strengthened by multi-stakeholder deliberation.*



Ron Wheatley

This handbook is a tool to guide users through the development and implementation of the PFOA methodology into their ERA procedures for GMOs, and those are the tasks to which we now turn in the chapters that follow.



# 3 WHAT IS PFOA?

Problem Formulation and Options Assessment (PFOA) can act as one cornerstone for conducting environmental risk assessments (ERA) of genetically modified organisms (GMOs). It was designed by the GMO ERA Project to help countries assess, in a deliberative and inclusive manner, the full range of potential benefits and harms that GMOs may pose within broader societal contexts (Nelson et al. 2004). Before designing or conducting a PFOA, you first need to have an understanding of what PFOA is and how it works. This chapter, which provides an overview of the PFOA methodology goals it helps achieve, is divided into the following sections:

- A. Goals of PFOA for ERA**
- B. The PFOA Methodology**
- C. Key Concepts underlying PFOA**

**IMPORTANT TERMS:** benefit; harm; stakeholder; need; interest; risk; precautionary approach; problem; option; governance; participation; transparency; accountability; environmental risk assessment (ERA); science-based; deliberation; multi-criteria analysis; state; future alternative; equitable; legitimacy; adverse effect; inclusiveness; collaborative approaches; future alternatives

**Box 3.1: What is a future alternative?**

Any available option that could be implemented in place of what presently exists. This can include options that currently exist, options that will exist in the future, and options that may exist in the future whether they have been thought of yet or not for the particular situation.

**A. GOALS OF PFOA FOR ERA**

Problem Formulation and Options Assessment, or PFOA, is a methodology for conducting deliberative formulations of problems and comparative assessments of future alternatives (Box 3.1) relative to the biosafety evaluation of GMOs. A PFOA process helps stakeholders collaboratively analyze and advise on the identification and reduction of possible harms and the enhancement of potential benefits within the specific contexts for which a GMO is being considered. To this end, a PFOA relies upon being transparent, inclusive of all appropriate stakeholders, and rationally informed by the best available science.

A PFOA process is a core component for any biosafety program's assessment of a GMO (Box 3.2). It uniquely and necessarily puts all people potentially affected by a proposed use of a GMO (i.e., stakeholders) at the center of risk assessment in a way that they can influence and contribute to the assessment. The healthy debate it engenders provides a forum for considering a GMO at multiple scales, across disciplines, between policy makers and regulators, and among stakeholders. It provides a viable means of combining public deliberation science-based analysis within a decision process. The major contributions that the PFOA process can make to an ERA include:

- Improving the science of ERA
- Providing for the possibility of a responsive relationship between citizens and between citizens and the ERA process
- Strengthening the legitimacy of the ERA and governance of GMOs
- Better linking ERA with the entire system of regulating and managing GMOs
- Helping society evaluate technologies in light of alternative futures

**Box 3.2: What PFOA is not:**

PFOA is not merely backgrounding or context setting to risk assessment.

PFOA is not an elaborate socioeconomic assessment.

PFOA is not a tool to understand how to sell the idea of GMOs to the public.

The precautionary approach can serve as a guide for the design of biosafety programs (National Research Council 2002). According to Principle 15 of the Rio Declaration on Environment and Development (1992), the precautionary approach holds that, “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” A key component of biosafety programs is ERA. Science guides an ERA, but through policy and regulation, a government

can take counter-measures to mitigate against a potential adverse affect, even when there is no definitive proof that the adverse affect would occur. In general, society demands precaution when a proposed change harms a group of people involuntarily without providing for relief of that harm, or when a proposed change is both adverse and irreversible.

A science-based ERA must also be a deliberative process designed to provide for social reflection and discussion (Forester 1999) about GMOs. The characteristics of a sound deliberative process are to be transparent, equitable, legitimate, and science-based when possible. Transparency allows for the open communication of information between all parties and easily accessible reporting of decisions to the public (Hermmati 2002). An equitable process is fair and just, and providing equitable needs assessment means that information from the broadest spectrum of society must be included with all stakeholders having the possibility to contribute. When transparency and equity are central to a PFOA, the process gains legitimacy in the public eye. This public legitimacy must be matched by traditional legitimacy or sanctioning by a formal political body that sponsors the deliberative process. The deliberative process can be tied to either a regulatory or legislative authority but it must provide a means by which evaluations from the PFOA inform government decision-making and action. Finally, the foundation of PFOA is a science-based inquiry promoting fairness and objectivity in appraisals of GMOs. Questions are answered with data, impacts are evaluated with valid indicators, and the limits of our understanding are clearly delineated by a research agenda.

Each country will develop a country specific deliberative process that fits the particular structure and authority of the relevant decision making bodies and implementing agencies. For many political systems in the world, the legitimating authority exists to incorporate needs assessment in a legislative or regulatory context. For some legislative or regulatory situations, a PFOA can be incorporated into the biosafety committee structures, or into the public consultative process within regulation. It may even be added as an alternative process, supported by civic society, that informs the debate in traditional decision making bodies. There is no requirement that all GMO assessments in a country use a PFOA.

*PFOA puts all people potentially affected by a proposed use of a GMO at the center of risk assessment in a way that they can influence and contribute to the assessment.*



Gabor Lövei

For a handout of the PFOA process questions, see Appendix E.

## B. THE PFOA METHODOLOGY

The PFOA process is comprised of specific brainstorming, discussion, and analytical components. This section outlines the specific steps and phases involved in the PFOA process (Figure 3.1). The PFOA steps do not correspond uniformly to the steps or tiers in classical risk assessment, because each country organizes its risk analysis differently. For example, a country may use the PFOA at a policy level for a needs assessment that would guide research and development decisions about GMO technologies (Steps 1-3). Or the PFOA will be used for environmental risk assessment of a specific GMO (Step 1-9). In addition, decisions will have to be made about whether you will develop a basic PFOA with a few essential meetings for deliberation or if you want a highly interactive PFOA with many meetings for exchange between stakeholders and scientists and/or regional consultations (See Chapter 6, pgs. 142-143 for more details.)

### SUMMARY OF PFOA STEPS:1-9

#### Pre-PFOA: Initiating Proposal

- A. Proposal to Use GMO
- B. Decision by Regulatory Body
  - Is there merit in moving forward to evaluate the GMO as a possible option or is the initiating proposal premature?

#### Problem Formulation and Options Assessment (PFOA) Process

Questions: to be answered by each group and shared in the deliberative process by the group representatives

#### **PFOA Step 1: Problem formulation**

1. What needs of the people are not being met by the present situation?
  - Whose need is being addressed and whose need is not being addressed?
  - What is the unmet need = the problem?
  - What are the causes of the problem?
  - How do these causes rank in their influence on the problem?
  - Whose problem is it? What are the effects of the problem?
  - What aspects of the present situation must be changed to meet the needs?

Formulation of Problem	Basic Human Need	Interests
An unmet need that requires change	Food, shelter, safety	A stakeholder group's values, goals and perspectives

**PFOA Step 2: Prioritization and Scale**

1. Is this problem a core problem for the people identified?
  - Do the people recognize the problem as important to their lives?
  - What are the potentially competing needs of these people?
  - How do the needs identified rank in important to these other competing needs?
  
2. How extensive is the problem?
  - How many people are affected?
  - In what part of the country are these people located?
  - How large an area is affected by the problem?
  - How severe is the problem (local intensity)?

**Step 3: Problem Statement**

A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people.

**Step 4: Recommendation to Move Forward**

If through a deliberative process the stakeholders can identify a high priority problem and they receive legitimating authority from the appropriate regulatory group, they will proceed with the options assessment. This is an essential prelude for characterizing the context for a full risk assessment.

1. Does PFOA move forward to identify options and conduct an options assessment?

**Step 5: Option Identification**

1. What are the options for solving the problem?

**Step 6: Assessment in Relation to the Technology and the Problem**

Technology Attributes:

1. What are the characteristics of the technologies involved?
2. What is the efficacy of the “technology” on the target?
3. What is the cost of the technology within the production system?

Sociopolitical Attributes:

4. What social and economic organization will be required?
  - What is the range of production systems and what is the geographic region the option is likely to be used in or have an effect on?
5. What laws, regulations, policies or programs currently exist that would regulate the option?

Production Attributes:

6. What current advantages do we have for implementing this option?
7. What barriers to use exist? i.e., is the distribution system in place; can the potential solution be integrated into present production; can the farmers afford the potential solution?
8. How does this option fit with current practices? (expanded in Step 7)
  - How might the use of the option change production practices, such as use of other species, tillage systems, pesticide use (including impacts on non-target pests)? What useful practices are reinforced by the potential?



Evelyn Underwood

Summary of how the option might solve the problem:

9. What is the current state of information and science related to this option?
  - What sources of baseline data are available on the agricultural system? What information is needed to show that the changes are likely to occur?
10. How confident are we that this option could successfully solve the defined problem?
  - How will anticipated changes in practices affect the needs identified in Steps 1 and 2?

#### **Step 7: Changes Required and Anticipated**

1. What changes in management practices might contribute to the solution?
2. What changes in the local community might contribute to the solution?
3. What changes in government support might contribute to the solution?
4. What changes in the structure of production might contribute to the solution?
5. What other changes would likely be needed to facilitate widespread use of this option?
6. How do the options compare in the extent of the changes required or anticipated?

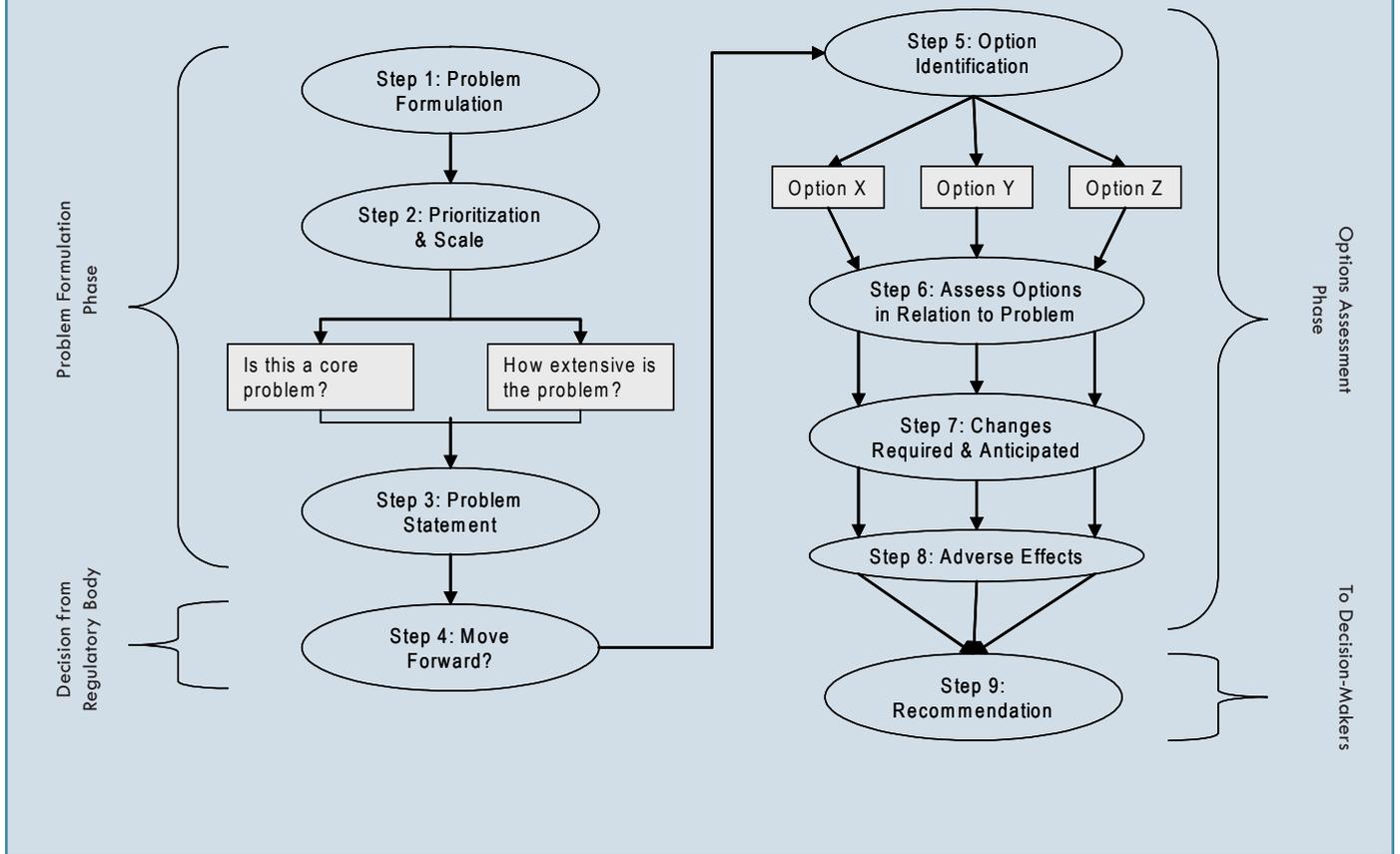
#### **Step 8: Adverse effects**

1. How might the potential solution affect production systems and their infrastructures?
2. How might the potential solution reinforce poor practices or disrupt useful practices?
3. What are the potential adverse effects/harms of these changes internally and externally to the production system?
4. How will its use affect (both positively and negatively):
  - a. Other nearby production systems (can its use be restricted to a particular system or geographic region)?
  - b. Other nearby ecosystems?
  - c. The conservation of genetic variability of species and other related biodiversity?
  - d. Important social, cultural, economic, or ethical values?
5. What is the scale and importance of the effects for a, b, and c?
6. Are any of these effects difficult to reverse once they occur?
7. How do the options compare in their potential of adverse and irreversible effects?

#### **Step 9: Recommendation**

The final report consists of recommendations from the PFOA participants to the decision-makers supported with documentation of the deliberation during Steps 1-8.

Figure 3.1: Four Phases of PFOA



**PRE-PFOA: INITIATING PROPOSAL**

**A. Proposal to Use GMO**

The request or suggestion that a particular GMO would be a beneficial alternative to the way things are currently being done in a particular system. These proposals may come from a variety of actors and each nation will have its own process for moving such a proposal through a common review process. For example, a PFOA designed for policy level recommendations may be initiated by a research and development branch of government as a needs assessment considering current problems and possible technology solutions, including GMOs. PFOA designed for environmental risk assessment of a specific GMO may be initiated by a national research institute developing a new GMO or a company proposing importation of a GMO. In this case, the PFOA uses Steps 1-3 to understand the societal needs and problems that would be addressed by the new GMO. These steps inform the system analysis and adverse effects questions in the options assessment.

**PRE-PFOA**

**B. Decision by Policy or Regulatory Body**

Is there merit in moving forward to evaluate the GMO as a possible option or is the initiating proposal premature?

Yes/No

**Problem Formulation and Options Assessment (PFOA) Process**

*Questions: to be answered by each group and shared in the deliberative process by the group representatives*

## STEP 1

### **STEP 1: PROBLEM FORMULATION**

Formulating the problem that will be addressed by the new technology is the initial and central component of PFOA that must be done by a multiple stakeholder group in an open deliberation of diverse perspectives. The problem is defined as an unmet basic human need that requires change. Basic human needs are most commonly identified as food, shelter, and safety. Other human interests are stakeholder specific such as enhanced economic opportunity, positive social interactions, cultural richness, etc. For example, individuals have the basic need for a certain amount of calories per day or the security that their children will continue to live healthy lives as a minimum foundation for well being. Once the needs for food, shelter, and safety are met, an individual can expand their interests to include numerous options for well being. These interests will differ from one individual to another and from one group to another.

*The problem is defined as an unmet need that requires change.*

### **Relevant Questions**

1. What needs of the people are not being met by the present situation?
  - *Whose need is being addressed and whose need is not being addressed?*
  - *What is the unmet need = the problem?*
  - *What are the causes of the problem?*
  - *How do these causes rank in their influence on the problem?*
  - *Whose problem is it? What are the effects of the problem?*
  - *What aspects of the present situation must be changed to meet the needs?*

Formulation of Problem	Basic Human Need	Interests
An unmet need that requires change	Food, shelter, safety	A stakeholder group's values, goals and perspectives

**STEP 2: PRIORITIZATION & SCALE**

The problem formulated in a deliberative process will clarify the relative importance of this problem as compared to other problems or issues. Those groups whose needs are not being addressed or those groups with the problem can be actively involved with the prioritizing process, providing a perspective as to their relative need. Other public actors will also share their perspective on the relative importance of this problem in relation to scale, impact, and uncertainty.

Systems research indicates that an initial step can be to consider two questions: whose problem are we addressing (the positive question), and whose problem should we be addressing (the normative question). There may be more than one “who” identified by this first step. The second step is to determine the needs of the identified people that are not being fulfilled by the present situation. This statement of unmet needs is a statement of the problem addressed by the technology. Changing the present situation to meet those needs is a statement of the “solution” to the problem. In developing protocols for these questions, it will be essential to detail the sources of information (kind of data, opinions, etc.) necessary to answer the questions.

All the stakeholder representatives participating in the PFOA should be involved in this problem formulation. Each representative for a stakeholder interest presents their perspective on the problem formulation and prioritizing. Through the deliberative process, the needs of each stakeholder sector will be clarified and a shared assessment of the problem can be developed.

**Relevant Questions**

1. *Is this problem a core problem for the people identified?*
  - *Do the people recognize the problem as important to their lives?*
  - *What are the potentially competing needs of these people?*
  - *How do the needs identified rank in important to these other competing needs?*
2. *How extensive is the problem?*
  - *How many people are affected?*
  - *In what part of the country are these people located?*
  - *How large an area is affected by the problem?*
  - *How severe is the problem (local intensity)?*

**STEP 2**

*The problem formulated in a deliberative process will clarify the relative importance of this problem as compared to other problems or issues.*

*The statement of unmet needs is a statement of the problem addressed by the technology.*

## STEP 3

### STEP 3: PROBLEM STATEMENT

A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people.

This stage of the multi-stakeholder process ends with a commonly agreed upon problem statement and a discussion of the merits in continuing the process or not proceeding further.

At this point, a decision should be made by the appropriate regulatory group: Should the PFOA process advance to develop the options assessment in relation to addressing this problem or not? Reasons for not proceeding may be based on the limited scale of the problem, the unimportance to stakeholders, or the unclear need for change, among others.

*A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people.*

## STEP 4

### STEP 4: RECOMMENDATION TO MOVE FORWARD

In a policy level needs assessment, the group would decide if the GMO should be considered as potential solution because it may address critical societal needs. For a specific GMO's environmental risk assessment, the stakeholders can identify the priority problem and how the GMO would address this problem. This analysis supplies information to the options assessment and risk assessment steps. In most cases the regulatory authority would oversee the environmental risk assessment.

#### **Relevant Questions**

1. *Do we move forward to identify options and conduct an options assessment?*

## STEP 5

### STEP 5: OPTION IDENTIFICATION

This is the identification of potential solutions for the identified problem (policy and technical options and potential alternative solutions). Some of the potential alternative solutions will address a much broader set of problem situations than the identified problem. Others will address only a part of the identified problem. It will be essential to identify both types of potential alternative solutions because both can alter the context for the risk assessment.

This is one of the most creative moments in a PFOA. It is the brainstorming of the multiple ways the defined problem could be solved or addressed. It is not a commitment to one

option or another but rather an open generation of ideas, the purpose of which is to “expand the pie” (Susskind et al. 2000). It is an effort to think about a problem in a new way or suggest how new resources can be brought to solve a problem. The entire group generates options without concern about defending them or the need to endorse them.

*Options assessment is not a commitment to one option or another but rather an open generation of ideas, the purpose of which is to “expand the pie”.*

This step can be completed by the multiple stakeholder group for the initial identification of options. A technical committee can develop a pre-report that covers information for Steps 6–8 and the multi-stakeholder group can use the document to begin their evaluation of options. Moving through steps 6-8 can be an iterative process, designed with multiple opportunities for exchange between the PFOA group, risk assessment scientists, and decision makers. The number of exchanges will be country specific with a minimum of two to three but could be designed with numerous interactive meetings.

**Relevant Questions**

1. *What are the options for solving the problem?*  
(Table 3.1)

**Table 3.1: Option Identification and Assessment Chart**

Option Identification and Assessment Chart				
Step 5	Step 6	Step 7	Step 8	
Options	Characteristics	Changes	Effects on the System	
	For problem solving	Required/ Anticipated	Internal	External
			(social, environmental, economic)	
Option A				
Option B				
Option C				
Etc.				

**STEP 6: ASSESSMENT IN RELATION TO THE TECHNOLOGY AND THE PROBLEM**

Identification of the attributes of each option provides the data necessary for a comparative assessment of potential alternative solutions. It begins the analysis of the merits of each option and how implementation would be conducted. Particular attention should be paid to the scale of impact for each option.

**STEP 6**

*What do we know  
about the options?*

**Relevant Questions**

*Technology Attributes:*

1. *What are the characteristics of the technologies involved?*
2. *What is the efficacy of the “technology” on the target?*
3. *What is the cost of the technology within the production system?*

*Sociopolitical Attributes:*

4. *What social and economic organization will be required?*
  - *What is the range of production systems and what is the geographic region the option is likely to be used in or have an effect on?*
5. *What laws, regulations, policies or programs currently exist that would regulate the option?*

*Production Attributes:*

6. *What current advantages do we have for implementing this option?*
7. *What barriers to use exist? i.e., is the distribution system in place; can the potential solution be integrated into present production; can the farmers afford the potential solution?*
8. *How does this option fit with current practices? (Expanded in Step 7)*
  - *How might the use of the option change production practices, such as use of other species, tillage systems, pesticide use (including impacts on non-target pests)? What useful practices are reinforced by the potential?*

*Summary of how the option might be solved:*

9. *What is the current state of information and science related to this option?*
  - *What sources of baseline data are available on the agricultural system? What information is needed to show that the changes are likely to occur?*
10. *How confident are we that this option could successfully solve the defined problem?*
  - *How will anticipated changes in practices affect the needs identified in Steps 1 and 2?*

**STEP 7: CHANGES REQUIRED AND ANTICIPATED**

Based on the identified attributes of each option the group will proceed to define the extent of changes required to implement each option. The main focus should be on the system but changes in the local economy, social organization of the sector, and policies will be necessary to consider as well. Changes may be necessary in order to implement the option or they may be an indirect effect of implementing the option.

**Relevant Questions**

1. *What changes in management practices might contribute to this solution?*
2. *What changes in the local community might contribute to this solution?*
3. *What changes in government support might contribute to this solution?*
4. *What changes in the structure of production might contribute to this solution?*
5. *What other changes would likely be needed to facilitate widespread use of this option?*
6. *How do the options compare in the extent of the changes required or anticipated?*

**STEP 8: ADVERSE EFFECTS**

Special attention should be paid to the potential adverse effects of the proposed options. These potential adverse consequences from solving the problem should not be more costly to society than continuing with the status quo. In general, society demands precaution when a proposed change is both adverse and irreversible. The most critical effects will be those that adversely effect the conservation or sustainable use of biological diversity in an area or will force hardship on a disadvantaged group.

**Relevant Questions**

1. *How might the potential solution affect production systems and their infrastructures?*
2. *How might the potential solution reinforce poor practices or disrupt useful practices?*
3. *What are the potential adverse effects/harms of these changes internally and externally to the production system?*
4. *How will its use affect (both positively and negatively):*

**STEP 7**

*Will any changes be required for the system?*

**STEP 8**

*Special attention should be paid to the potential adverse effects of the proposed options.*

- a. *Other nearby production systems (can its use be restricted to a particular system or geographic region)?*
  - b. *Other nearby ecosystems?*
  - c. *The conservation of genetic variability of species and other related biodiversity?*
  - d. *Important social, cultural, economic, or ethical values?*
5. *What is the scale and importance of the effects for a, b, and c?*
  6. *Are any of these effects difficult to reverse once they occur?*
  7. *How do the options compare in their potential of adverse and irreversible effects?*

## STEP 9

### STEP 9: RECOMMENDATION

The multiple stakeholder group should consider recommending an option. If no option is acceptable the report should clearly explain why. The PFOA report is sent to the decision making body to inform their considerations and final decision. The legitimacy of the delegated government decision makers rests on their ability to reflect the interests of diverse groups within society. Under their Biosafety Frameworks, each nation has identified the particular decision making body for GMO biosafety (UNEP-GEF 2003a/b, Nelson *et al.* 2004, Capalbo *et al.* 2006, Nelson *et al.* 2007, Nelson and Banker 2007). Environmental risk assessment completed with a PFOA encourages the decision makers to continue good governance through transparency, accountability, and participation.

### C. KEY CONCEPTS UNDERLYING PFOA

Problem Formulation and Options Assessment (PFOA) is a methodology based on key concepts in two areas: environmental risk assessment (ERA) and governance. The foundational concepts in ERA are 'science-based', 'deliberation', and 'multi-criteria analysis'. Within the umbrella of governance, 'participation', 'transparency', and 'accountability' are most relevant.

All of these concepts are part of broader discussions about ERA and governance in countries around the globe. Thus, they have all received extensive treatment by scholars and practitioners elsewhere. For the purposes of this handbook, it is not necessary to be familiar with the full scope of these

discussions. However, it is worthwhile to have a grasp of each concept as it relates to PFOA. Here we will provide a brief overview of each plus an explanation of how each is embodied within PFOA.

### **Key Concepts in Environmental Risk Assessment**

Environmental risk assessment (ERA) broadly refers to the studies and analyses undertaken to inform decision-making processes about potential adverse effects and their consequences that a proposed activity may pose for the environment; in this case, the introduction of a GMO. As a process, an ERA generally involves (Suter 2007, Hill 2005), (also see Chapter 2, page 13):

- Identifying the problem a proposed activity is intended to address;
- Identifying potential adverse effects, and their causes, posed by an activity;
- Identifying possible consequences of an activity's potential adverse effects;
- Comparing the range of potential adverse effects and possible consequences identified for an activity;
- Estimating the likelihood and degree to which potential adverse effects and possible consequences could occur.

An ERA is undertaken to help decision-makers make socially acceptable decisions when faced with a choice involving risk (Stern & Fineberg, 1996). A proposed activity involving risk compels decision-makers to weigh the possible impacts of allowing the activity in comparison to alternative approaches, such as not allowing the activity or allowing the activity in some restricted form. It is common for decision-makers to accept some degree of risk in decisions, particularly when a proposed activity offers significant benefit for addressing some societal problem. However, risk should never be accepted lightly or blindly. An ERA helps to ensure that decisions involving risk are well-informed and made in the best interests of society.

Conducting an ERA always involves making judgments in the face of uncertainty. Because the judgments made in an ERA could impact critical societal decisions, it is important to narrow the options available in a judgment as much as possible in order to make the judgment as accurate as possible. There are a variety of methods and tools used in



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ERA to help increase accuracy in judgments. These include:

- Basing an ERA in scientific knowledge, information, and analysis;
- Using peer deliberation to determine the best responses to key questions;
- Integrating some degree of multi-criteria analysis to help compare types of information that are different or otherwise incomparable.

An additional means of increasing accuracy in judgments made within an ERA is to directly involve societal discussion in the process so that judgments can also better respond to a society's core values, concerns, and needs. PFOA is a means of increasing accuracy in judgments within an ERA by integrating societal discussion directly into the process. Additionally, as a distinct process, PFOA also embodies the same means as ERA for helping increase the accuracy of judgments made within PFOA itself: science-based, deliberation, and multi-criteria analysis.

#### *Science-Based*

A science-based decision-making process uses thorough consideration and accurate interpretation of the most relevant scientific information available to inform decisions (Mills, Quigley & Everest, 2001). Decision-makers are always challenged by the greater or lesser degree of uncertainty that exists about information. This is particularly true when trying to determine and weigh the consequences of a decision on a complex issue for the future. Even though science is also subject to uncertainty, science can serve as an important foundation for decision-making processes because of the nature of scientific information and the way it deals with uncertainty.

Science aims to determine what information about the world can be relied upon as true through a systematic process of testing hypotheses about how phenomena in the world function. Scientific information is usually reached through the use of mutually agreed upon methodologies that have been developed over time specifically to help minimize bias and promote greater objectivity. For example, scientists carefully document their work and clearly indicate the assumptions underlying it, including any known uncertainties, and then subject the work to peer review by other scientists to evaluate its quality and accuracy. These systematic methodologies help scientists acknowledge the limits of

*A science-based decision-making process uses thorough consideration and accurate interpretation of the most relevant scientific information available to inform decisions.*

their information and thus be more effective at judging the reliability of their findings. Additionally, scientific practices such as these make it so there is a degree of transparency and accountability built into science. For these reasons, scientific information can carry more credibility amongst people, particularly when diverse groups of interests are involved.

There are various debates within society surrounding the topic of science and the grounding of decision-making in science. A prominent example within governance has to do with concerns people have about the role of science in informing policy. Some people question whether scientific information should be privileged over other information, especially when issues are more social or cultural in nature. Others argue that doing “good” science takes too long and that science doesn’t provide information at the pace policy requires to keep moving forward. Some question the objectivity of science, arguing that it is a social process influenced by values and cultural norms. These are legitimate and important concerns, and the larger debates they are involved in are ongoing. However, at least in the case of risk assessment, there is enough evidence to show that science can play a critical role in informing policy, such as with the assistance it can provide in the evaluation of uncertainty. As for concerns about the pace and elaborateness of the scientific process, it is important to note that these concerns are being addressed. There are many efforts to make scientific methodologies more efficient, accessible, timely, and still rigorous in their ability to produce information for policy. These are main objectives behind the work of the GMO ERA Project.

PFOA brings science-based information into the broader societal deliberation represented by stakeholders in an organized manner to help answer the questions surrounding an issue. For example, PFOA can assist an ERA with understanding the degree of acceptable risk or potential advantages that any particular option poses. Science has a history of methodology that is well-accepted by experts. Using the information from commonly agreed upon methodologies as the basis for new understandings makes these understandings more reliable. In fact, developing commonly agreed upon methodologies for conducting ERAs of GMOs is the overall goal of the GMO ERA Project, the group from which PFOA has emerged. A science-based approach like PFOA, where a group answers questions



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together using scientific information, may reduce the political fights among stakeholders for controlling interpretation around an issue. Science-based information offers a mutually credible basis for discussion, leading more people to see a discussion as a reasonable dialogue rather than positional fighting over power, which detracts from dealing with the actual issue under discussion. The GMO debate tends to be highly politicized. Science-based information in PFOA helps minimize, or at least reduce, the conflicts between stakeholders over the use of GMOs. This is done by grounding the disputes between stakeholders in the answering of questions together supported by scientific information relating to GMOs. In turn, this initial grounding in science also actually helps set the stage for participants to later bring other types of information into the discussion, such as social, economic, and ethical factors. Once a reasonable dialogue has already been started around scientific information, these other types of considerations can often be raised without creating as much instantaneous resistance between divergent stakeholders as discussions about these more subjective factors otherwise might.

### *Deliberation*

Deliberation is the means by which all participants involved in a governance process carefully consider, as a group, all relevant sides of an issue in order to understand differences and possibly reach some shared conclusion. Deliberation differs from a positional process of assessment in which a collection of different interests come together to argue for their particular pre-defined positions. Rather, deliberation seeks to reach a common answer, and this requires a collection of different interests coming together to openly share and listen to diverse views.

Deliberation requires a collaborative process in which individuals with different interests ask questions as a group in order to identify and be as inclusive as possible of all relevant considerations in their process. During deliberation, disagreement and uncertainty are openly acknowledged in order to facilitate the identification of alternatives for dealing with an issue. For participants, deliberation produces mutual understanding of different interests and where differences exist, as well as shared learning about answers that are common to those different interests. Deliberation acts as a structured means for people to exchange information, clarify their understandings, create new possibilities, and compare options. For this reason,

*Deliberation is the means by which all participants involved in a governance process carefully consider, as a group, all relevant sides of an issue in order to understand and possibly reach some shared conclusion.*

deliberation is also capable of moving people closer to agreement on some issues and identifying differences where they exist.

Critics of deliberation express concerns about the potential for deliberation to degrade into open conflict. This is a valid concern in that a deliberation can only be effective if the atmosphere remains cooperative. Anytime conflicting interests are brought together this becomes a challenge. However, deliberation does not mean posturing or fighting, and it is not occurring when such are present. Deliberation also does not mean there will be a forced consensus. Differences of opinion will exist just as they do in broad societal debates. A deliberation is a place where more listening, questioning, commenting, and sharing around such debates can occur. A process intended as a deliberation needs to be designed with this in mind by ensuring that participants have both the intent and the incentive to deliberate as opposed to simply fight.

PFOA alters traditional conceptions of ERA by incorporating a more deliberative approach. Historically, many ERAs have not gone much beyond a consultative approach: an agency might define recommendations based on conclusions from scientific evaluations, the recommendations are presented to the public, and stakeholders take positions relative to the agency's recommendations. However, the possibilities are confined by the limits of the recommendations. With PFOA, an ERA is centered around a deliberation where stakeholders answer questions about a problem together throughout the evaluation process rather than after it has been completed. They can exchange information and jointly analyze topics with scientists. The idea is that in doing so, new information and organization of ideas will be brought into the process, creating new possibilities for future alternatives. As opposed to the limited positional stances that arise in a consultative approach, the deliberation in PFOA is better able to generate and add new information into an ERA. For one, deliberation requires stakeholders to work together, allowing for shared reflections among a broad range of interests. Additionally, new insights can be generated as stakeholders share information; something less likely to occur when stakeholders start out positioned against one another. Deliberation also allows stakeholders to identify shared points where their interests meet. Moreover, deliberation helps stakeholders clarify their understanding, such as resolving what information is relevant and identifying areas where uncertainty exists.

**Box 3.3: Design Questions for Deliberation (Chap. 5)**

- What are essential components of deliberation within PFOA?
- How will decisions be made within the PFOA?



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### *Multi-criteria Analysis Approach*

A multi-criteria analysis approach assumes that PFOA will expand the scope of a traditional ERA to address wider concerns for a comparative assessment of risk. The European Union regulations consider cumulative or synergistic effects, among others. The National Resource Council (NRC 1996) discusses effects on future generations and ripple effects. Multi-criteria analysis refers to formal methods that people can use to help deal with complexity and incompatibility within an issue. Issues, especially related to the environment, are often complex because there are so many different factors and competing interests that people need to consider. For example, a given analysis might need to consider ecological factors, social factors, ethical factors, political factors, and economic factors. However, all of these factors can measure differently in the actual objectives of different stakeholders, and they cannot be easily condensed into a common measurement, such as a dollar value, in order to compare them to one another. Multi-criteria analysis allows a group to create a conceptual model based on assumptions about the way something works and how different factors relate to one another. Then the group can take different and otherwise incomparable units and incorporate them into the created model to weight the units according to the assumptions built into the model.

When complexity and incompatibility are not effectively dealt with in risk considerations, important information may be discarded or relevant perspectives may go ignored because they are difficult to measure. For example, scientific information has certain advantages, such as greater reliability, but a disadvantage is that science might not be able to account for a people's ethical or cultural concerns. Multi-criteria analysis involves an explicit effort for bringing complexity and incompatibility together. It helps people make full use of all relevant information to identify alternatives and make more informed, more robust decisions that are appropriate to a particular context.

PFOA does not currently require a formal, model-based multi-criteria analysis process, per se, but it does embody the basic elements underlying multi-criteria analysis and it allows for the possibility of integrating a model-based analysis if desired. Like multi-criteria analysis, PFOA involves asking questions that look at changes at different scales and relationships within a system. These might range from an individual farm, to the agricultural system of a country,

*Multi-criteria analysis allows a group to create a conceptual model based on assumptions about the way something works and how different factors relate to one another. Then the group can take different and otherwise incomparable units and incorporate them into the created model to weight the units according to the assumptions built into the model.*

and to regions beyond a country's borders. As a PFOA group asks their questions, they then develop answers using the assumptions people have about the functioning of a system. This involves doing analysis across different units, such as different economic, ecological, and social considerations. The key elements of multi-criteria analysis are present in PFOA, and integrating formal modeling into a PFOA is possible. However, doing so is not essential to a PFOA and different countries can use PFOA to guide their discussions of GMOs with or without making the effort to do a more elaborate modeling process based on their specific needs and contexts.

### **Key Concepts in Governance**

Governance broadly refers to the activities carried out by individuals and institutions, public and private, to reach their shared goals and manage their common affairs (Bingham, Nabatchi, & O'Leary, 2005; Hemmati, 2002). Use of the term 'governance' today also pertains more specifically to different practices intended to promote a working two-way relationship between government and citizens, namely through participation, transparency, and accountability. From the perspective of the State, governance is the capacity to learn and understand what the citizenry needs and wants, and to effectively and respectfully respond. From the perspective of the citizenry, governance is the capacity to be informed about and involved in the State's activities, and to effectively communicate and negotiate with the State about interests and concerns. There are a number of ways in which today's concept of governance is expressed in practice. Examples include efforts to involve a range of citizen perspectives in decision-making, open-sharing of information between the public and the State, and keeping practices open to oversight and challenge. Governance is the means by which the State and the citizenry meet their responsibilities to one another and in relation to agreements with other nations.

Relative to the concerns of this handbook, the ERA of GMOs is a State responsibility because GMOs have the potential to impact society at all levels, from individual citizens to other countries. The Cartagena Protocol is an international agreement meant to help individual nations manage this responsibility, and PFOA is a specific methodology designed to assist with this management. As part of an ERA, PFOA opens up discussions about GMOs into a more horizontal, societal discussion between the government and the representatives of civil society, as opposed to a closed-door,

*Governance broadly refers to the activities carried out by individuals and institutions, public and private, to reach their shared goals and manage their common affairs.*

expert-driven approach to ERA. In this way, PFOA embodies the governance principles of participation, transparency, and accountability.

### *Participation*

In governance, participation is the foundation for a two-way relationship between citizens and the State. For any given issue in society, there are various interests or stakeholders (i.e., individuals and groups that hold a stake in what happens). For citizens, participation is the means by which individuals and groups can get involved with State processes so as to provide input about their interests and influence decisions relating to an issue. For the State, participation is the means by which governing institutions can learn about and respond to various interests. Communication must be effective in both directions to support a genuine impact on policy as well as social learning. Participation helps ensure that the rights of citizens are protected and it helps the State do a more effective job of governing. In this way, participation also helps support the legitimacy of the State.

*Participation is the foundation for a two-way relationship between citizens and the State.*

#### **Box 3.4: Design Questions for Participation (Chap. 5)**

- Who will participate in the PFOA?
- How many stakeholder representatives should participate in a PFOA?
- How important is the continuity of stakeholder representatives?
- How will differences in power between stakeholders be dealt with within the PFOA?
- What happens if stakeholders decline invitation to participate in a PFOA?

The effect that participation has in governance depends upon the extent of citizen participation relative to State efforts to involve citizens. One method that has proven particularly effective in many countries are collaborative approaches in which stakeholders and State agency representatives work together to reach common agreements. However, participation can occur in a number of different ways. Traditionally, participation has consisted of public comment periods, during which individuals comment on draft decisions near the end of the process through letters or public hearings. Increasingly, governments are implementing procedures that involve citizens from consultation sessions at the beginning of a project throughout the evaluation and decision-making process in more advisory roles. The difference is that rather than people just responding to a final draft, they instead share knowledge early in the process and shape evaluations directly by providing input and helping analyze problems and the options for solving them.

Key to participation is inclusiveness and the way it allows for better societal decisions. When the range of stakeholder voices, with their different backgrounds and concerns, are included in decision-making processes, decisions can be based on more complete information. Better informed decisions generally make for better decisions. In addition,

such inclusive decisions can also be more durable. When all relevant stakeholders take part in the decision-making process and are allowed to express themselves or have “voice”, stakeholders are more likely to develop ownership and commitment toward resulting decisions. Along with voice, stakeholders must have the sense that there is the potential to contribute to the decision making process; that their “voice” has the capacity to “influence” considerations in a decision. Through a process that provides opportunity for voice and influence, an increased ownership and commitment decreases the probability of a decision being challenged, which increases the overall durability of the decision. More durable decisions generally make for better decisions.

A concern sometimes raised about participation is that it will take too much time or make processes too complex. There is some truth to this. Participation does take time. However, it has been repeatedly found that with thorough planning, participation can be designed to function efficiently and effectively.

In risk assessment, efficiency is never a singular goal and certainly not at the expense of a rigorous risk assessment. In fact, participation can make processes more efficient than traditional processes that lack it, which can get mired in prolonged legal battles and/or political conflict. Many who have had experience with participation see the points raised by these criticisms as outweighed by the greater benefits that result from participation.

Participation is embodied in PFOA through its involvement of stakeholders in the consideration of GMOs throughout the ERA process. Traditionally, ERA is framed as a task to be carried out by scientists who study the risks posed by whatever is being evaluated and then make recommendations to decision-makers to create policy based on their findings. However, this may not be the most robust procedure for conducting an ERA. Policy formation is a social process because it deals with the relationships between people, particularly the relationship between a State and its citizens. Additionally, although ERAs are traditionally based on scientific studies for evaluation, ERAs ultimately serve a social purpose because they are conducted to inform policy. The science in ERA has an essential role in informing policy, such as quantifying the potential risk something poses to society, but it is also just one component that needs to be considered in policymaking. Decision-makers also need to understand



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information, such as the acceptability of risk, which is grounded within the broader human values and judgments of societal discussion. By embedding citizen participation into the ERA process, PFOA makes ERA more rigorous because it allows decision-makers to place the science within the context of societal discussions. Through PFOA, diverse stakeholders can better inform and be informed by scientific information in the ERA. This benefits the science because it can help direct what needs to be studied, and it helps stakeholders because it allows them to directly work with the scientific information and consider its implications at an earlier stage in the ERA process. PFOA incorporates citizen voice and influence in the process of defining the problem that a GMO is intended to address, in assessing the range of future options for addressing the problem, and in evaluating the relative harms and benefits.

### *Transparency*

Transparency implies that governance processes are open to public review and that information is being freely shared between government and citizen. Instead of closed-door bargaining between officials and experts, a transparent system suggests that a process is visible. Traditionally, government reporting and information sharing occur late in a process and on a more need-to-know basis. Transparency suggests a process provides timely updates about what is happening throughout a process and that the information is available to everyone interested in receiving it, particularly the people to be most directly affected by it (i.e., stakeholders). This can occur through a number of different means ranging from observation and reporting procedures to participatory practices that put stakeholders in the same room together.

Transparency ideally means information is easily accessible and understandable. If information is to be useful to people, they need to be able to readily retrieve it and comprehend what is being said, especially the implications and consequences for their own lives. This is an issue of particular importance in ERA, and specifically in the ERA of GMOs, because ERAs often involve highly specialized scientific and technical information that many people may not have the background to understand. Additionally, since ERAs tend to be based out of urban areas and centered in research and policy institutions, in the case of GMOs relevant information may not readily make its way to rural communities that might be most directly affected by decisions about GMOs.

*Transparency implies that governance processes are open to public review and that information is being freely shared between government and citizen.*

Information accessibility and understandability are a crucial component of an effectively transparent system.

Objections raised about transparency often relate to the apparent magnitude of the tasks involved in achieving it. It is possible to pursue transparency by making information available in a few select and efficient ways. For example, increasingly the Internet is an easy way to provide information to and get feedback from some parts of society, and the Internet is relatively easy and inexpensive to use in this way. In communities without Internet access, radio announcements and programs have served to inform citizens. An intent and effort in encouraging transparency, even in limited ways, provides a basis that can then be improved upon as resources, capacities, and needs evolve.

PFOA embodies transparency on a number of different levels. Foremost, a PFOA creates transparency within ERA simply through the inclusion of stakeholders in the process. So, as opposed to an expert-driven ERA that reports its findings after a conclusion is reached, a PFOA allows ERA information to be shared with stakeholders earlier in the process and at appropriate intervals. Additionally, since a PFOA group involves representatives from a range of different stakeholder interests, an ERA process can become directly visible to a greater range of the public by way of representatives reporting back to the different sectors. Moreover, for scientists and regulators, a PFOA also provides a good means for evaluating the accessibility and understandability of ERA information and processes. It offers a direct means of receiving ongoing feedback from representatives about what needs to be better explained and what information is reaching whom. The overall structure of PFOA simply allows for and encourages broader reporting about the ERA process to the general public; additionally, it helps facilitate the process of making information accessible and understandable to the public.

### *Accountability*

Accountability refers to the State's responsibilities to its citizens and the degree to which governance processes are open to external oversight and challenge by the public. Any person or institution delegated power to make decisions that will affect society is accountable to the citizens from whom that power is derived. There is accountability in governance when people are free to examine and ask questions about governance actions and their consequences, and the

#### **Box 3.5: Design Questions for Transparency (Chap. 5)**

- What information is needed to conduct a PFOA process?
- How will you identify the gaps?
- How will you evaluate the legitimacy of the information used in the PFOA process?
- How will information used in the PFOA process be communicated and managed?
- How will information be communicated and managed outside of the PFOA?

*Accountability refers to the State's responsibilities to its citizens and the degree to which governance processes are open to external oversight and challenge by the public.*

individuals and institutions behind any given action are bound to such scrutiny.

Accountability is closely related to transparency; it is the checks and balances aspect of government openness. In fact, it is partly through transparency that a State achieves accountability. By freely sharing information about government processes in a way that is accessible and understandable to citizens, accountability is strengthened because it makes the internal work of governance visible to external parties. It is only through this visibility that any external party can begin to have oversight and consider supporting an action or initiating a challenge. In this sense, like transparency, there is also a practical side to accountability. To be useful for citizens, accountability practices need to be transparent, having a clear indication of how external feedback can be provided and how such feedback will affect a given process. A benefit of ensuring accountability in governance is that it builds legitimacy. This is especially true when stakeholders are invited to participate in a process from the very beginning.

**Box 3.6: Design Questions for Accountability (Chap. 5)**

- How will you evaluate the legitimacy of the PFOA process?
- What resistance might you encounter and how might you overcome it?
- Who manages the PFOA?
- Who convenes the PFOA?
- Who does it report to?
- Where does PFOA fit in existing legal and regulatory frameworks?
- What does a PFOA need to finance?
- How will PFOA be financed?

While accountability is important, those who suggest that accountability must occur within reason also make an important point. A State exists because its citizens grant it the authority to govern. To do so effectively, a governing body needs the authority to move forward on decisions. A reasonable set of checks and balances needs to exist to encourage the larger purposes of governance, like maintaining an effective two-way relationship between the State and its citizens. However, just as accountability suggests citizens have the capacity to place checks on governance processes, there also needs to be a balancing check on citizens to ensure the State can effectively function and perform what is necessary to fulfill the governing role citizens have assigned it. Sometimes the tasks involved in governance are controversial or unpopular, and governance processes need to have some capacity to avoid becoming overly impeded by accountability. Generally this means that accountability exists within defined systems and procedures.

PFOA embodies accountability through the feedback it provides and by ensuring different interests are represented. Throughout the PFOA stages, there is feedback from various stakeholders about how they perceive information or decisions within an ERA. This might include what questions are investigated in an ERA, how potential harm is evaluated,

and opinions about what a scientific study suggests about risk. As the PFOA group examines the information it receives, participants can provide feedback to administrators and scientists, which can then be used to shape the ERA process. Additionally, PFOA embodies accountability by ensuring a breadth of interests are involved in ERA. Different stakeholders may interpret information differently. If a breadth of stakeholder voices is not represented in ERA, such as with an expert-dominated approach to ERA, the process leaves itself open to criticisms of bias toward particular perspectives and interests. Part of accountability is being accountable to the full spectrum of citizens. Thus, a PFOA creates legitimacy for ERA by allowing relevant stakeholders to contribute and by defining how stakeholder voices may influence the process.



# SUMMARY FINDINGS FROM PFOA WORKSHOPS

Several trial runs of the PFOA methodology have been conducted. These trial runs played a critical role in helping to evaluate and refine PFOA as well as develop this handbook (See Appendix D for trial run examples). Each PFOA trial run, in four separate workshops, resulted in specific findings and an evaluation of the PFOA methodology. The findings helped produce a successively refined version of the PFOA methodology. Chapter 4 presents the findings about PFOA derived from the four workshops. To simplify the explanation of these findings and emphasize the end results of the succession, we work our way backwards through the findings from the most recent workshop during which the participants analyzed the advantages and challenges of using a PFOA methodology, to the earlier workshops, during which the participants provided specific insights and built their findings on three successive workshops: Kenya, Brazil, and Vietnam. This chapter is divided into two sections:

## **A. Malaysia Workshop on Transgenic Fish**

## **B. Workshops in Kenya-Bt maize, Brazil-Bt cotton, and Vietnam-Bt cotton**

**IMPORTANT TERMS:** transgenic fish; precautionary approach; transparency; deliberative; science-based; societal need; interest; risk; benefit; future technology options; risk assessment; biosafety; governance; participatory; uncertainty; stakeholders; equity



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### A. MALAYSIA WORKSHOP ON TRANSGENIC FISH: REPRESENTATIVES FROM CHILE, CHINA, CUBA AND THAILAND

Nelson, K.C., Z. Basiao, A. Cooper, M. Dey, M. Lorenzo H., Sathin Kunawasen, Li Sifa, Domingo Fonticiella, Blake D. Ratner, Maria-Isabel Toledo, and Wattana Leelapatra 2007. Problem Formulation and Options Assessment (PFOA): Science-based deliberation in risk assessment of transgenic fish. In: Kapuscinski, A.R., K.R. Hayes, S. Li and G. Dana (eds). (E. M.Hallerman and P.J. Schei, series editors). *Environmental Risk Assessment of Genetically Modified Organisms Volume 3: Methodologies for Transgenic Fish*. Wallingford, UK: CABI Publishing.

Overall, participants in the Malaysian Workshop on transgenic fish found there were many advantages and challenges to using the PFOA. One of the main advantages of PFOA is that it provides a systematic way to integrate scientific evidence and public interests. This distinguishes it both from expert-driven review processes that rely exclusively on scientific expertise as well as open-ended public debate in which participants are often poorly informed about the state of the science. As a structured, deliberative process, PFOA allows stakeholders with different views to learn about the current state of scientific information, to hear each other's ideas, to find the points where they agree and disagree, and to understand the rationale behind each other's perspectives. Unlike public debates that tend to reinforce the positions of advocates and opponents of a technology, in a PFOA, participants often adapt their views as their understanding of the issues deepens. This makes it less likely that any one perspective will dominate the deliberation.

Other advantages relate to the PFOA's emphasis on transparency and consideration of multiple options. By explicitly examining different options in addition to the technology being considered for adoption, the PFOA encourages participants to think in terms of the most appropriate way to meet an identified social need. Risks as well as benefits of future technology options are considered together. Because the process is transparent, it provides interested parties a way to understand not only the conclusions or recommendations of a PFOA but also the steps taken, the information brought to bear, and the options considered. Because information used in a PFOA needs to

be presented in terms that are broadly understood, it is also relatively easy to link the PFOA to a broader education effort to help the public understand the significance of risk assessment and biosafety.

Finally, PFOA offers potential advantages in terms of good governance – helping decision makers make wise decisions in the best interest of society and make them efficiently. A good PFOA may support different ministries in agreeing on a common decision regarding a future technology. Though the process requires a significant investment of time and effort, it may ultimately save time for the regulatory board to make decisions or avert extended public conflict. It may also lead to the identification of other priorities to guide technological innovation (e.g., direct research towards the development of disease or cold resistance traits in selected fish strains rather than or in addition to increased growth rates). An effective PFOA in one country can be used as a resource for other countries in the region because both the information and the process are clearly documented for others to see.

The decision to adopt the PFOA process may present planning and capacity challenges in many countries. Questions regulators and other stakeholders may ask include:

- Will the current regulatory body accept PFOA as part of its ERA processes?
- If PFOA is accepted as part of ERA, who should convene the PFOA so that it has appropriate legitimacy?
- How open should the PFOA be during the deliberations?
- What capacities are required to manage the process?
- Is there adequate capacity to ensure quality scientific and risk assessment information in the process?
- How much will it cost, and who will fund it?
- How long will the PFOA process take – and could conducting it mean missing the ‘window of opportunity’ for adopting a technology?”



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## B. WORKSHOPS IN KENYA-BT CORN, BRAZIL-BT COTTON, AND VIETNAM-BT COTTON

Text modified from:

Capalbo, D.M.F., Simon, M.F., Nodari, R.O., Valle, S., Santos, R.F. dos, Coradin, L., Duarte, J. de O., Miranda, J.E., Dias, E.P.F., Quyen, Le Quang, Underwood, E. & Nelson, K.C. 2006. Consideration of problem formulation and option assessment for Bt cotton in Brazil. In: Hilbeck, A., Andow, D.A. & Fontes, E.M.G. (eds) *Environmental Risk Assessment of Genetically Modified Organisms Volume 2: Methodologies for Assessing Bt Cotton in Brazil* (pp. 67-92). Wallingford, UK: CABI Publishing.

Nelson, K.C., G. Kibata, M. Lutta, and J.O. Okuro, F. Muyekho, M. Odindo, A. Ely, and J. Waquil.. 2004. Chapter 3. Problem Formulation and Options Assessment (PFOA) for Genetically Modified Organisms: The Kenya Case Study. In Hilbeck, A. and Andow, D.A. (eds) *Environmental Risk Assessment of Genetically Modified Organisms Volume 1: A Case Study of Bt Maize in Kenya*, (pp. 57-82) Wallingford, UK: CABI Publishing.

Nguyen van Uyen, Nguyen van Chi, Nguyen van Bo, Le Minh Sat, Hoang Thanh Nhan, Nguyen Xuan Hong, Le Quang Quyen, Arjen. Wals, Deise M. F. Capalbo, & K.C. Nelson. (forthcoming) Consideration of problem formulation and option assessment for Bt cotton in Vietnam, In: Andow, D.A., Nguyen Van Tuat, & Hilbek, A. (eds) *Environmental Risk Assessment of Genetically Modified Organisms Volume 4: Challenges and Opportunities for Assessing Bt Cotton in Vietnam*. Wallingford, UK: CABI Publishing.

Overall, participants in the trial runs felt the PFOA Model was:

- Practical;
- Encouraged open dialogue;
- Proved to be expert driven;
- Required very few process-modifications to be applied.

The potential weaknesses were that:

- It is only as good as the minds in the room;
- Meetings can be long and tiring;
- Too many people participating could make it ineffective.

The following findings summarize the major conclusions from the trial runs of the PFOA Model in Kenya in 2003, Brazil in 2004, and Vietnam in 2005.

***Finding 1: PFOA is a good idea for any agricultural technology but critical for GMOs. It should be done taking into consideration a precautionary approach on a case-by-case basis.***

A science-based PFOA provides an opportunity for multiple stakeholders to review the extent of the problem, the merits of a range of options that can address the problem, and choose to support or not support a technology based on its merits in relation to other options. As the Kenyan trial run of the PFOA Model was finishing up, one of the participants said, “This was a really good idea, we should do this for all of our agricultural technologies.” As a deliberative problem identification and technology review process, PFOA offers a systematic, participatory approach to making decisions about GMOs that will impact the nation, its people, and its environment.

Participants believed that a process such as PFOA is especially important when implementing a GMO technology because there is a possibility for irreversible consequences that could negatively impact society beyond the user. This uncertainty makes a PFOA process critical to ensure that multiple stakeholders can contribute their views and science is used to inform the discussion. Several participants in Brazil also believed it would be necessary to take a precautionary approach for each GMO technology. A precautionary approach, as represented in European regulation, balances between the need to take action and scientific uncertainty (Skorupinski, 2004), with the philosophy that if there is a “reasonable assumption of possible harm” then the government should take measures for protection (CEC, 2000). Certainly, any country interested in exploring such an approach to GMOs will need to develop its own understanding of the precautionary approach.

Vietnamese colleagues supported this finding from the two previous workshops and added that the PFOA should be considered and applied in the whole process of making the decision.



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***Finding 2: PFOA proved to be particularly useful for encouraging constructive dialogue and potential agreements.***

We find there is a demand for a new way to host societal discussions, just as scholars have documented the need for creative approaches to critical natural resource problem solving and risk assessment in various countries (O'Brien, 2000; Wondolleck and Yaffee, 2000). The use of a multi-stakeholder PFOA process in the ERA of GMOs provides a framing for risk assessment stages in which all stakeholders can contribute to the public discussion about the role of transgenic organisms in their nation. It focuses discussion on broad societal concerns rather than narrow individual interests. It requires that participants struggle to frame the risks and benefits of a technology in terms of multiple social goods. After framing the discussion in this way, participants can begin a participatory process, using the best data available to understand the contribution and impact of a particular technology in relation to other options. It creates the potential for informed evaluation and planned development at the national level and encourages the exploration of potential agreements among many stakeholders. In particular, Kenyan participants suggested that the PFOA helps identify important issues, create constructive dialogue, and identify possible consensus building points. Brazilian participants agreed and added that it initiates the discussion of options.

***Finding 3: For a successful PFOA, a nation should reduce uncertainty about GMOs when possible.***

One of the most difficult aspects of the PFOA Model is dealing with uncertainty related to the potential effects of GMOs and specific information about the agricultural conditions in a country. Once uncertainties about GMOs are identified and acknowledged within a PFOA, there are three ways that participants identified for helping to deal with uncertainty in the short-term:

1. Be sure the right minds and representatives of all the stakeholders are in the room
2. Establish a national and regional database of studies that address common questions
3. Understand if and when the answers will be available based on the proposed work in other sections

In the trial runs, some of the uncertainty in the discussions emerged because experts in a particular discipline or representatives from particular stakeholder groups were not present to share their knowledge. We were limited by the minds in the room, which could be the case for any PFOA. To minimize this limitation, the agency convening a PFOA should invite the key expertise required to discuss a particular GMO technology and the major stakeholders for a particular problem. To enhance learning and increase a clear understanding of the issues, it is important that expert scientists and representatives of major stakeholders have the opportunity to discuss the PFOA questions together. Since there is a “reasonable limit” to the number of participants in a productive discussion (estimated at ~15 people), the PFOA questions could be sent out to a broader range of stakeholders and experts in an attempt to gather information and representative opinions about the topic under discussion. There could also be a staggered series of committee sessions during which specialists prepare responses to specific scientific questions that can be considered by the larger group.

Uncertainty related to the genetic traits and environmental impacts of GMOs may never be completely addressed, but it would be possible to reduce uncertainty by maintaining a national and regional database of all the studies that address common questions about a GMO. Studies done in other ecosystems or agricultural systems should not replace site-specific research but they can provide some insights into the background necessary for reviewing the potential effects of a particular organism. For example, problem formulation (Steps 1 and 2) could be made more efficient if a database was established where the information from several sources (e.g., census statistics; existing studies, including economic, social, etc.; papers; surveys) can be organized and integrated in a way that every person can understand it. When no studies exist, an inclusive research agenda should be developed to fill critical gaps using available resources and working to enhance the multi-disciplinary nature of data over time.

Finally, other components of environmental risk assessment are designed to suggest ways to answer many of the questions that emerge during discussions in a PFOA. For example, during the Kenyan workshop, our discussion in Stage 6 was limited by many uncertainties, but we imagined that other ERA sections were addressing them. We realized

that future applications of the PFOA model should consider how the timing of a PFOA discussion interrelates with the outcomes from the non-target, gene flow, and resistance risk assessments. Alternatively, a PFOA could be developed as an ongoing process that receives feedback from these scientific assessments as data emerge.

***Finding 4: PFOA requires an organized and integrated database.***

In Brazil, participants pointed out that an organized database would be necessary if science was going to inform the PFOA discussion and the decision process in general. There are substantial amounts of data and research available in Brazil but its highly dispersed among government agencies, private companies, and research institutions. Kenyan participants did not feel sufficient information or research existed to support biosafety needs in general and the studies would need to be done in order to reduce uncertainty. In Vietnam, participants identified many existing information sources that could be used in the PFOA process and risk assessment in general.

***Finding 5: The discussion of a case study provides applied insights about key issues and consensus building.***

In Kenya, PFOA participants included people who had experience with insect control technologies from diverse national and professional backgrounds. However, this diversity did not deter us from building common points of agreement on matters of PFOA. Participants were encouraged to discuss the pertinent issues associated with Bt-maize, freely drawing from their knowledge and experience. Each topic was considered in turn, and the group moved to the next topic only when the whole group was satisfied that the major and pertinent issues for each topic had been considered and covered. Wider representation of stakeholders would be desirable in an actual PFOA. It is possible that this diversity would lead to intractable disagreements. However, based on the experience in the Kenya workshop, it seems more likely that this diversity would prevent differences in opinion from becoming entrenched publicly and would instead facilitate the mutual understanding of divergent values and framings of the problem at an early stage. In cases where consensus is impossible, the PFOA process can add to the legitimacy of

the decision-making process if dissent is recognized and reported transparently.

Furthermore, since there was insufficient time for comprehensive discussions for each topic in Kenya, only key points were considered. For example, in the selection of various alternative technologies and options for addressing the problem, the participants listed the various pest management options open to the farmer, but selected only two contrasting future scenarios for the trial run. One option based on Bt-maize, and the other on agricultural practice, which is also in its early stages of adoption, the Push/Pull technology. Using the PFOA Model, strengths and weaknesses of these two approaches for stem borer management could be reviewed in detail, and the attributes, potential benefits, and potential weaknesses of each technology were discussed and documented.

The availability of leading questions and topics for discussion and the stepwise arrangement of each topic made the discussions orderly, and gave the participants direction and their discussions depth. Factors that could have led to dissent and controversy were noted (e.g., moral issues, laws and litigation on GM crops, farmers' rights on genetic resources, seed ownership issues). While it was clear that these were significant issues, the structure of the model enabled the group to acknowledge their validity and importance, and avoid entanglement in these issues. This aspect of the model should be maintained for future applications of PFOA.

It is unlikely that the PFOA case study could be shortened to a one-day process. The two and a half-day review worked well in Kenya. The group was coming together for the first time, and GMO organisms are often new and controversial technologies for a country, such as Bt-maize in Kenya. Discussion takes time, as participants have to agree on the issues under discussion. At the Kenya workshop, timing and content proved to be an excellent way forward and should be used for other similar conferences.

Participants in the Brazil workshop, which included a diverse group of Ministry officials, also believed a PFOA Model would be useful for constructive dialogues, new insights, and the consensus building necessary for possible agreements, a finding supported by studies of multi-stakeholder dialogues in other countries (McLean et al., 2002; Glover et al.,



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2003; Irwin, 2001). Even in the highly politicized debates about Brazil's use of GMOs, we see some promise in a guided discussion about the range of issues in the societal consideration of a new genetically engineered product.

***Finding 6: Additional questions and clarifications will strengthen the PFOA: What is the distinction between 'needs' and 'interests'? What loss has occurred as a result of the problem in productivity as well as environmental, social, and economic aspects? How will the technology's use affect the environment? How will use of the technology affect the conservation of genetic variability of the species and other related biodiversity?***

Different aspects of both workshops revealed additional questions and clarifications that could be integrated into a PFOA to further strengthen the process. In the Kenya trial run, formulating the shared problem statement made the group aware of the difficulty of directly linking a problem such as stem-borer damage to basic needs for food, shelter, and safety. Issues of profitability and competitiveness could not be excluded, but they also blurred the distinction between "needs" and "interests". This is a problematic area that should be refined through further analysis and case studies. In Kenya it was also revealed that while each option was considered separately, further analysis would need to address combinations of technologies. It would be possible for two control strategies to be complementary, for example the Push-Pull combined with Bt-maize for mixed cropping systems in many parts of Eastern Africa.

The Brazil trial run of PFOA illustrated that the options assessment would have to include more specific questions about environmental risks and a well-documented analysis of the crop losses a new technology would address. The adoption of a new technology might cause changes in environmental and societal aspects, which are not necessarily explicit. Purely economic questions should not obscure other aspects related to the problem. Participants also decided that a PFOA must consider the entire ecosystem involved, as well as the consequences for human health and well-being. For example, in the past some newly introduced technologies in a production system (e.g., CFCs, pesticides) largely served to produce economic gains for multinational companies, but without regard for other consequences that could alter the components of the water-soil-atmosphere system and its relationship with living organisms.



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Workshop participants in Vietnam believed the questions were a helpful guide. They suggested that the appropriate Ministry could use these questions to collect multiple stakeholder views and consider these views as they made the final decision.

***Finding 7: The PFOA should be organized by government authorities and discussed by a multi-stakeholder group.***

A successful PFOA should produce socially acceptable recommendations about GMOs. National governments are often critical actors for facilitating socially acceptable choices (Stern and Fineberg, 1996), especially when uncertainty exists about the impacts of a choice. Several participants in the trial runs pointed out that it was fundamental to the conceptualization of a PFOA that it be embedded in government regulatory systems in such a way that it reduces uncertainty for all members of society.

At its best, a PFOA should serve as a forum for all stakeholders to understand the problem that needs to be addressed and the comparative impact of different options for solving that problem. Among its numerous functions, a PFOA involves processes in which the gaps in the needs of a society are identified and possible future solutions are compared. A PFOA assumes that the actual people affected are the center of the assessment. Therefore adequate and fair representation should be ensured during such assessments. The initial data gathering for a PFOA can take the form of a participatory rural appraisal (PRA), participatory learning and appraisal (PLA), focus group discussions (FGD), or questionnaire interviews (QI) (there are numerous resources that provide possible methodologies, a few include Krueger and Casey 2000; Nicoles 1991; Chambers et al., 1989. Sources of pamphlets, manuals, and short books include International Institute for Environment and Development, Intermediate Technology Publications, among others). To increase efficiency, efforts should be made to use existing data and encourage any ongoing studies to collect data that may be relevant for future PFOA discussions. Once the existing data are organized, representatives of the various stakeholders should participate in the PFOA review of the GMO. As mentioned above, an actual PFOA would ideally involve a wide group of stakeholders, including farmers, consumer groups, industry, environmental representatives, policy makers, technology scientists, etc. Whoever has the duty of selecting stakeholder participants

for the PFOA will need to be bear in mind that the process is only likely to gain public legitimacy if all relevant stakeholders have the possibility to contribute and they understand how their voices will influence the process. This argument for transparency, equity, legitimacy, and a data driven process is well supported in the literature (Susskind et al., 2000; Hemmati, 2002).

***Finding 8: In Kenya Brazil, and Vietnam the PFOA should be embedded in the policy and regulatory process.***

The participants in both the Kenya and Brazil workshops concluded that PFOA should be embedded in their respective policy and regulatory processes surrounding GMOs. Vietnam workshop participants agreed and added many suggestions for funding, technology development criteria, and decision-making processes.

***Finding 9: PFOA serves as a good foundation for future monitoring of environmental and societal impacts of the technology.***

Brazilian participants suggested that once a particular option has been accepted by the decision makers, its implementation and impacts will have to be monitored to identify possible shifts in the environment and society. The participants recommended that the nation develop systems for monitoring new technologies, and consider the PFOA Model as an approach that can be adapted to post-release monitoring as well as pre-release evaluation.

***Finding 10: PFOA assists with public education.***

Participants in the Vietnam workshop mentioned that there was a tremendous need for public education and training on GMO risk assessment. They point out that the PFOA would be one contribution to enhance awareness of GMOs and public options for influencing decision-making.



# DESIGNING AND IMPLEMENTING A PFOA

This chapter focuses on the practical process of actually implementing a Problem Formulation and Options Assessment (PFOA) during a country's environmental risk assessment (ERA) of genetically modified organisms (GMOs). PFOA can play a role in multiple scales of governance and regulation. The PFOA methodology is adaptable to the specific contexts in which it is intended to be used. Thus, the first step in implementing a PFOA is the process of designing it according to your country's particular circumstances, needs, and goals. This chapter examines:

## **A. Objectives in designing and setting up a PFOA**

## **B. Questions to guide the PFOA design**

**IMPORTANT TERMS:** stakeholder; stakeholder sector; stakeholder representative; interest; deliberation; facilitator; primary stakeholder' secondary stakeholder; observer; ERA partners; support personnel; database; summary; synthesis; consensus; majority votes; supermajority; legitimacy; multi-stakeholder

### A. OBJECTIVES IN DESIGNING AND SETTING UP A PFOA

Each country interested in implementing a PFOA during its ERA for GMOs must customize the methodology to its specific contexts. The sorts of contextual factors that are relevant to the design of a PFOA include existing laws and regulations, cultures, and political infrastructures and boundaries. This list is not exhaustive, but rather demonstrates the range of considerations that can be important to designing an effective PFOA process.

It is essential to adapt PFOA to a country-specific context so that it can accomplish its designers' and participants' goals. When a PFOA process is not appropriate to the particular contexts in which it is meant to occur, essential considerations can be overlooked. These might include considerations relating to legitimacy within governance, effectiveness or appropriate advising mechanisms, specific stakeholders, local environmental factors, or particular regulations.

Even though a PFOA is country specific, there are consistent attributes of a PFOA for all countries. Examining how a PFOA is used in another country could help you design a PFOA for your particular context. For example, a group considering using a PFOA to evaluate Bt maize can definitely learn from examining how, say, a PFOA for Bt maize was conducted in Kenya. However, the particular circumstances in whatever country you may be from – whether it be Nigeria, Cuba, Jordan, Ukraine, Thailand, or elsewhere – are always unique enough to necessitate some fine-tuning of the PFOA.

Ultimately, as discussed in Chapter 3, a PFOA is a means of comparatively evaluating a GMO in relation to other possible solutions for addressing a particular societal problem. One of the greatest benefits of PFOA is that it creates a forum for healthy deliberation between a variety of different interests and stakeholders. For example, a PFOA can put local farmers in communication with national policymakers, scientists in communication with regulators, and environmental NGOs in communication with private corporations. The forum that PFOA creates is capable of bringing the full range of considerations from these various interests into a discussion. PFOA provides a way to examine such things as scientific, economic, social, environmental, and ethical considerations alongside one another.

A PFOA plays a role at multiple scales of regulation and governance, and so the design of a PFOA requires paying

*Each country interested in implementing a PFOA during its ERA for GMOs must customize the methodology to its specific contexts.*

attention to all of these different scales (Box 5.1). Designers must consider the smaller scale of logistics of the actual PFOA process itself and the issues with which it will be dealing. They must plan at the medium scale for the place of PFOA within the broader ERA process. Further, they must consider the larger scale where PFOA will fit into the larger governance structures and regulatory frameworks to which it will be accountable. Later on in this chapter, we examine specific questions to help guide users through the process of designing a PFOA that takes each of these scales into account. First, though, let us briefly preview the sorts of considerations that each of these scales entail.

### ***Small Scale Considerations***

Considerations at the smaller scale relate to the purpose and logistics of the PFOA. This is the most involved aspect of designing a PFOA. Relevant issues at this level range from the very concrete, such as how the PFOA will be financed, to the more abstract, such as the goals for the specific PFOA. For example, you will need to think about the intended length of the process, rules for governing the process, and the product you want the PFOA to result in. Additionally, you will need to determine who is going to be involved in the process. This includes what stakeholders you will invite to participate and how they will be involved; it also requires making decisions about who will be responsible for managing the PFOA and who will facilitate it. Considerations at the process level are the most basic to the overall design of the PFOA.

### ***Medium Scale Considerations***

The medium scale involves considering the PFOA in relation to the rest of the ERA process. In essence, this means designers must determine the timing of when the PFOA will occur in relation to the rest of the ERA process. It also means they will need to identify the subsequent changes in current ERA procedures that will be necessary to help the PFOA best guide and assist the rest of the ERA. Presumably, your country has ERA procedures in place for other environmental concerns, if not yet for GMOs. Whatever your present situation may be, PFOA may be a unique addition or a modification of existing methodologies in the ERA structures and procedures with which people are familiar. Because it entails change or the addition of something different, considerations of where PFOA will fit within the broader ERA process deserve special attention.



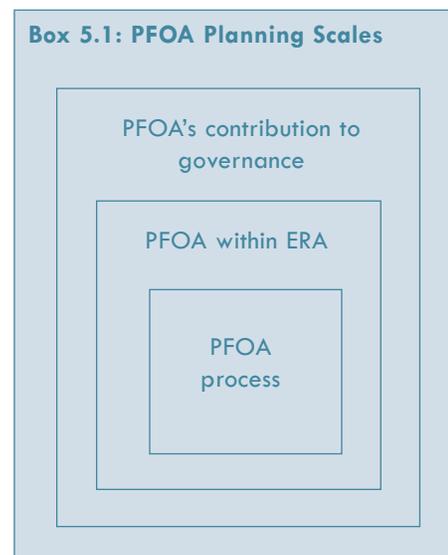
Thomas Isler

#### **Box 5.1: PFOA Planning Scales**

PFOA's contribution to governance

PFOA within ERA

PFOA process





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For a handout of questions to guide PFOA design, see Appendix E.

### **Large Scale Considerations**

The broadest scale of consideration in designing a PFOA involves examining its relationship with the larger governance systems to which PFOA will be accountable. When considering PFOA in relation to broader governance systems, designers must determine where PFOA fits into existing systems and what changes to the existing systems will be necessary because of PFOA. As well as fitting PFOA into existing system, designers can also use other procedures as examples of what may work well in a country specific design. For example, if there are other procedures in other parts of governance systems that are similar to PFOA in process, such as facilitated discussions, or that embody some of the same underlying concepts as PFOA, such as transparency, these can be used by designers for reflection about what might work and what could be improved upon in the development of the PFOA.

### **B. QUESTIONS TO GUIDE THE PFOA DESIGN**

Designing a PFOA means customizing the structure of the methodology to your country's particular circumstances, needs, and goals. To do so requires considering many specific factors relating to these contexts. This section compiles the critical questions (Box 5.2) that need to be answered when designing a PFOA.

#### **Box 5.2: Questions to Guide the PFOA Design**

##### **I. PFOA in Governance and Regulation**

- A. What are your goals for PFOA?
- B. Where does PFOA fit in existing regulatory and legal frameworks?
- C. Who manages the PFOA? Who convenes the PFOA? Who does it report to?
- D. What are PFOA costs and how will they be financed?
- E. How will you evaluate the legitimacy of the PFOA process?
- F. What resistance might you encounter and how might you overcome it?
- G. What are essential components and appropriate rules of deliberation within PFOA?

H. What other multi-stakeholder processes that embody principles similar to PFOA exist in your nation?

I. How will decisions be made within the PFOA?

## **II. ERA and PFOA**

A. How should the PFOA be staged within the ERA?

B. How will PFOA link into risk management planning and implementation?

## **III. PFOA Process Design**

A. Who will facilitate the PFOA? What are the roles and responsibilities of the facilitator?

B. Who will participate in the PFOA?

C. How many stakeholder representatives should participate in a PFOA?

D. How will stakeholder representatives be involved in the PFOA?

E. What happens if stakeholders decline invitation to participate in a PFOA?

F. How important is the continuity of stakeholder representatives?

G. What preparation, training, and/or resources will different people need prior to participating in the PFOA?

H. How will differences in power between stakeholders be dealt with in the PFOA?

I. What information is needed to conduct a PFOA process? How will you identify the gaps?

J. How will you evaluate legitimacy of the information used in the PFOA process?

K. How will information used in the PFOA be communicated and managed within the PFOA?

L. How will information be communicated and managed outside of the PFOA?

M. How will you evaluate the PFOA?

## I. PFOA IN GOVERNANCE AND REGULATION

### A. What are your goals for a PFOA? (Box 5.3)

The overarching goal of PFOA is to provide multi-stakeholder deliberation about a GMO technology in relation to other future alternatives. A PFOA interacts with traditional ERA processes and builds upon them to make the overall consideration of the GMO more inclusive and robust. Accordingly, a PFOA serves the additional goals of informing the science of ERA, assisting in improving the science, and allowing the ERA science to accurately inform multi-stakeholder deliberation.

Among these larger goals, each country will emphasize certain aspects of a PFOA differently according to their specific needs and contexts. Consequently, the selection and prioritization of your individual goals for the process will determine the ways in which you design your PFOA. For example, among others that you might identify, is one of your goals:

#### Box 5.3: What are your goals for PFOA?

- Select and prioritize goals to guide your PFOA design.
- Protect the ability for stakeholders to deliberate among themselves.
- The final report produced by a PFOA provides a summary of the deliberation and final recommendations regarding the GMO.

- To inform ERA science with information about stakeholder perceptions and evaluations?
- To assist with identification of hazards, management issues, or key components of uncertainty?
- To verify through deliberation that you are pursuing the best option?
- To allow diverse stakeholders to deliberate and arrive at a new understanding of GMOs in relation to alternatives?
- To increase and improve on communication about GMOs and ERA?
- To increase transparency in communication?
- To enhance accountability?
- To prioritize government investment in biotechnology and biosafety?
- To evaluate policies and programs associated with technology development, risk assessment, and society needs?

Nevertheless, it is an important goal to make multi-stakeholder deliberation an integral part of ERA and this should remain at the center of a PFOA design. PFOA is not just an additional source of information, nor is it just an elaborate societal forum for consideration of GMOs. If a PFOA only acts as an information source for informing ERA

scientists, the concern is that it could become little more than a sophisticated form of social science data gathering. If a PFOA is only a forum for deliberation between stakeholders in such a way that it has no impact on ERA science, then the concern is that many opportunities for improving the ERA could be lost. If a PFOA is not interacting with or informed by existing ERA science, then the concern would be that it may not move far beyond existing public debate, and the public could miss the chance to develop a more complete and accurate understanding of the issues. Overall, a PFOA should act to broaden and improve societal considerations of a GMO.

It is also important and useful to think of the goal of a PFOA in terms of the product you want as this is what will be provided to decision-makers for their use:

- Should the PFOA produce a summary report of what happened during the process? This would allow the decision-makers to see evolution of the deliberation and how the group came to their recommendations.
- Should the PFOA produce a comparative assessment of the options identified? This would allow the decision-makers to see how the group evaluates the alternatives and weighs their respective attributes.
- Should the PFOA produce a recommendation around the issue among the alternatives? A report with a recommendation allows the PFOA group to provide suggestions for action to the decision-makers that can be added to all the other information under consideration.

The more clearly you can define the intended goal of a PFOA and how that product will be used, the more successful the process will be at producing it.

### **B. Where does PFOA fit in existing regulatory and legal frameworks? (Box 5.4)**

Every country has a unique regulatory system and biosafety framework for GMOs, but how a country administers environmental risk assessment will be the first determining factor as to where PFOA fits into existing structure. Risk analysis may be the umbrella under which a country incorporates PFOA. In this case PFOA may be informing policy decisions using Steps 1-4. Or, it may be informing

**Box 5.4: Where does PFOA fit in existing regulatory and legal frameworks?**

Three options are:

- Single agency administration
- Umbrella decision-making body
- Divide PFOA administration according to mission

an environmental risk assessment for a specific GMO by guiding the research questions and scientific results to inform the PFOA deliberation over options (See Chapter 2). Your goals for using a PFOA and current administrative structures will influence this decision. In previous work, governmental officials and scientists have suggested three generic options to fit a PFOA into existing frameworks:

1. Administered by one agency in collaboration with others;
2. Administered by an umbrella decision-making body with support by multiple agencies;
3. Conducting PFOA Steps in different agencies based on the specific agency mandate.

We present examples of these options as support for the discussion and decision-making you will have as you develop a PFOA within your context.

### Single Agency Administration

The first possibility would be to place administrative responsibility for PFOA within a single agency, which provides a variety of benefits for coordination of the PFOA activities and efficiency. When one agency handles all the responsibilities you reduce cross-agency communication problems in planning, struggles between agencies over funding and control, and time required to get two or more agency authorities to organize the recommendations for the final decision-makers. The challenges are that authorities from other agencies may ignore PFOA recommendations or view the outcomes as biased and captured by the interests most closely aligned with the host agency. To mitigate these challenges, the agency responsible for PFOA will have to develop a transparent and responsive consultation process with other appropriate agencies.

A choice for the single agency responsible for PFOA could be the agency that conducts the environmental risk assessment. For example, in Kenya the Kenyan Plant Health Inspection Service (KEPHIS) would be responsible for administering a PFOA Board for GMOs, but could do so in coordination with the Kenya Agricultural Research Institute (KARI) when the GMO is an agricultural product (Nelson et al. 2004). In another example, for transgenic fish in Chile, the National Fisheries Service regional office could be responsible for conducting a PFOA as part of the Technical Report required for new aquaculture proposals (Nelson et

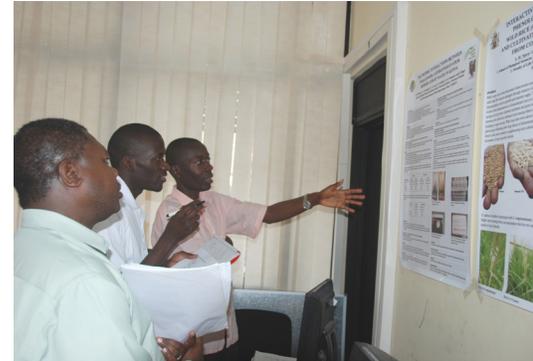
al. 2007). In both examples, the host agency consults with all relevant agencies but the administration and oversight of the PFOA rests with one agency.

### **Umbrella Decision-Making Body**

A second option would be a PFOA administered by an umbrella decision-making body with support from multiple agencies. This approach ensures that all appropriate agencies are involved with the PFOA but cross-agency coordination will require additional time. If this umbrella body is responsible for the final decision about the GMO technology, it also moves the PFOA process and recommendations closer to the seat of decision-making authority which could give it greater legitimacy and influence as an integrating methodology. One critical challenge in this approach is preventing PFOA from becoming an “orphan” with no agency that views it as a central responsibility within their mandate, resulting in no one advocating for it when tough budget decisions or work priorities are considered. An example of this option is a proposal to send the PFOA report to the Brazilian National Biosafety Committee (CTNBio) within the Ministry of Science and Technology (Capalbo et al. 2006). The PFOA would be conducted by the CTNBio, but an umbrella oversight group of the Ministries of Environment, Health, and Agriculture would provide licenses for testing, review the PFOA report, and conduct public hearing sessions.

### **Divide PFOA Administration According to Mission**

A third option would be to consider the products of the PFOA Steps and assign different parts of the PFOA methodology to distinct agencies based on their respective legislative mandate. An advantage of this approach is that a PFOA can provide insights for broad policy formation and research agenda setting on technologies that may be administered by different agencies. It could be used to inform the long-term planning in these agencies. Whereas, an environmental risk assessment for a specific GMO has a specific goal, administered by a regulatory agency. The greatest risk of this approach is that the insights from each Step could be separated in time and administrative space, weakening the contribution for a single GMO. If the Problem Formulation Steps (1-3) are conducted for a broad problem analysis, every ten years, it will be necessary to ensure that the recommendations are reviewed and considered as the foundation for the specific Option Assessment Steps (5-8) in an environmental risk assessment for a specific GMO technology.



Joy Owango

We provide one example of how you could design an approach to have the PFOA products more closely aligned with agency mandates by breaking up the Steps. Steps 1-3 in PFOA provide societal-level planning about problems. These steps could be administered by the agencies charged with research and development for the nation. In the case of China, it might be the Ministry of Science and Technology (MOST) or in Brazil it could be the Brazilian Agricultural Research Corporation (Embrapa).

Steps 5-8 in PFOA focus on future alternatives for addressing a problem and their associated system effects, in this case with an emphasis on adverse effects or risk. These PFOA Steps could be administered by the agency(s) responsible for risk assessment. In China, for example, the Aquatic Organism Expert Group of the National Committee on Biosafety in Agriculture (NCBA) housed within the Ministry of Agriculture (MOA) would conduct Steps 5-8 for the case of transgenic fish (Nelson et al. 2007). In Thailand, as another example, the proposing institution's Institutional Biosafety Committee (IBC) would conduct Steps 5-8, with their Department of Fisheries (DoF) conducting the Steps for fish and their Department of Agriculture conducting the Steps for crops (Nelson et al. 2007).

In summary, as you design how the PFOA will fit into the existing regulatory system, you will consider many options. It will be important to situate the PFOA so that it strengthens environmental risk assessment and decision-making about GMOs, and is administered so that all agencies have the opportunity to contribute to its findings and view it as important to their mandate and administrative priorities.

### **C. Who manages the PFOA? Who convenes the PFOA? Who does it report to? (Box 5.5)**

It is important to determine the administrative structure that will exist throughout the life cycle of a PFOA. If you are already in the process of designing a PFOA, perhaps some of this structure has already been decided. However, fully considering and clearly defining the complete range of administrative responsibilities and accountabilities will only make the PFOA that much more likely to achieve your intended goals. This is especially important given that a PFOA is likely to straddle different roles that may be the responsibilities of different agencies. For instance, in your country, one agency may be responsible for regulating GMOs; however, the expertise for evaluation may exist in

#### **Box 5.5: Who manages the PFOA? Who convenes the PFOA? Who does it report to?**

- A PFOA needs to be managed by a government agency with oversight from multiple parties.

other agencies. Things you will need to consider relating to PFOA administration include:

- What administrators or agencies will house and manage the PFOA?
- Who will be responsible for conducting the process?
- Will all PFOA processes be managed and convened by the same administrators or agencies?

One option for administration is to have a single agency responsible for managing and conducting the PFOA. This can benefit the efficiency in communication and interaction around the PFOA because the one agency has ownership in managing the process. A potential problem with assigning the PFOA to a single agency, though, is that there may be limited buy-in to the process from certain parties if they perceive the process as being too much under the control of the single agency. This may be a problem in some countries and not in others. If a single agency is assigned responsibility for the PFOA, a multi-agency review committee could reduce potential problems. This committee could occasionally check in on the PFOA and have oversight over it to ensure that it is serving all mandates of a society's governance.

Another option for administration exists if your country already has an interagency committee for oversight of environmental or GMO technologies and biosafety – you may be able to assign administration to this group. The strength of this is that the PFOA may have increased legitimacy across agencies if the interagency group is managing the PFOA. The weakness is that there may be very few resources associated with the interagency group and PFOA may become an orphan that no one owns or supports financially.

#### **D. What are PFOA costs and how will they be financed? (Box 5.6)**

These questions obviously relate closely to determining administrative structures relevant to PFOA. Just like any government process, a PFOA will require financial support. It should be clear what financial draws a PFOA may require and where the budget for this will come from.

This list is not exhaustive, but some of the possible financial costs involved in conducting a PFOA could include:



Thomas Isler

**Box 5.6: What are PFOA costs and how will they be financed?**

- Finances will depend on how extensive a process you design and the funding available.
- It is very likely there will need to be cooperative financing from both the government and the industry parties proposing a GMO, in addition to in-kind services from other societal organizations.

- Support costs – clerical staff; travel expenses for staff and participants; per diem for participants; meeting spaces; general office materials
- Process costs – facilitation for the PFOA (a significant expense); science and research needing to be conducted to supply the PFOA with necessary information; information management
- Communication costs – ongoing communications with various government agencies and decision-makers; ongoing communication with stakeholders and PFOA participants; communicating with the public about the PFOA, such as through print or web publications
- Training and evaluation costs – training participants in deliberation techniques in the beginning of the process if necessary; evaluating participant satisfaction as well as monitoring the general legitimacy of the PFOA

The most independent option for financing a PFOA would be a dedicated fund that is not under the discretion of any particular stakeholder, agency, or governing body, and which gets renewed in such a way that it is perceived as independent funding. This could ensure that no group is able to manipulate the fund and that the funding party cannot be perceived as having undue influence over the outcome of the PFOA. A dedicated fund could be achieved through a special allotment of tax dollars by the legislature for the PFOA. It could also be achieved through an endowment supported by industry, NGOs, and non-government foundations interested in GMO biosafety. Or, it could be achieved through some sort of trust, as long as the trust is adequately protected.

Another option for financing a PFOA is to divide the costs among all of the agencies involved in the ERA of GMOs. Perhaps a formula could be created whereby each agency contributes a certain percentage of the cost depending on their roles and interests. In this way, no one agency has control over the PFOA or has to carry the full burden of paying for it.

Another possibility for financing a PFOA is to make it the responsibility of the party submitting the GMO technology for review. The PFOA process could be defined as part of

the costs of review for a GMO and the submitting party could be required to pay for the PFOA in the same way as they are often responsible for financing experiments and various other costs in a traditional ERA. If you were going to go with this option, you want to be careful that the cost of submitting a GMO for approval does not become prohibitive to a party. Otherwise, the process might come to be seen as unfair. You also want to be careful that the financing cannot be manipulated by the submitting party through undue influence. The submitting party could pay a fee to a third party or independent agencies to conduct the PFOA. If the fee is appropriate to the costs, this arrangement would prevent the submitting party from prematurely saying that “enough has been discussed” or from being burdened with an ever expanding PFOA process.

Depending on the country, there are many different ways that governance can be funded. What is critical for the PFOA process is that it be cost effective and that it maintain legitimacy through independence in relation to its funding source.

### **E. How will you evaluate the legitimacy of the PFOA process? (Box 5.7)**

If a PFOA is to serve the ends for which it is intended, the process needs to have societal legitimacy. This means that the process is perceived as legitimate across multiple scales of society. There are three scales you can use to determine the societal legitimacy of the PFOA: the state, the stakeholders, and the general public.

The first scale for evaluating the legitimacy of the PFOA is in relation to the state and relevant government agencies. Examine the ties that a PFOA has or will have with traditional government processes:

- Do all of the relevant government agencies acknowledge the PFOA?
- Do they seem willing to provide information to the PFOA when it is requested or necessary?
- Do they seem willing to accept the contributions that the PFOA provides and to use the information in their own processes?
- Does it seem that the PFOA is having an effect on external decision-makers in some way?

#### **Box 5.7: How will you evaluate the legitimacy of the PFOA process?**

- The PFOA needs to be acknowledged by relevant government organizations.
- Key stakeholder sectors have to recognize that the PFOA can assist in ERA.
- General public has to see PFOA as independent from undue influence.



Angelika Hilbeck

PFOA's influence on traditional processes - either by providing input or affecting decisions - is a good measure of legitimacy the process.

The second scale for evaluating the legitimacy of the PFOA is in relation to the stakeholder representatives. Examine the stakeholders that have chosen to be involved in the PFOA:

- Are there a diverse array of stakeholders participating?
- Were most stakeholders readily willing to participate or was it difficult to get some to agree?
- If there was resistance, what were the reasons?
- Are there significant stakeholders that declined participation?
- Do you feel the stakeholders agreeing to participate represent all of the most critical perspectives on the issue?

The diversity in the array of stakeholders involved in the PFOA, and the degree to which those stakeholders welcomed the opportunity to be involved, suggests a lot about the legitimacy of the PFOA.

Participants satisfaction with the PFOA process will influence their perception of its legitimacy. Satisfaction is a complex attribute to measure and not necessarily a good measure of the quality of the outcome. Participant satisfaction is most closely related to the representative's "voice," the ability to express their ideas and concerns in an equitable process as well as the degree of organization during the process. Use participant satisfaction cautiously as a measure of legitimacy.

The third scale for evaluating the legitimacy of the PFOA is in relation to general public opinion. Examine the public's perspective on the PFOA:

- What are the public perceptions about the participatory nature and involvement of the PFOA process?
- What are the public perceptions about the contribution the PFOA will make to decisions?
- How well does the PFOA re-create a microcosm of societal debate about the issue?
- Does the public perceive that the societal debate is being re-created responsibly?

Public opinions about the PFOA and the degree to which the broader public debate is reflected in the process indicate much about the legitimacy of the PFOA.

To determine whether a PFOA process has societal legitimacy, it is important that all three of these scales be considered independently. All of these scales are interrelated and legitimacy at one scale will likely influence legitimacy at another scale. However, each of these scales has its own independent concerns, and evaluating the legitimacy of the PFOA at any one of these scales alone does not tell enough about the other two scales to determine how the PFOA is perceived. For example, the public could potentially be influenced to be strongly against a PFOA if one powerful stakeholder group that strongly opposed the PFOA were to run a vocal media campaign criticizing the process. Yet perhaps this one stakeholder group is the minority voice opposed to the PFOA and all of the other stakeholders, as well as the state, are in favor of it but lack the resources or media influence to counter the campaign by the opposing group.

For a PFOA process to have any societal legitimacy, it must be able to demonstrate some legitimacy at all three of these scales. Ideally, broad support and confidence will build around the PFOA at all of these scales, indicating strong societal legitimacy. However, since the PFOA is dealing with conflicting interests, there will realistically be differences in the extent of perceived legitimacy within any one of these scales and across them. Your main concern will be that adequate legitimacy for the PFOA can be demonstrated through some combination of support and confidence in the process across these three scales.

#### **F. What resistance might you encounter and how might you overcome it? (Box 5.8)**

Resistance to implementing a PFOA may be encountered. It is important to try to anticipate and strategically think about resistance during the PFOA design. This will prepare you for dealing with it, but it will also help enhance the capacity of PFOA to be a valuable contribution to the ERA process. Resistance will vary with context. However, the main resistance is likely to arise from the status quo around existing processes relating to ERA.

One form of resistance can arise from a government bureaucracy that is cautious about change. In general,

**Box 5.8: What resistance might you encounter and how might you overcome it?**

- To reduce misunderstandings, be sure the goal, design, and contributions of the PFOA are well-documented.
- Highlight the benefits that the PFOA can provide in multiple governance arenas.
- Keep appropriate government officials informed about PFOA.
- During the first few uses of a PFOA, encourage timely evaluations of the process to allow broader sectors to learn about it.

government bureaucracies are perceived to be overly-cautious institutions. This caution can provide important benefits. Governments are delegated both the power and responsibility of making major societal decisions. It is important for them to be overly-cautious about change that could have huge, unanticipated, negative ramifications for society in order to guard societal safety. To an extent, an overly-cautious attitude in government bureaucracies can be compared to the guidance offered by the precautionary principle not to adopt change without substantial reflection and evaluation.

Another form of resistance can arise from concerns and fears about losses of power and control. Processes and decisions relating to ERA currently occur in a certain way. Relevant institutions are usually somewhat comfortable with existing procedures because they know what is involved and what to expect. Institutions have learned to adjust and organize their own efforts within existing contexts. Important relationships between institutions are already established. Adding PFOA into current practices leaves questions open about the potential impact that changes will have on individual parties and institutions. There can be concerns about how a change will affect a group's ability to do what they want or need to do. There can also be concerns about losses of efficiencies that exist in current practices that have taken a lot of time and effort to create.

In thinking about how to deal with resistances to PFOA, it is first important to recognize some things about change. Foremost, people usually have some initial resistance to change. Whenever something new is proposed, people need to go through a process of reflecting on what the change means for them in terms of their relationships and the way they do their jobs. Sometimes providing this opportunity to reflect is all that is required to overcome resistance. Furthermore, implementing a change like PFOA will have an impact on people and it is important to be up front and not pretend otherwise. Taking people's concerns seriously and recognizing why they are important and where they come from can only help you to work with people rather than against them to overcome their resistance. You can use these concerns to adapt PFOA to your context.

The best overall approach for overcoming resistance to implementing a PFOA will be to emphasize the benefits a PFOA can provide to existing ERA processes. Here are some things you can do to help accomplish this:

- Document the design, purpose, and planned contributions of the PFOA explicitly and understandably so that resistance is less likely to arise from misunderstandings.
- Document the benefits of PFOA compared to the costs or downsides of current practices across multiple governance arenas.
- Keep relevant parties informed about the PFOA throughout the design and implementation so no one feels the process will move forward without them.
- Encourage relevant parties to try out and study the PFOA model for themselves so that they can independently conclude what they think works or does not work in comparison to current practices.
- Never act as though you have identified all stakeholders and all societal concerns.

### G. How do you encourage deliberation within PFOA? (Box 5.9 and 5.10)

Deliberation within PFOA is framed around participants answering common questions together. This differs from the classic positional approach found in many political venues where each participant comes to the table prepared to persuade others toward options that favor their specific interests. Within deliberation, the driving motivation is to use questioning to gain a shared understanding of the implications of options from diverse perspectives. Deliberation in a PFOA seeks to focus consideration not on a single type of criteria, such as economics, but on multiple criteria side by side, such as economics alongside agronomics, culture, ethics, etc. Deliberation achieves this through answering questions that have the capacity to be answered from many different perspectives. Overall, though, the deliberation is always centered around understanding the various risks and benefits of a GMO technology in relation to other future alternatives.

When designing a PFOA, it is important to define rules for deliberation and to appoint a facilitator who keeps the group focused on the deliberation. Rules for deliberation can assist and govern interactions between participants in a PFOA by providing a basic structure for discussion and by helping to maintain order within the process. A lot has been written about rules for deliberation. For the most part, your

## Deliberation

### Box 5.9: What are essential components of deliberation within PFOA?

- A PFOA is not based around politically-based positional arguments.
- A PFOA is based around questions that the entire group answers together.
- Deliberation creates shared understanding of diverse perspectives.

own cultural context may ultimately be the best guide for determining what is acceptable and not acceptable within your PFOA because rules are based on cultural norms of what is 'right' and what behaviors are acceptable. However, based on our own synthesis of materials addressing rules for deliberation, we suggest a few rules that we believe are critical to having an effective deliberation in a PFOA.

**Box 5.10: What are appropriate rules for deliberation?**

- Respect each other's right to speak and keep an open mind.
- Listen to each other and do not interrupt the person speaking.
- No personal attacks, speak to the issues/ ideas.
- Respect the process.
- Stay focused on the task.

**1. Civil discourse must be maintained throughout a PFOA.**

Part of the reason for conducting a PFOA is to create a neutral arena where stakeholders with different viewpoints can productively deliberate about an issue. Maintaining a civil discourse in a PFOA is the best way to ensure that the types of learning and reflection necessary for such deliberation can occur. For a PFOA to maintain a civil discourse suggests that participants are respectful of one another during their discussions. It suggests that participants carefully listen to each other and try to understand perspectives that are different from their own. It suggests that participants avoid making personal attacks on one another or encourage others to attack. It also suggests that participants make efforts to temporarily suspend judgments of ideas as they are first expressed. Room for disagreement remains in a civil discourse, but disagreements are to be handled in a considerate manner. You should define appropriate rules for your PFOA that will ensure a civil discourse is maintained.

**2. All participants must have an equal opportunity to speak and be heard.**

Deliberation is meant as a means to assist the PFOA group in understanding and considering the full range of opinions, concerns, and arguments among the multiple stakeholders present at the table. As you determine who the stakeholders are and who to invite to participate in your PFOA, you will be ensuring that a diversity of voices are present. However, an effective deliberation relies on more than just the presence of diverse voices. If a single voice or group of voices is dominating discussion and limiting the depth of diverse opinions being shared with the group, the value of the deliberation is diminished. Stakeholder participation can be lacking for a variety of reasons and there are tools available to assist with many of these situations. Ensuring that all participants have an equal opportunity to speak and be heard is a more fundamental issue, though. To serve the purposes of a PFOA, it is best to have rules defined

to guarantee that no voice of a PFOA participant is ever excluded or omitted, either accidentally or intentionally.

### **3. The group must use a collaborative approach to seek out common agreements.**

Participants coming into the PFOA will be intent on influencing the process in favor of the positions with which they enter the process. This is normal. However, if such a positional approach were maintained by everyone throughout the PFOA, there would be limited progress made and deliberation would not move beyond a debate about who is right or wrong. The most successful PFOAs will have occurred because participants were able to shift from the positional approach to a more collaborative, open-minded approach that works for a common agreement. This means that participants realized the process was about sharing ideas and building understandings, not winning a deal largely in favor of only their interests. A collaborative approach requires participants to be open to exploring both agreements and disagreements, and using deliberation to actively seek out shared answers to the issues at the center of the PFOA.

#### **H. What other processes that embody principles similar to PFOA exist in your nation? (Box 5.11)**

Processes elsewhere in your society and government that embody some of the fundamental principles underlying the PFOA methodology can be excellent models and learning resources for designing a PFOA. Chapter 3 described the fundamental principles of PFOA as 'participation,' 'transparency,' 'accountability,' 'deliberation,' 'science-based,' and 'multi-criteria analysis.' Identifying examples of processes in your own country that embody these same principles can be valuable because it allows you to see aspects of PFOA already at work within the contexts of your society. You might find possible examples within government procedures or within larger civil society.

For instance, in the case of public participation, you might identify situations where the state has held public hearings or comment periods relating to some societal issue. This is a regular practice among the traditional ERA processes of some countries. Perhaps you have a public hearing or comment period already involved in your own current ERA process.

#### **Box 5.11: What other processes that embody principles similar to PFOA exist in your nation?**

- Identifying similar processes allows you to learn from what has and has not worked.
- The PFOA is not the same as a standard comment periods done in most public participation; it complements and goes beyond such.

Among other things, examining such procedures in detail can help to illustrate what is unique about the public participation involved in a PFOA. That is to say, the public hearings and comment periods that occur in some traditional ERAs usually involve single individuals or groups providing their opinions on an issue. Although such information can be invaluable to decision-makers, input received from public hearings and comment periods has limited influence beyond political processes because these sorts of public participation usually occur in the later stages of an ERA and have little interaction or impact on the ERA science or the process itself. Whereas in a PFOA, stakeholders are directly involved from early on in the ERA. Information from stakeholders still ultimately informs decision-makers, but as stakeholders are deliberating and achieving shared understandings about an issue, they are also interacting with the ERA and providing ongoing feedback to help shape the process.

In general, it can be quite valuable to find examples from your own society that embody the fundamental concepts of PFOA. Even if the examples are centered around very different subject matter than ERA or GMOs, you can still learn useful things from them to help with the PFOA design. Nevertheless, this will best serve you as a preliminary exercise for understanding the functioning of a PFOA within your society. The information or insights that the exploration of general examples can provide will not be very specific to the PFOA process itself. However, examples such as facilitated policy discussions can provide ideas for culturally appropriate techniques or challenges that have to be overcome with improved techniques in the PFOA. Of the examples you may uncover, the most helpful could be multi-stakeholder processes that have been previously used in your region.

**Box 5.12: PFOA is a multi-stakeholder process.**

- Multi-stakeholder processes will give you even more insights into the best way to use a facilitator and discussion within your social, cultural, and political context.
- If science was involved in another process you identify, there may be good ideas on how to incorporate science into multi-stakeholder deliberation.

Multi-stakeholder processes (Box 5.12) may have already been used in some way in your country at some level of government, or somewhere else within broader sectors of society, public or private. For example, a multi-stakeholder process may have been used to gain community input on proposed economic development, deal with a pollution problem in a local water source, or consult on problem-solving for a national health campaign.

Examining other cases offers the opportunity to gain practical information about conducting a multi-stakeholder process within similar contexts as well as providing a sense

about possible societal expectations for the PFOA you are designing. For example, in some cultures it may be an expectation that the facilitator of the PFOA be an older, well-respected individual in order to gain legitimacy. Whereas, in another culture, age may be a less important factor with expectations placing a greater emphasis on the facilitator being someone with an expertise in the subject area or who has a particular level of competence in the skills of facilitation.

If you can identify other examples of multi-stakeholder processes, concentrate on what you can learn that will help you in the design of a PFOA. At the broadest level, it can be useful to try and determine:

- Which multi-stakeholder processes were successful and why?
- Which multi-stakeholder processes were not successful and why?

More specifically, a process that focuses on regulation will generally be more closely aligned with PFOA than some of the broader multi-stakeholder processes you might come across related to health, education, or human rights, for example. At the same time, whenever there is deliberation that asks a diverse group to answer questions together, there may be something to learn.

### I. How will decisions be made within the PFOA? (Box 5.13)

Ultimately, the PFOA will produce a report of the deliberation and recommendations. Achieving this will require participants to come to agreements and make some decisions. There is a range of possibilities for how agreements can be reached and decisions can be made in a PFOA. The most useful of these include consensus and majority votes.

Consensus means that a group as a whole has reached agreement on the wording for answering a question or making a recommendation; it is the strongest form of agreement because it implies the broadest support. Consensus is achieved by seeking agreement while simultaneously working to resolve objections. The benefit of consensus is that it suggests that the group has actually identified what is common among the diverse views of the different stakeholders and have together integrated the commonalities into a report or recommendation.



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#### Box 5.13: How will decisions be made within the PFOA?

- Consensus and supermajority votes are the best means of reaching agreements and making decisions in a PFOA.
- The aim of deliberation is to achieve shared agreements having the broadest support possible.



Nevertheless, there are potential problems with consensus. Some critiques are concerned that consensus forces a recommendation to the least common denominator of agreement rather than the best decision. This can be partially addressed by reporting what is a consensus decision and what was not. This maintains all the ideas present on the chance that the “best recommendations” may be agreed on by only a few participants. This arrangement highlights the social discourse about what is “best” or most “informative”. Consensus highlights what is agreed upon.

Consensus can be time consuming and occasionally difficult to achieve. This makes it possible for a single stakeholder or small group of stakeholders to use efforts toward consensus to manipulate a process as a whole. If some party wants to ground a process to a halt based on their individual interests, they can block consensus by refusing to make any compromises or concessions. In this same way, consensus runs the risk of providing more benefit to the parties who are less accommodating to the detriment of parties that are more accommodating. Another possible problem is that some representatives can feel they are discouraged from raising objections, if they perceive that everyone else wants to be done.

Many multi-stakeholder processes use supermajority as a means for achieving shared agreement. Supermajority is one way of overcoming some of the problems that can arise from consensus. A supermajority is a strong version of a simple majority. Whereas a simple majority means there is support from some fraction of the whole greater than half, a supermajority is generally defined as support from some fraction greater than two-thirds of all parties. Although, to use supermajority in a PFOA, we actually recommend an even stronger version, with supermajority meaning support from at least 75% or more of all participants, as is deemed appropriate. The benefit of supermajority is that it forces a group to at least try to create mutually agreeable options through deliberation. Because blocking behavior could potentially be overruled in supermajority, stakeholders must listen to and attempt to understand one another. A supermajority also doesn't assume a uniform final position.

Oftentimes, with a supermajority, the minority will be provided with the opportunity to provide a supplementary statement to be considered alongside agreements reached

Deise Capalbo

by the majority. This allows for differences in opinion to still exist while also providing decision-makers with an understanding of where diverse parties managed to find commonalities through their deliberation.

The main potential problem with majority votes is that they can be used to suppress a minority. Less desirable forms of majority voting in a PFOA that we note only to help illustrate potential issues with majority votes, generally, is that of a simple and relative majorities. A simple majority means support is anything greater than 50%. A relative majority means that a judgment or decision only requires the greatest overall support from participants and that parties only need achieve more support for their position than exists for any others. A relative majority can be achieved with less than 50% support if the opposition was divided among other possibilities that received less support. Both of these can be used to enforce “majority rule” and suppress minority voices. Whereas the aim of deliberation is to achieve shared agreements having the broadest support possible.

The weakest possibility for reaching shared agreement in a PFOA is to simply use the process to produce a summary of what judgments are shared and what judgments are not shared among stakeholders. Producing such a listing as a product for the PFOA would be beneficial as a summary of what stakeholders think, but defeat much of the purpose for holding a PFOA. It would not necessarily require participants to engage in deliberation or work toward creating common ground because it goes no further than identifying existing commonalities. Such a product would only be an efficient means of organizing diverse positions around an issue in terms of their differences and what they deem important. While this could be informative for decision-makers, it would provide only minimal guidance on how to resolve those differences or prioritize the importance of different positions.

## II. ERA AND PFOA

### A. How should PFOA be staged within the current ERA? (Box 5.14)

This is a fundamental design issue: how often and at what points in the ERA procedures will the PFOA meet? At what point or stage of the ERA can the PFOA be most effective? A key issue will be planning the timing of a PFOA relative to



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**Box 5.14: How should PFOA be staged within the current ERA?**

- A minimum of three PFOA meetings can strengthen an ERA.
- A highly interactive and iterative PFOA process may involve multiple meetings between stakeholder participants and ERA scientists.
- If the exchange between the PFOA and the ERA process is not well-designed and well-timed, the worth of the PFOA will be diminished.

*A PFOA can be a highly iterative process with intensive meetings that occur at many points in the ERA or it can be reduced to a minimum of three meetings before, during, and near the end of the ERA.*

the rest of the ERA process. For example, a PFOA would not be helpful at the end of risk assessment, nor after regulatory approval, nor after a GMO crop has been released into the environment. In all three scenarios, the purpose of conducting a PFOA is defeated. The PFOA methodology was designed to assist and improve the overall ERA process and help decision makers in their consideration. Specific components of a PFOA can be helpful to different parts of the ERA.

A PFOA can be a highly iterative process with intensive meetings that occur at many points in the ERA or it can be reduced to a minimum of three meetings before, during, and near the end of the ERA. With multiple meetings, the PFOA group could function as a consultation group with ERA scientists and the PFOA group working together on things such as hazards and values identification, conceptual mapping of the system and adverse effects, specifically a strategy for addressing or managing uncertainty. At a minimum, though, a first meeting of PFOA is necessary at the beginning of the ERA because it will assist with problem formulation, which can then advise on what scientific studies should be undertaken in the ERA and what research questions are critical. Other components of PFOA could run parallel with the ERA. For example, once the early stages of the PFOA are conducted, gaps in the information will be identified that will presumably be answered by previous scientific studies, as well as lab- and field-testing. As these results emerge, the PFOA group would need to reconvene to discuss what the additional information or ERA findings mean for their evaluation and recommendations. For instance, if the PFOA group had limited information about the effectiveness of the GMO, and testing found it to be highly effective, perhaps the GMO is a more promising technology than the PFOA group initially considered, implying that the group should reevaluate. You will need to consider your process for ERA and determine what components of PFOA are most helpful to particular ERA components.

It is also important to identify necessary changes to existing ERA procedures to effectively integrate a PFOA process. For example, say a PFOA was to be integrated into existing ERA procedures that required submitting a final report on GMOs to a review panel of biologists to assess the findings. The panel could probably do a fine assessment of the ERA components relating to biology but may not have the expertise to adequately assess the social or economic factors brought into the ERA by PFOA. Such review procedures might

need to be altered to bring others with different expertise into the review.

### **B. How will PFOA link into risk management planning and implementation? (Box 5.15)**

PFOA creates a process and information that forms a natural bridge to risk management, and governmental oversight. The US EPA defines risk management as “Selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results” (1998). First, the PFOA process establishes a staged series of meetings that exemplifies how new information from lab and field trials in risk assessment can be incorporated into deliberation by multiple stakeholders. The PFOA sets a precedent that can be continued into risk management as a dynamic social and natural context requires an approach that incorporates new information to support adaptive management. For example, PFOA participants answer questions in all the steps with the best available information but fully anticipate that the risk assessment may produce new information that could change their recommendations. By allowing for changes, PFOA reflects a process that could be incorporated into adaptive management, a necessary tool for managing risk overtime.

Second, PFOA develops information that can be used in designing risk management strategies. During Step 7, the participants discuss the anticipated system changes that will be necessary to maximize the benefits and minimize the risks of each technological option. This is the type of system-level thinking required for risk management strategies. For example, at the farm-level PFOA, participants pointed out that if transgenic fish were to be grown, containment systems would have to be developed and used by farmers in order to minimize fish escapes, which would reduce a farmer’s overall productivity and potentially create a risk of inter-breeding with wild relatives. In another example, at the national level, PFOA participants suggested that a well-monitored seed distribution system would be necessary to ensure that a GM seed stock was clearly identified, so farmers would have confidence in what they were buying.

Finally, the PFOA identifies multiple values that need to be protected as a new technology is adopted. Risk management scientists can use these to evaluate acceptable risks and develop management strategies as well as monitoring information that can best inform government oversight of the

#### **Box 5.15: How will PFOA link into risk management planning and implementation?**

The PFOA process:

- allows information from lab and field trials in risk assessment to be incorporated into deliberation;
- develops information that can be used in designing risk management strategies;
- identifies multiple values that need to be protected as a new technology is adopted.

new technology. For example, risk managers can develop a targeted strategy if PFOA participants identify that a culturally important plant has high value for members of society and people are worried that a new GMO will compromise the continued existence of that plant. Risk managers could declare exclusion zones for planting the GMO or develop a sensitive monitoring system that informs a government oversight board about the status of genetic contamination.

Overall, PFOA establishes a process, identifies values, anticipates system changes, and lays a foundation for monitoring that can be used in risk management, strategies, and oversight.

### III. PFOA PROCESS AND DESIGN

#### A. Who will facilitate the PFOA? What are the roles and responsibilities of the facilitator? (Box 5.16)

In a PFOA, like many multi-stakeholder processes, the actual meetings involving the stakeholder participants are conducted by a facilitator. The facilitator – or facilitators (i.e., sometimes more than one person shares this responsibility) – plays what is arguably the most critical individual role in the overall PFOA process. Facilitators are responsible for guiding the process and keeping it functioning effectively and efficiently. Choosing a facilitator for your PFOA is one of the most important aspects of designing and implementing a PFOA.

Choosing the right facilitator for your PFOA can be a tricky process, especially if multi-stakeholder processes are a relatively new practice in regulation. Because of differences in cultural norms and differences in the scenario your PFOA will be addressing, it is not possible to offer a set list of criteria that will definitively qualify or identify someone to be the ideal facilitator for your PFOA. Like some other aspects of designing a PFOA, choosing the facilitator for your PFOA is something that will depend heavily on your particular context.

However, the facilitation of multi-stakeholder dialogue is a topic that has been extensively treated under many different scenarios and in terms of many different considerations (e.g., pollution control, watershed management, international resource management) . Thus, there is a wealth of information

**Box 5.16: Who will facilitate the PFOA? What are the roles and responsibilities of the facilitator?**

**The facilitator should:**

- be trusted by stakeholders.
- maintain impartiality.
- able to organize the process.
- be protective of the process.
- have some awareness about the content to be involved in the PFOA, but does not need to be an expert in the content.

on facilitators and facilitation practices available to draw from in helping you choose a facilitator.

We have derived some baseline considerations and suggestions that you can apply within your context to begin the process of choosing the facilitator that is right for your PFOA. Our focus here is on what is most relevant to choosing a facilitator for a PFOA. However, we have also included a list of suggested resources on facilitation in Appendix F if there are any aspects that you would like to examine further (See page 230). Although this handbook provides information that will be useful to anyone thinking about how to facilitate a PFOA, it is not intended as guide for how to be a facilitator per se – if such information is needed it can be acquired through some of the suggested resources.

In choosing a facilitator for your PFOA, it first helps to consider the specific tasks and responsibilities of a facilitator in a PFOA. Generally, most of the facilitator’s work will be concentrated in conducting the PFOA meetings. However, the facilitator can also assist in advanced planning. For example, a facilitator might be able to assist with stakeholder identification. As a foundation, though, the main tasks and responsibilities of the facilitator in a PFOA include:

- Being accountable both to the internal parties directly participating in the PFOA and to the external parties that have some stake or indirect involvement in the process;
- Training and/or ensuring that all stakeholder representatives participating in the PFOA understand the process and can competently participate in it;
- Managing the timeline and the different tasks involved in the PFOA;
- Assisting participants with getting the information and resources they need;
- Keeping the PFOA group on task and on schedule;
- Ensuring that all stakeholder participants can equitably participate;
- Helping participants work together to accomplish tasks and achieve overall objectives for the PFOA.

Next, there are some basic characteristics and criteria that a PFOA facilitator should have. These guidelines are meant as



Areca Treon

suggestions and you may have difficulty finding someone that meets all of them perfectly. Nevertheless, the closer a person comes to fulfilling these guidelines, the better they will be at facilitating a PFOA:

The facilitator should be ***trusted by stakeholders:***

If stakeholders do not trust the facilitator of a PFOA, it will diminish their perceptions of the fairness and legitimacy of the process. Subsequently, the quality and openness of participation in the process is likely to be affected.

The facilitator should ***maintain impartiality:***

A facilitator needs to be fair and work equally on behalf of all stakeholders throughout the PFOA. This means the person ought to be free from undue pressure by parties either within or outside of the process. It also means the facilitator will not try to influence outcomes beyond what occurs in the deliberations between the participants themselves. Ideally, a facilitator will also be neutral in their affiliations, but this is not always possible.

The facilitator should be ***protective of the process:***

The facilitator must protect the voice and influence of all participants during the PFOA. This can mean ensuring that discourse remains civil, helping participants to be heard when they are not, and working to assist and encourage the active involvement of participants.

A facilitator needs to both ***conduct the PFOA as well as train participants*** in how to participate effectively in it:

The facilitator should be familiar with methodologies and tools relating to facilitation and multi-stakeholder processes. The facilitator needs to be comfortable running and leading a group process. The facilitator also needs to be someone that is flexible and multifaceted enough to fill the variety of roles they may need to play.

The facilitator should be skilled at ***assisting groups to achieve goals:***

The facilitator ought to work to guide the PFOA without controlling it and to assist the group while maintaining some separation from them. On one hand, the facilitator will need to counsel the group and help them wherever necessary or appropriate. On the other hand, the facilitator will not want to be intervening any more than the minimum necessary to keep the process running effectively. In a sense, the facilitator provides the necessary tools and the knowledge on



Joy Owango

how to use them in the PFOA, but it is up to the participants to provide the labor to make the process work.

The facilitator should be an **overall resource for the group**: The facilitator ought to be prepared to provide assistance not just with the PFOA process but also with the content of the PFOA. It is always helpful for a facilitator to have some knowledge of the subject matter they are facilitating, but this is particularly true with a PFOA because of the complexity surrounding GMOs. This does not mean the person needs to be an expert on all facets of the issue. A multi-stakeholder process can benefit, though, if the facilitator is well enough versed that they are familiar with the boundaries of an issue, can assist with questions about existing information, and are able to empower stakeholders to find and learn about relevant information.

Finally, in choosing a facilitator for a PFOA you should determine who will be able to best fulfill the role given your existing constraints and available resources. It is important to acknowledge and accept that you need to work within your context with what is available to you. Whatever limiting factors might exist, it is still likely that you can find someone to facilitate your PFOA effectively and efficiently.

We mentioned above that it will be difficult to find a facilitator that has all of the qualities you desire or think necessary for them to have, and that you may need to make some compromises in finding the person that best meets your criteria. However, another possibility for dealing with this situation is to find a combination of people that can together fulfill your criteria and then having them co-facilitate. Perhaps you could have one person that is strongly qualified in terms of multi-stakeholder deliberation and conducting the PFOA process. Then you could have another person who has an excellent background on the issues surrounding GMOs and could assist more in terms of the content being discussed in the PFOA.

We also mentioned above that ideally a facilitator will be neutral in their affiliations. Neutral affiliations increases the chance that such a person would be better protected from external pressure and have an easier time maintaining impartiality. Usually, this would mean hiring an external party to facilitate that is not employed by any of the primary agencies, NGOs, or industries involved with the PFOA. Instead the facilitator's working relationship with the

PFOA and the issues it will be focusing upon would begin at the time they accept the position as facilitator for the process. However, hiring an outside party to facilitate is often not feasible because the resources necessary to do so are not available.

If you find yourself unable to bring in an external party to facilitate, there are other possibilities available to you that can help maintain the legitimacy of the facilitation. One possibility is to have a facilitator that is associated with one of the organizations involved, but then also having an oversight committee made up of individuals from the other organizations that regularly check in on the facilitator throughout the process. This could help to ensure the person is being fair and remaining free from external pressure. For example, if you were considering having a facilitator from your government's department of the environment, you could also create a small subgroup of individuals from other agencies, NGOs, and industry that can work together to oversee this person. Another possibility, which we just mentioned above as a means of dealing with a different challenge, is to have co-facilitation. Perhaps a team of a few individuals representing a diversity of potential interests could divide up tasks and share facilitation in order to provide checks on one another.

Lastly, we point out that it is also important to consider providing participants and the decision-makers that will receive the results of the PFOA with some means of control over the facilitator. As was mentioned above, the facilitator needs to be accountable to both the internal parties directly participating in the PFOA and to the external parties that have some stake or indirect involvement in the process. One way that this sort of accountability can be achieved is by having a rule where if at any point there is unanimous agreement, or at least a strong majority, that a current facilitator is ineffective, there are procedures available for requesting a different facilitator.

## Participation

### **B. Who will participate in the PFOA? (Box 5.17)**

A PFOA involves participation from a number of different parties, including those engaged in the core deliberation as well as those interacting with the PFOA by informing, supporting, or observing the process. Here, we focus on participants in a national level process, therefore they should be defined at a national level. However, if you

expand the process to incorporate regional or local level consultation, different stakeholders may be appropriate. As you determine who will participate in a national level PFOA, you will be:

- Identifying all the parties that should be involved.
- Defining criteria for participation.
- Selecting who will be invited to participate and their role.

There are four categories of PFOA participants, each with a different role:

- **Stakeholder representatives:** representatives of the stakeholder sectors involved in the deliberation.
- **ERA partners:** ERA scientists and other agency personnel who will interact with and/or help to inform the PFOA deliberation but not engage as stakeholders.
- **Observers:** parties with an interest in the PFOA and its outcome – such as the media, agency personnel, and government decision-makers – but who are not involved in the deliberations.
- **Support personnel:** those people directly responsible for managing the PFOA, such as the facilitator, management staff, clerical staff, etc (The roles of this category of participants will be covered by other questions within this chapter).

For the most part, focus on identifying participants in each of the different categories independently. There are techniques/tools (e.g. stakeholder analysis for stakeholder representatives) to help with identifying and analyzing potential participants for each of the above categories (see Chapter 6).

### **Stakeholder Representatives**

Stakeholder representatives have the central role in the PFOA (see question “*How will stakeholder representatives be involved in the PFOA later?*” in this chapter for more in-depth discussion of this) – they represent the various stakeholder interests in the core deliberation. A stakeholder is any sector of society that stands to be affected positively or

#### **Box 5.17: Who will participate in the PFOA?**

- The primary stakeholder representatives are the core of the PFOA deliberation; identifying them is a principal task.
- Primary stakeholder representatives need to represent the diversity and range of stakeholder interests.
- Other participants may be involved in the PFOA as observers, informers, or partners to the process.



Ronald Schuster

negatively by a decision (i.e., those who have an interest in the outcome of a decision). Stakeholder sectors include individuals and groups that share some common interest in relation to a specific issue. For example, in a decision about a GMO, one broad stakeholder sector might be “farmers.” The farmers sector might include farmers with different-sized landholdings, but their interest in relation to the GMO could be similar. If the interests of the different members of the farmers sector were not similar, then the sector would be defined too broadly and would need to be divided (e.g., farmers with only a few hectares of land and those who manage many hectares, organic farms and conventional farms). It is not practical or effective for a multi-stakeholder process like PFOA to involve every sector member directly (see question “How many stakeholder representatives should participate in a PFOA later?” in this chapter for more information on size considerations). Instead, stakeholder sectors are represented in a PFOA by a stakeholder representative: an individual participating on behalf of the interests of a sector or grouping of sectors (different sectors can have shared interests). Below, we outline a framework of considerations for identifying stakeholder representatives; more specific guidance is provided in Chapter 6.

Stakeholder representatives can be identified by accounting for the range of sectors that may be impacted by a GMO – a process known as stakeholder analysis can help ensure this. Stakeholder analysis involves identifying the range of sectors that have an interest in an issue and then attempting to understand and evaluate the nature of each particular sector’s interests. By doing a stakeholder analysis for a PFOA, you should be able to:

- Identify stakeholder sectors that capture the diversity of sectors.
- Classify each sector according to how critical each is to the PFOA deliberation (see below).
- Decide whether any sectors share interests or are similar enough that they could be represented by a single stakeholder representative.
- Choose stakeholder representatives that can participate in the deliberation on behalf of each sector or grouping of sectors.

There are two classes of stakeholders, which determine the role and extent of involvement a sector has in the PFOA:

*Primary stakeholders are those groups or sectors of society that are absolutely essential to the PFOA deliberation in order for the process to function effectively and have legitimacy.*

primary stakeholders and secondary stakeholders. Primary stakeholders are those groups or sectors of society that are absolutely essential to the PFOA deliberation in order for the process to function effectively and have legitimacy. For example, if the GMO under consideration was a transgene cotton species, a primary stakeholder would be cotton growers. However, there may also be more than one primary stakeholder among the broad population of cotton growers. Different growers, such as those with larger land-holdings versus smaller land-holdings, can have different interests.

An effective guide for determining primary stakeholders is to follow public norms of who should be present in a stakeholder discussion about a particular issue. If a group's absence from a PFOA could mean that a significant collection of considerations surrounding a GMO issue would be missing from the discussion, resulting in a biased or less rigorous outcome, then that group is a primary stakeholder. If forgetting some sector of society would cause the legitimacy of the process to be questioned either internally, by other PFOA participants, or externally, by non-participants such as the general public, then that sector is a primary stakeholder.

It is important to identify and find ways to include all primary stakeholders. Nevertheless, doing so is admittedly a balancing act dependent on size limits, resource availability, and other choices that you make in designing your PFOA.

Secondary stakeholders are those groups or sectors whose presence could enhance a PFOA deliberation but who are not central to the process. For example, for a PFOA addressing transgene cotton, the end users of the cotton, such as clothing consumers, might be a secondary stakeholder if they had reason to believe that they would reject products made from transgene cotton. In other cases, consumer groups are primary stakeholders with concerns about how their buying choices affect the environment. A secondary stakeholder might be able to make a unique contribution to a PFOA, but their absence would not substantially reduce the legitimacy or results of the process. Oftentimes, the interests of secondary stakeholders could be represented in the PFOA through some other related or larger sector such as the industry that uses cotton as a raw material that has been classified as a primary stakeholder.

The best way to determine whether a stakeholder is primary or secondary is to examine them in terms of how the absence

*Secondary stakeholders are those groups or sectors whose presence could enhance a PFOA deliberation but who are not central to the process.*



Areca Treon

of their presence would affect the legitimacy and results of a PFOA. For example, in most cases of multi-stakeholder dialogue, if business or if civil society were not involved, the process would lose legitimacy as a broad multi-stakeholder dialogue. Making this determination about who is a primary versus a secondary stakeholder will vary between cultures as well. In a society where religion is a primary norm of governance, religious groups may be a primary stakeholder. In other cultures, religion may have a different societal role and religious groups might be a secondary stakeholder.

In terms of who will participate as a stakeholder representative for a sector, there are several important considerations that should guide your choice. Foremost, every participant needs to have some form of legitimacy for representing the larger sector of stakeholders. For example, if one stakeholder sector identified for a PFOA included farmers with small land-holdings, the president of a farmers union that represents small and medium-sized farms may be a legitimate representative for this group because he or she would have the support as well as the credibility to speak about their interests.

Additionally, a PFOA participant acting as a representative for a sector needs to be an acceptable representative to the sector as a whole. The representatives present at the PFOA are charged to think about and represent the broad interests of the entire stakeholder sector on whose behalf they have been chosen. Within the same stakeholder sector, though, different members can and often will be in disagreement on particular points around an issue. In this case, the person chosen to participate in the PFOA to represent the farmers with small land-holdings sector would need to be able to reasonably think beyond the interests of their particular organization.

Overall, a person participating in a PFOA as the representative for a sector, or grouping of sectors, should be someone that is:

- A legitimate representative for the sector.
- An acceptable representative for the different interests within the sector.
- Comfortable representing the broader shared interests of their sector.

**ERA Partners**

A PFOA is likely to have stages where stakeholder representatives could use some clarification or where additional information is necessary, or where the ERA process requires information that benefits from working with PFOA representatives. For example, stakeholders may need a better understanding of an ERA's definition of a hazard.

ERA partners are those who participate in the PFOA by way of informing it and/or working in a problem solving partnership. Generally, ERA partners will be scientists involved in the ERA but could also be agency personnel, such as lawyers or regulators, whose presence at some point in the PFOA could help the process. ERA partners interact with the deliberation occurring between stakeholder representatives, but they do not actually engage in the deliberation. The role of ERA partners is to do things such as provide information to the deliberation, seek guidance for system analysis or research agendas, or work with the PFOA representatives in risk assessment. The extent of these roles will differ depending on how iterative PFOA process is – the more iterative, the greater the role of ERA partners.

You should clearly define the role of ERA partners, particularly the extent of and limits upon their participation. ERA partners might be familiar with traditional processes of getting societal input on ERA, such as a public comment period. However, a PFOA is not just a public comment period and should not be approached by ERA partners in this way. A PFOA is truly meant as a partnership intended to improve an ERA. You want to avoid interactions during which ERA scientists, or other ERA partners, dominate or shift discussions to specific scientific issues, laden with jargon or minutia of theoretical points, according to the agendas of their own inquiries. In such a situation, some stakeholder representatives could be less able to contribute to discussion.

Given the above, it is worth noting that in choosing specific individuals to act as ERA partners in a PFOA, there are some characteristics that usually prove to make a person more effective in this type of role. Experience suggests that the more comfortable and able a person is in working across disciplines, the more successful they will be as an ERA partner. Particularly in the case of scientists, for example, this might be individuals that are skilled in thinking from a variety of different perspectives and in communicating

the essential components of a scientific understanding to a broader audience.

### **Observers**

The third category of participants, referred to as observers, are individuals or groups with an interest in the PFOA and its outcome, but who do not have a role in the deliberations. Observers may be allowed to be present during a PFOA but only have limited direct involvement within the process as a whole. Observers are not present to judge or guide the process. Specific examples of observers include the media, political officials, representatives from other government agencies, and particularly those who will ultimately be the end users of a PFOA's results, such as decision-makers or some ERA scientists that are interested in observing the process as it occurs. Whether to allow the media to observe the PFOA should be a decision balancing laws controlling "public meeting" requirements and transparency vs. the PFOA members desire to explore ideas and debates, media presence can repress or open exchange. It is important to define who will be allowed to be an observer because it is the outermost layer of direct participation in a PFOA and your guidelines will act as the final cut for who is going to be a part of the PFOA process and who is not.

### **C. How many stakeholder representatives should participate in a PFOA? (Box 5.18)**

The size of a PFOA deliberation is an important consideration. The key criterion to keep in mind when determining the number of stakeholder representatives participating in a PFOA is how well the diversity of perspectives will be represented in the process and the degree to which those different perspectives will be able to enter into effective deliberation. While a PFOA should include as many relevant perspectives as is feasible, the number of participants in a PFOA would rarely go above 30 because of the difficulty in giving everyone time to speak and prohibitive costs. There are thresholds of group size beyond which group dynamics and communication constraints become limiting, making the PFOA less effective.

However, specific size limits will depend on culture and governance bodies. Some cultures may find that beyond about 15 participants the effectiveness of deliberation begins to suffer. Such a smaller-sized PFOA will tend to be more cost effective and probably function more efficiently.

#### **Box 5.18: How many stakeholder representatives should participate in a PFOA?**

- The number of stakeholder representatives participating in a PFOA can range from 15 to a maximum of about 30.
- Beyond 30 stakeholder representatives, the capacity for discussion within the group becomes greatly diminished.

Unfortunately, this efficacy may come at the cost of the PFOA's ability to capture the diversity of perspectives. Other cultures will find themselves able to carry on effective deliberation with as many as 30 participants. However, the larger-sized PFOA will be more complicated to manage and will require an investment in tools for efficient communication and decision-making.

If you want to design an expanded PFOA process for broader public participation there are many ways you can approach increasing the number of participants. You could have more than one group meet but then you need to have an oversight group that organizes the consultation and incorporates it into recommendations. You could conduct interviews to broaden the consultation and use the insights to inform the PFOA.

#### **D. How will stakeholder representatives be involved in the PFOA? (Box 5.19)**

The stakeholder representatives are the core of the PFOA process and together they will be analyzing the problem, answering questions together, and creating mutually agreed upon recommendations.

Before and during the early stages of the PFOA, the involvement of representatives will consist of reviewing information and thinking about the PFOA questions from the perspective of their sector. This might include preliminary materials that are provided for everyone, access to a common information databank, and in-person presentations by relevant people.

As a knowledge foundation begins to build, the participants will begin to engage more directly with the problem. This will involve them answering questions together about the problem's scope and scale, defining priorities of issues relating to the problem, and then deliberating to filter the problem down to its core issues.

Once the problem has been formulated, the representatives will start examining options for dealing with the problem. This will involve brainstorming, listening to and learning from one another, working to identify common interests, examining the effects of options, and deliberating about the recommendations that the group will cooperatively provide to decision-makers.

#### **Box 5.19 How will stakeholder representatives be involved in the PFOA?**

- Stakeholder representatives must be informed enough to review all of the information provided.
- Stakeholder representatives must understand the interests and concerns of their sector, and be able to represent them in the PFOA.
- Stakeholder representatives must be open to understanding the interests and opinions of other stakeholders.



Pierre Silvie

Much of the involvement of representatives in the PFOA revolves around their ongoing internal deliberation, although interactions with external parties, such as the ERA scientists, will likely occur as well – particularly if the PFOA is an iterative process. Throughout the PFOA, these interactions will allow the group to have their questions answered and help to ensure that the deliberation is effective.

### E. What happens if stakeholders decline invitation to participate in a PFOA? (Box 5.20)

When individual stakeholder sectors decline to participate in a PFOA, it can hurt the legitimacy of the process. A group's decision not to participate can occur prior to the start of a PFOA, or it can occur after a PFOA has begun with a stakeholder deciding partway through the process that they no longer want to be involved. If a stakeholder does decline to participate, it is then critical to determine what that stakeholder's reasons are for not wanting to participate. It may be possible to change the declining party's mind, and understanding their reasons for not wishing to participate will guide you on what to do to address the situation.

There are three major reasons why stakeholders may decline to participate in a PFOA:

- Individual representatives may feel burdened by participating;
- Sectors may have doubts about the effect their participation will have within the process;
- Sectors may have doubts about the larger effect the PFOA will have beyond the process.

A first reason a stakeholder may decline to participate, which is usually the easiest to remedy, is an individual representative declining because they don't feel they have either the time or financial resources to be involved. If a straight-up lack of time is the problem, and there is no way around it, you could have another individual from the same sector serve as the representative. Ideally, though, a lack of something should never be the main reason keeping an individual from participating in a PFOA.

An option for addressing an individual's lack of resources is to help the representative. If the individual lacks the finances to pay for costs associated with participating, such as travel to and from the meeting site, perhaps the PFOA funding

#### Box 5.20: What happens if stakeholders decline invitation to participate in a PFOA?

- Explore whether other individuals can effectively represent the declining party.
- If a stakeholder sector is declining due to a lack of time or resources, perhaps assist them by covering the costs of participation.
- If a stakeholder sector is declining because of a lack of trust in the process, clarify the process so they can evaluate whether their voice and influence will count.
- If a stakeholder sector declines, keep them informed.

source could help pay for some costs. Or, if the individual is short on time because, say, the person is a farmer in the middle of harvest season, you might consider providing a per diem to cover lost labor hours or help them hire substitute labor. This second option adds on additional costs to conducting a PFOA, but the cost is justified because including as many of the voices of critical stakeholders as possible is essential to the legitimacy of PFOA and the ERA process as a whole.

If a group's lack of resources cannot be overcome by other means, an option for addressing the situation is to streamline that stakeholder's participation by conducting direct interviews with them and then providing their responses to the rest of the PFOA participants. In this way, you can still get the stakeholder's voice included in the PFOA. What is lost in doing so is that the declining stakeholder is still not a part of the deliberation process. Nevertheless, some involvement is better than none.

A second reason that a stakeholder may decline to participate in a PFOA is because they do not believe their voice will really be heard by participating. Dealing with a lack of trust in the PFOA will often be a matter of providing further information and education about the process. It is normal for people coming into multi-stakeholder processes to be concerned about being heard. Many of us have been involved in meetings where there was no effective way to have input, but ensuring just that is actually one of the foundational premises for conducting a PFOA.

Nevertheless, there can be concerns about the PFOA process itself, and in such a case you would want to identify potential problem characteristics of the process and address the representatives' concerns. One option is to build certain deliberation tools and techniques into your PFOA design that can help ensure that every representative has the opportunity to provide their input. An experienced facilitator would be able to use the best deliberation tools and techniques for your context.

A key means for helping stakeholders develop trust in the PFOA is enlisting an effective facilitator. A major role of a facilitator in multi-stakeholder processes is ensuring that all voices are heard throughout the process, and there are things facilitators can do both outside and within a PFOA to assist with this. If a party is worried about their voice being heard,

a facilitator might work with the group to educate them and develop their skills for participating in a PFOA to alleviate some of their concerns. It is also within the facilitator's power to modify the process midway through a PFOA if some representative's voice is not being heard.

A third reason a stakeholder may decline to participate is their perceptions about the larger influence the PFOA will ultimately have. Perhaps stakeholders think the process will just be a place for talk and not really have any capacity for actually influencing a final decision. In this case, they might perceive the PFOA as not being worth their time.



Pierre Silvie

Often, concerns about influence can have to do with stakeholder perceptions based on past experiences. You will want to start by thinking about why the stakeholders might have such a perception. Have there been processes similar to PFOA in the past that have been little more than a stage for discussion and have failed to have sufficient influence? Have your informational and educational efforts about PFOA been adequate for helping the stakeholders understand the process? You can lessen the likelihood of concerns about influence if when you seek a stakeholder's involvement in the PFOA, you spend time carefully defining and explaining the PFOA process and the role it will play in decision-making.



Lewis Wilson

One additional but less ideal option for dealing with a stakeholder group declining to participate in a PFOA, no matter what the reason, is to examine whether there is a distinct party that can adequately represent the same viewpoints and interests as the declining stakeholder. Usually, the definition of the sector that the stakeholder would have been representing will be broad enough that there is more than one party that you could invite to provide the PFOA with that sector's voice. One particular party may be better than another, and the declining party may have been the best choice, but if it seems reasonable to consider going to a second party and inviting them to participate in the PFOA, you should do so. You could even suggest that the participating party consult with the party that declined. A second party is less ideal because if you identified the first group as the best choice stakeholder to participate, then that is the party you want to be involved in the PFOA. Furthermore, you don't want to find yourself moving down a list of secondary choices if each successive group declines because it could impact the legitimacy of the PFOA. If you do find yourself doing so, it is possible that the cause of

parties declining involvement has something to do with the design of the PFOA itself. In which case, you need to quickly identify and work to alleviate the problems.

In general, you can expect some participants to decline to participate in a PFOA for numerous reasons. This only really becomes a problem when a number of primary stakeholders are declining participation. For example, if all representatives from business walked out of the PFOA and decided they would no longer participate, significant questions about the legitimacy and effectiveness of the PFOA would likely arise. However, even in such a case, you may still decide to proceed with the PFOA because the benefits of the deliberation occurring between the parties still remaining in the room are sufficient, even with the other voices missing. At the same time, you want to keep the declining stakeholders informed about the deliberation and recommendations.

Finally, to gain and maintain the trust of stakeholders, the process must have a genuine influence on decisions and policy. Stakeholders will not stay involved if the PFOA process is controlled by one stakeholder group or evolves to be a 'listening session' with no influence.

#### **F. How important is the continuity of stakeholder representatives? (Box 5.21)**

The PFOA benefits from having the same stakeholder representatives participating throughout the process. Through deliberation, participants in a PFOA are building relationships with one another, asking questions together, learning to appreciate each other's respective viewpoints, and wherever possible, arriving at shared understandings around the GMO issue. However, the strength and worth of all these achievements is very dependent on having the same stakeholder representatives continuing to interact and work together over the majority of the process.

If a new representative is present for each meeting, the shared investment previously built up between participants is lessened, or can even be lost altogether depending on what percentage of representatives are new. A new representative may be informed about what occurred at previous meetings, but only through the accounts of others. The new representative was not actually involved in the experience with the other participants and working with them to achieve the relationship goals of deliberation. A lack of continuity in stakeholder representation places a burden on minutes

#### **Box 5.21: How important is the continuity of stakeholder representatives?**

- Because of the cumulative nature of deliberation, it is extremely important that there is continuity of stakeholder representatives throughout the PFOA's involvement with ERA.
- If a PFOA is a very involved, iterative process, then it may be possible to delegate some task-based meetings to other representatives to spread out some of the work.
- If a PFOA continues to assist with risk communication and management, that is a time when it could be appropriate to change stakeholder representatives.

and reporting that most simple communication tools cannot achieve given the aims of a PFOA.

Nevertheless, there are potential circumstances in a PFOA in which having different stakeholder representatives participating might be desirable or even more effective. For example, it is conceivable that a PFOA be designed such that there are main meetings and sub-group meetings that report to the whole group. The main meetings would be the summative backbone of the PFOA and involve a main representative for each stakeholder group. In these, representative continuity would be important.

Another possibility where it could make sense to have new stakeholder representatives in the PFOA would be if the PFOA group had a role beyond the ERA process, such as risk management oversight or risk communication. A PFOA is initially designed as a component of ERA, but you may find reasons to involve the PFOA group in other aspects of the GMO technology management. If so, the change in task may be large enough that it would be appropriate to do a reassessment of the group to determine who else should be involved and who may drop out of the group.

#### **G. What preparation, training, and/or resources will different people need prior to participating in the PFOA? (Box 5.22)**

Prior to the PFOA, you will want to provide some preparatory assistance to those people who will be directly involved in some capacity. Everyone will minimally need to have a base understanding of the issues surrounding the proposed GMO and the processes that will be involved in evaluating it, particularly the structure and function of the PFOA. Additionally, those participating as representatives for a stakeholder group will require more extensive training on PFOA. Finally, ERA scientists will need training on how to most effectively interact with the PFOA.

Everyone who will be directly involved with the PFOA, either as a participant or as someone informing the process, needs a preliminary understanding of:

- The proposed GMO technology and the petition submitted on its behalf;
- The existing systems that pertain to the GMO;
- The processes that will be involved in evaluating the GMO, including PFOA.

The way we suggest that you accomplish the above is by preparing a summary report covering the information noted and distributing it to all relevant parties (30 pages is a suggested length). Existing ERA processes can probably assist with preparing such a report. This report is not meant to be an exhaustive document; rather, it is intended to provide enough information for people to obtain a broad understanding of the main issues. Additionally, the report could also suggest resources for researching topics further, either through sources you will make available elsewhere or through people's own sources. If you will be making sources available elsewhere, a good means for doing so is by having a website or some other information database already set up and ready for people to start using at the time of distribution. The timing of the distribution is also important. Everyone needs to have enough time to read the report and begin examining additional sources of information if they choose. Furthermore, each stakeholder participant needs to have sufficient time to begin consulting with the sector they are representing.

Beyond some base understanding of relevant issues, those who will participate as stakeholder representatives will also need to receive information or possibly training on participating in a multi-stakeholder process like PFOA and on the PFOA process itself. Usually the facilitator can do all or at least some of this either through a short interview with each stakeholder or through a small gathering of the participants prior to the PFOA beginning. Another option would be to have those who have previously participated in a PFOA assist with training.

The types of information related to process that stakeholders should receive guidance on include:

- Goals for the PFOA;
- Rules for the PFOA;
- Types of activities, discussion, and deliberation that will occur in the PFOA, and how to effectively participate in each;
- Responsibilities related to participating and expectations that others will have for them;
- The outcome of the PFOA in terms of what is to be expected and how it will be used.

The depth of training required in the above areas will depend on your situation and some decisions you make

**Box 5.22: What preparation, training, and/or resources will different people need prior to participating in the PFOA?**

- There will be differential skills among the participants in a PFOA.
- Everyone will need a basic training on the PFOA process to be effective participants; some will need more training in either the content of the GMO case or in deliberation processes.
- For an effective PFOA in which all participants have voice, you need to address these needs prior to starting the PFOA.



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about who can act as representatives for stakeholders. The abilities and preparation that different participants will have for participating in the PFOA will be uneven. Training stakeholder representatives to participate can be minimal relying on short conversations, or it can be a resource intensive process depending on how extensive the training needs to be. For example, someone with no experience in multi-stakeholder processes or deliberation may require a half-day workshop as opposed to someone who previously participated in a PFOA and only needs to be updated on changes in the process. However, you want everyone to be as functional as possible to successfully represent their interests, and this may mean that some participants receive greater assistance.

To reduce the burden of training, you could consider requiring that those allowed to act as stakeholder representatives be skilled in areas relevant to participating in a PFOA, such as representing a group's interests or deliberating. However, there is a balance that you will want to try and create. If the criteria for stakeholder representatives only allows those who need minimal training to participate, you will be unnecessarily limiting the number of individuals capable of participating. Among other undesirable consequences, this can result in concentrations of power, voice, and influence.

Thus, there are benefits to be derived from investing more time and energy into training. For one, you expand the pool of stakeholders who are capable of representing their sectors. In addition, you are enhancing citizen capacities to engage in governance processes and contributing to the democratization of ERA and science-based deliberation in your society.

Finally, ERA scientists will need training on how to most effectively interact with the PFOA. The role that ERA scientists will play in a PFOA can range from cooperative information source to partners in deliberation for specific ERA techniques. This role will be different from the expert driven reporting function between peers and administrators that many ERA scientists might be used to in their more traditional roles. For ERA scientists to be most effective in their relationship with the PFOA participants, it will be beneficial to provide them with training in how to communicate about their findings and the methods of their science in accessible terms.

The effective communication of science is actually becoming increasingly recognized as an important task of scientists – slowly, more scientists are receiving such training as part of their education and professional development. In fact, providing ERA scientists with training in communication for their involvement in a PFOA can initially be seen as contributing to broader professional development. Over time, this capacity will be enhanced within the larger scientific community and may cease to be necessary as a part of preparing for a PFOA.

#### **H. How will differences in power between stakeholders be dealt within the PFOA? (Box 5.23)**

There will be differences in power between stakeholders within the PFOA. At the societal level, there is a tremendous range of power and differences in power. The relatively neutral participatory space created by a PFOA can potentially diminish some of these differences. However, PFOA participants will inevitably bring some of the differences in power, and some of their consequences, into the PFOA.

Beyond the participatory structure of PFOA and its ability to balance some power differences, there are also additional things you can address during your PFOA design to further alleviate some of the power differences that can persist into a PFOA.

One important difference that might exist between stakeholders is in their skills and capacities relating to deliberation. As we mentioned earlier, for a PFOA to be successful, every participant needs to have some level of comfort and competency around the process. As the facilitator is responsible for ensuring that everyone has some minimal level of training, the attention of the facilitator is the first means for dealing with this. However, if the differences in skills and capacities are large enough, there may be reason to consider additional options. The possibilities will depend upon your context and available resources. One option might be to hire a special consultant or trainer to hold more extensive supplementary training sessions with certain participants.

A second type of power difference that can persist into a PFOA has to do with information. At least initially, some

#### **Box 5.23: How will differences in power between stakeholders be dealt within the PFOA?**

- Power differences can persist because of disparities in skills and capacities, knowledge and access to information, financial resources, and strength of voice.
- A PFOA can be designed to encourage balance in voice and influence.
- To help balance power, particular attention should be paid to training and to using process tools that ensure everyone speaks their ideas and that the group gives serious consideration to ideas from all participants.



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stakeholders will likely be more informed or have access to more information than others. A means of dealing with this disparity, which was discussed earlier, is to make all information shared in a common pool or database that everyone can draw from and to which everyone can contribute. This would ensure access to the same information for everyone. Additionally, it would help those with new information to more easily share it with the group. One important note about creating such an information pool, though, which was also alluded to earlier, is that it should be transparent: it is important that whomever contributes information be required to indicate themselves as the contributor and to provide enough information that someone else could track down the original source if desired. Otherwise, a database can be the cause for a different type of power disparity, such as if a group were to load the database with information that favors their interests or even false information.

A third type of power difference that can persist into a PFOA relates to finance. It is important to recognize that some stakeholders will have more financial resources available to them, and will thus be less burdened by travel costs and taking time away from other activities. Additionally, some participants will be more financially vested in the process, particularly those who attend the PFOA as a part of their paid jobs versus those who attend voluntarily. One potential way of dealing with financial disparities is to set aside a fund to be used for alleviating the burden on those that demonstrate a need or lack of support. This is especially true for member organizations such as farmer's organization and NGOs that have very limited budgets. For example, if a representative does not have a paid job that includes participation in meetings such as PFOA, then funding could be provided to compensate for the salary or labor time lost to prepare for and attend PFOA meetings. In fact, you should avoid paying people just to participate as this causes its own problems. Ideally, participation in a PFOA should be seen as part of citizenship and you want to avoid having individuals participate only for financial gain. However, if compensation can be provided in such a way as to alleviate some of the costs of attending for those with fewer resources, greater equity will exist in the process as a result.

A fourth type of power difference that can persist into a PFOA has to do with voice. In society, louder and more

powerful voices generally have more influence. This can carry over into a PFOA even though one of the main intents behind PFOA is to balance this. It is possible that an individual or group of individuals will begin to dominate the PFOA either intentionally or unintentionally. Much of dealing with this will have to do with the capacity of the facilitator to ensure that at any given point, every stakeholder has the opportunity to share their opinion. However, mechanisms can also be built directly into a PFOA to help counter dominance. Perhaps a PFOA might necessitate that whenever a position begins to gain wider acceptance, the group must step back together to see if there are any opinions that are not being heard. This acts to ensure that minority voices are not left silent.

It is important to recognize societal power differences that may persist into a PFOA to ensure the effectiveness of the process. Nevertheless, it is also important to acknowledge the limits of PFOA in dealing with these power differences. A PFOA can only realistically diminish differences in power partially and temporarily. Power exists in society and you cannot eliminate it as a factor. The best that can be done in a PFOA is to be aware of power differences and manage the PFOA so all participants have voice and influence.

### **I. What information is needed to conduct a PFOA process? How will you identify the gaps? (Box 5.24)**

A PFOA expands the scope of information required during the ERA process. Traditionally, the bulk of the information used by the ERA is derived from the biological, ecological, and agronomic sciences, and some consideration of information grounded in the social sciences, particularly economics. However, the discussions raised by a PFOA have the potential to broaden the information needed for an ERA to include a much greater information base in the social sciences, as well as types of information infrequently considered during traditional ERA, such as cultural, spiritual, and ethical information. You will need to determine what information is needed for the PFOA, how the information will be obtained, how you will identify information gaps, and what limitations on information exist.

Your initial assessment of information needs plays a critical role that will resonate throughout the PFOA as it moves forward. You will want to contribute as much time and resources as you can toward anticipating potential information needs during the design phase as this will make the PFOA run smoother once it is underway. However, it is

**Box 5.24: What information is needed to conduct a PFOA process? How will you identify the gaps?**

- A PFOA needs a broad range of information beyond science, including social, cultural, and values based information.
- The amount of information available for informing a PFOA depends on the resources and infrastructure available.
- The resources available to you should help guide your information gathering efforts; i.e., do what you can with what you have and improve as you go as additional resources become available.

important to realize that there is a limit to the information you will be able to identify before the PFOA begins, and your efforts should correspond accordingly. Gathering information for a PFOA is an ongoing process and information needs will continue to reveal themselves over the course of the discussion.

Although information needs will be highly contextual according to your scenario, they can be organized according to six categories of consideration for GMOs (Box 5.25). These six categories can help to organize your process of identifying information needs:

- The GMO as a technology
- The GMO as a plant or animal species
- The GMO in terms of agroecological systems
- The GMO in terms of ecosystems
- The GMO in terms of production systems
- The GMO in terms of sociopolitical systems

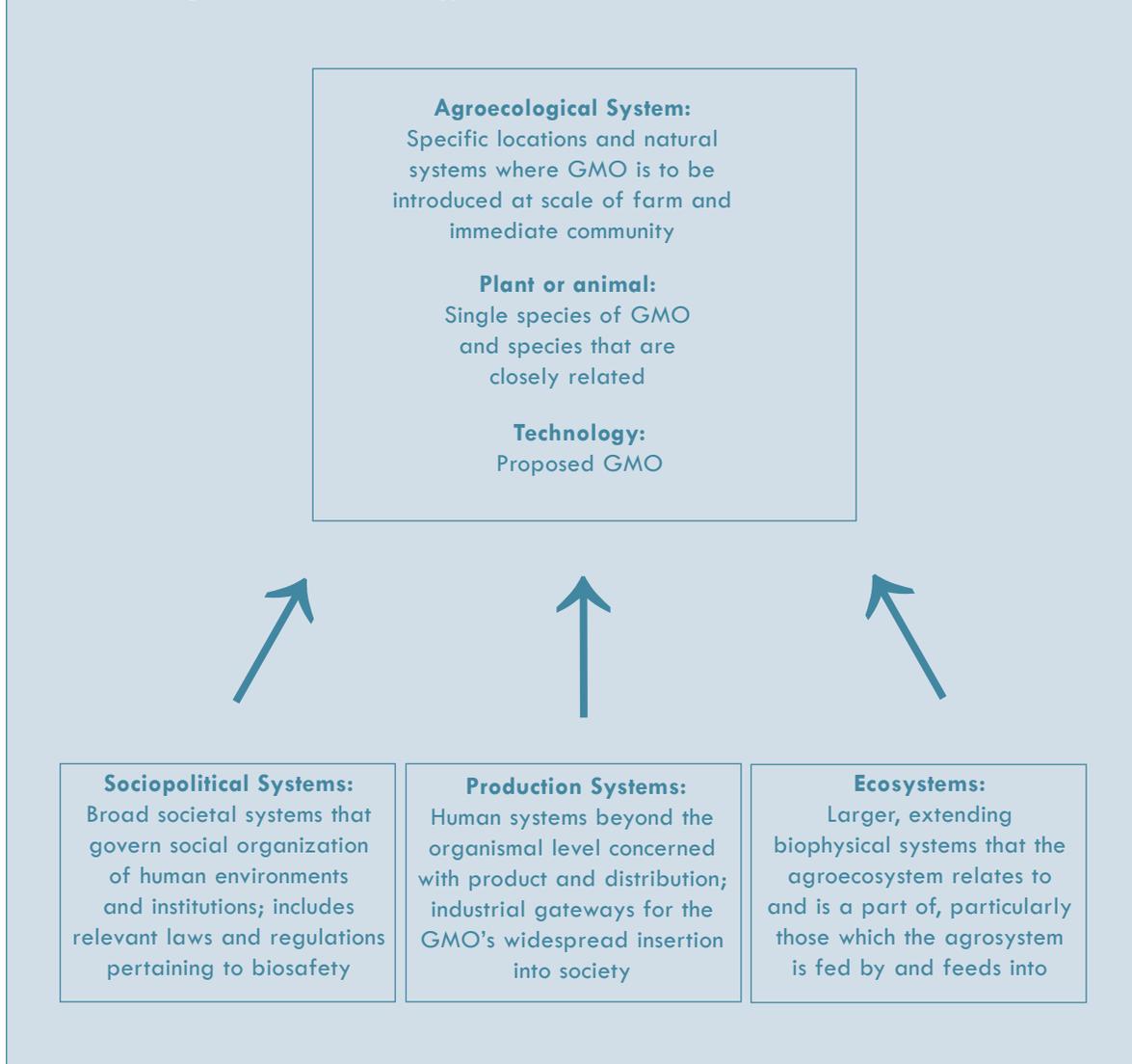
Within each of these six categories, there are also various types of information that can be considered for the PFOA. These include but are not necessarily limited to:

- Biological science information
- Ecological science information
- Social science information
- Culturally-based information
- Spiritually-based information
- Ethically-based information
- Production-based information

Once you have an idea of what information is needed, you determine how the information will be gathered. There are three main groups of sources from which most information for the PFOA can likely be gathered: scientific studies specific to your country, management studies and discussions specific to your country, and studies and discussions pertaining to areas outside of your country.

### **Scientific Studies**

Reviews of existing scientific literature can provide information about a GMO in terms of genetics, biology, ecology, economics, sociology, and policy. These sources will provide you with specific data for your country on things like

**Box 5.25: Categories of information types needed for a PFOA**

the plant function, natural systems, number and size of farms, products produced, trade, and relevant regulations.

### ***Management Studies and Discussion within Your Country***

The next group of sources to examine are management studies, and discussions from within your country that relate to the GMO or other relevant issues throughout your broader society. These other studies and discussions will generally relate to values held by individuals, communities, society, and the nation as a whole. They might be ethical, cultural, or spiritual in nature, and they will reveal assumptions and perceptions about particular issues surrounding the GMO, such as health and technology.



K. Ghosh

### ***Studies and Discussions from Outside Your Country***

The last group of sources to examine is studies and discussions from either of the first two categories but that pertain to areas outside of your country. Information for a PFOA should be as specific to your context as possible; however, some information can be generalized across different contexts and can still be relevant when obtained from outside of your context (e.g., information on the transgene locus structure). Depending on the type of information, outside sources of information that could be useful might include studies and discussions that have occurred in other nearby countries or countries far abroad. For example, an ERA of a proposed GMO in your country will usually still require field tests that occur specifically within your country, but if the GMO is one that is already being widely used elsewhere in the world, there is likely reports on transgene locus structure from other countries that can be helpful. Of course, not all studies can be generalized. Field test data from a nearby country with similar climatic and ecological conditions is likely to be more useful than data pertaining to a place far away with very different conditions.

Using information from other contexts can be cost effective, but it is important to be careful about the limits to the information from outside sources. For one, it will generally be best that information from exterior sources be either nation or organism specific, and you will want to be clear about the contexts for which the information applies. You do not want to make the mistake of making generalizations from these sources and applying them to your context if doing so is not justified or appropriate. In addition, there can be technical issues related to the transportability of data and the scale.

As you think about what information is needed and how that information can be obtained, you should also identify a process for assessing the completeness and representativeness of the information. Identifying information needs and gathering information will continue throughout the PFOA as different questions and discussions will call for additional information. In this way, the PFOA itself provides an ongoing means of identifying gaps in information. Nevertheless, it is a good idea to make a conscious effort to evaluate whether there is available enough of the information needed for a full consideration of some issue.

We have two suggestions for what we think to be the simplest methods for identifying information gaps. First, you could have additional parties reviewing information that has been gathered around a particular issue or question to assess its completeness and representativeness. The participants will be able to help with this, particularly in areas that they specialize in or are more familiar with. For example, a representative for farmer interests might be able to identify a lack of information about some farming practice, or an industry representative might be able to identify a lack of information about trade issues. Additionally, though, you may also want to consider asking parties external to the PFOA for their input. For example, if you are gathering information on the ecology of the GMO, you might inquire with some ecologists whether you have identified the most critical information that needs to be considered. Or, if you are gathering information about a specific cultural perspective on a GMO, you might make inquiries with cultural or community leaders that are well-versed in the topic.

Second, to help identify gaps in information you will want to make it easy for PFOA participants to submit additional information for consideration wherever they feel information is lacking. It is an important component of the PFOA for participants to bring new and additional information into consideration. For participants, it may not be the amount of information but a clarification of definitions and values that frame the understanding of the information. Participant contributions of information do raise some issues relating to information legitimacy, but these can be dealt with (in fact, this is the focus of the next question in this section).

Overall, there will be limits on your ability to satisfy information needs and you always have to be realistic by determining priorities within those limits. The time and resources available for identifying information needs, for gathering information, and for ensuring the completeness and representativeness of information, are limited. These processes can be expensive and can continue for long periods of time. However, a PFOA will need to occur within set time periods with set resources to serve set goals.

The way to deal with limits on obtaining needed information is to prioritize information according to how much and why it is needed. It is not feasible for a PFOA to gather every possible piece of information that is relevant to a particular

*The key to transparency is information management and communication. Work to achieve timeliness, accessibility, understandability, and visibility.*

issue or context, or to consider every factor in a particular issue or context. It may be possible to have basic information on most major considerations or possibilities surrounding an issue, but you need to determine the importance and relevance of these various possibilities. Then you can focus on those that are most critical and possible according to the limits within which your PFOA is working. For example, a PFOA group might identify 12 different additional options for dealing with whatever issue a GMO is being proposed to deal with, but perhaps the information needs for assessing all 12 of those options, or necessary time for that matter, are prohibitive. In this case, you might select a limited number of options that are feasible and represent the priorities for the primary stakeholders. By narrowing the options considered, you narrow your information needs.

#### **J. How will you evaluate legitimacy of the information used in the PFOA process? (Box 5.26)**

Information used in a PFOA needs to meet some standards of legitimacy in order to keep the deliberation process fair and truthful. Some information, such as science-based information coming out of the ERA process, will already have some inherent legitimacy built into it either because of the process by which the information was derived or because of the originating source. This information may be guided standards of evidence in risk assessment from the Organisation for Economic Co-operation and Development (OECD) or the Office of the Gene Technology Regulator (OGTR). For other information, such as outside information that PFOA participants wish to admit into the deliberation, you will want to have some criteria to evaluate legitimacy.

#### **Box 5.26: How will you evaluate legitimacy of the information used in the PFOA process?**

- Be sure information used in the PFOA has some form of legitimacy; e.g., it has been peer reviewed or, minimally, there is documentation of who supplied the information and how they acquired it.

Determining the legitimacy of 'scientific' information can begin with norms used in the scientific community. Assuming the information is being provided from a completed study following the scientific method, one criterion to determine if the information is legitimate 'scientific' information is that it has undergone peer review. Peer review is a traditional part of the science process that is used to allow other scientists to comment on the quality and accuracy in information being labeled as 'scientific'. This check on scientific information is part of the basis for the enhanced credibility that scientific information holds among its peers. Characteristics that scientists use to evaluate articles include the journal status, greater confidence in the results conducted under agreed methods, the interpretation is more controversial.

Determining the legitimacy of information originating from some other particular sources will depend on several factors. Generally, this includes information coming from certain institutions (e.g., government agencies, universities, and some other public organizations) that have their own checks in place to ensure that information being released under that institution meets certain standards. Usually the standards and practices of these types of institutions are such that it is commonly recognized by the broad public that information coming from that particular institution is legitimate. If there is any question about whether a particular institution has adequate standards and practices for ensuring legitimacy in their information, it is important to ask the institution to explain their evaluation procedures for information, as well as getting a sense of broadly-held public perceptions about the institution.

However, if information is coming from an independent source or a source that does not carry inherent legitimacy, you will want to have some criteria by which to determine the legitimacy of the information before admitting it into the PFOA. These criteria can apply for any information that participants would like to admit into the PFOA, or any information that is not coming directly from some official source affiliated with the PFOA.

Two information sources that may be controversial are news articles and industry information that limits disclosure due to proprietary information. News article may be public information but it is important to identify and evaluate the source of the ideas presented in the text. The information in the article is the writer or editors interpretation and may be a good example of the public discourse but not necessarily an accurate representation of the original sources. Industry information may include scientific studies or lack critical details that are proprietary but in both cases, the interpretation of the data is from the perspective of the industry source. One question to ask is how has the source been evaluated by an independent review.

Generally, it is best when participants in a PFOA wishing to share information can do so in as complete a form as possible. Ideally, this means a copy of a published report, but otherwise reference information, such as the author's name, the group producing the information, and where and how the information was gathered. Participants in a PFOA should be welcomed to share any information with the rest

of the group that they think would be appropriate or useful, as this is one of the main reasons for conducting a PFOA. It makes it easier for everyone, though, when information can be provided in its full form and context. For a base minimum, if a participant wishes to admit information into the PFOA, particularly if the information is published or factual in nature, they need to provide a source and referent for the material. Doing so gives the information some verifiability and reduces the chance that people make up whatever information they need to support their view. Furthermore, a source and referent allows other participants to find and judge the information for themselves if they so choose.

Here are a few additional suggestions for ways to qualify independent sources as legitimate and, depending on your context, you can probably come up with others (e.g. in some cultures oral history carries inherent legitimacy). One option is to allow information from independent sources to be admitted with a note of caution to PFOA participants on the verifiability of the information. Although a major weakness of this option is that prefacing information with such a notice could unjustifiably diminish the credibility and perceived worth of the information to other participants.



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A second option for qualifying information from independent sources as legitimate is to have it undergo some basic level of review by a neutral party, such as a government agency or civic group, before being admitted into the PFOA. Depending upon the sophistication of the review, it could minimally act to filter out blatantly problematic information from independent sources. This option raises issues around the degree of review that must be done, choosing a neutral party that is deemed acceptable to do the review, and allocating time and resources to conduct the review. Nevertheless, it could serve a useful purpose in some contexts.

A third, and probably the best, option for qualifying independent sources as legitimate is requiring that the methodologies or reasoning for achieving the findings or positions that are included in the information are clearly laid out. This makes it easier for individuals to evaluate the information themselves because the underlying process is visible. For example, people can use statistics to suggest something that may only be partially true. Yet when the process behind reaching a statistic is clearly laid out, people have the opportunity to judge for themselves whether they

agree with whatever the statistic is meant to represent. A potential weakness of this option is that it could place an undue burden on some sources. For instance, perhaps a study was conducted informally many years ago and a party would need to dedicate resources, which they may or may not have, to go back and document the process involved. This might be a case where a note of qualification would be justifiable as a work around.

Another type of information that raises some legitimacy issues, which is alluded to by the third option above, is information that is more informal, subjective, or qualitative in nature. This might include cultural information, religious or spiritually based information, information relating to ethics, information coming from speeches or interviews, statements from organizations, information derived from oral traditions, etc. Allowing such information into a PFOA is one of the foundational premises behind the PFOA methodology, and doing so is an important component of having an effectively diverse and representative deliberation. It is still important to think about the legitimacy of such information, though. How you decide to qualify the legitimacy of information that is more informal, subjective, or qualitative in nature will be highly dependent on your context and societal norms; however, there are a few basic guidelines we can suggest that you might use as a foundation.

First, you will want to ensure that the source of the information is provided. As discussed above, this is part of the base minimum for determining the legitimacy of any information. In addition to the source, it is probably a good idea for these less verifiable sources to also require that some explanation of the context (e.g., public meeting, personal experience) for the information be provided. For one, a referent may not even be available (e.g., if material is unpublished). Even if a referent is available, though, providing the context serves the additional purpose of helping people understand material, particularly material that they are less familiar with. Greater background explanation helps when there is information for which people have less of a common background.

Second, to qualify the legitimacy of information that is more informal, subjective, or qualitative in nature, consider the source itself. How credible is the source? What are the source's qualifications on the subject matter? For example, if the source is speaking on a religious topic and they are



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a high-ranking church official, they would usually carry an enhanced credibility to talk about that subject. Then there is the representativeness of the source. The greater agreement or support that exists behind information, the more legitimacy the information carries. Is the information the statement of a single individual? Or is the information coming from an organization with multiple members that voted on or are openly supportive of the information?

Third, consider how many times removed the information is from its original source. The closer information is to its original source, the better. For example, if information were being cited from a speech, it carries more legitimacy if the person providing the information can refer firsthand to the actual speech than to things they heard about the speech secondhand from, say, a colleague who read a news article discussing it.

**Box 5.27: How will information used in the PFOA be communicated and managed within the PFOA?**

- A synthesis of information is easier for a PFOA group to use than a library or an annotated bibliography of individual sources.
- As new information is developed or becomes available, you will need to update syntheses; as this is done, be sure new information does not appear to have a privileged position.
- There are many ways to communicate and manage information, but at the very minimum, the information should be posted on a website that is accessible.

**K. How will information used in the PFOA be communicated and managed within the PFOA? (Box 5.27)**

The PFOA process itself will make use of a broad scope of information, including studies and discussions covering many topics, and it will also be creating new information. A great deal of the information that is produced as part of the ERA process will be the foundation. This information will need to be communicated and managed within the PFOA process so that participants can build on it and understand it in a timely manner. Processes need to be in place to ensure this. For the purposes of this handbook, we will only draw your attention to a few considerations we think are important to keep in mind. We will introduce these select areas broadly here, but focus on more particular considerations and techniques in Chapter 6.

To begin, communicating and managing information effectively within a PFOA requires thinking about the purpose and audience for the information as a guide for your efforts. Within the PFOA, the primary purpose of information is to support the deliberation between participants. Information should act as both informant and assistant of the deliberation (e.g., clarifying understandings, organizing the process, promoting innovation and collaboration, keeping a record of progress and interactions).

It can play a critical role in stabilizing networks among participants and focusing deliberation. Within the PFOA, the primary audience for information includes the PFOA

participants, the facilitator, and other individuals, such as ERA scientists, that are directly involved. This audience will be made up of individuals with varied levels of knowledge and experience (i.e., some may have backgrounds in business and industry, some in science, some in environmental activism, some in agriculture, etc). For information used in the PFOA to serve the deliberation, it must be communicated and managed so it is easily understood by these diverse individuals.

To share information, it is most efficient in summarized and synthesized forms, but the readers should always be aware that a summary can be written with a bias, sometimes subtle, but sometimes overt. This is important for information coming into the PFOA, such as from ERA scientists, but it is equally relevant for information produced by the core deliberation, such as requests for studies going to ERA scientists, or recommendations. For example, individual sources of information, such as specific studies, could be accompanied by a summary or abstract that allows users to get an overview of key points. Or, when there are multiple information sources all pertaining to a shared topic, a synthesis could be created that combines the key points from the various sources to represent the current state of understanding about that topic. In a PFOA, raw data alone is not sufficient because the various members of the audience for the information may not have the particular expertise or the time necessary to make adequate sense of it. Communicating information in summarized and synthesized forms better serves the diverse needs of those involved in a PFOA because people can be more efficient and effective in their review of information. The amount of information requiring review is reduced and the amount of review necessary to gain a baseline understanding of any particular topic is lessened. If the participant questions a summary, the original studies and information sources should be accessible.

All the information within a PFOA will need to be organized and accessible, including:

- Information gathered for the PFOA by those administering the process;
- Information submitted by other parties, particularly PFOA participants, to assist the process;
- Information created by the PFOA, such as meeting minutes and notes, recorded

information derived from the deliberation (e.g., brainstormed ideas), and conclusions and recommendations reached by the PFOA.

Information management can be a complex and overwhelming task; however, it is such a common aspect of most professional interactions today that, fortunately, there are many techniques and tools now available for simplifying the process. Chapter 6 will discuss these in greater detail, but a couple components require planning and allocated resources, so we wanted to bring them to your attention now.



Areca Treon

1. You will likely want a qualified individual assigned specifically to the task of managing information within a PFOA. Poor information management practices could diminish the effectiveness and efficiency of the PFOA.
2. We strongly recommend creating an electronic database when possible, ideally web-based. An electronic database allows you to organize information in a systematic way and it can be customized to your needs, made widely available for user access, and retain flexibility for changes that can arise as the PFOA progresses.
3. Provide access to the information at least one month prior to the PFOA meetings.
4. Provide meeting summaries no later than one month after each meeting.
5. As the process proceeds, ask the participants if the amount and quality of information is satisfactory and make adjustments if necessary.

#### **L. How will information be communicated and managed outside of the PFOA? (Box 5.28)**

We discussed earlier how information will be communicated and managed within the PFOA, but you also need to consider how information will be handled for those outside the PFOA. This includes the government decision-makers who will be receiving the results, members of the stakeholder sectors being represented, the media, government agencies and interest groups not directly linked into the PFOA, and the general public. How information is shared with groups

outside of the PFOA will affect its broader influence and serve the governance requirements for transparency. It will also contribute to risk communication strategies.

The extent of information sharing and the processes for doing so will depend on existing agencies and procedures, existing regulations, available resources, and your goals for PFOA. Furthermore, even within the array of information sharing efforts that you may be capable of doing, there is the matter of determining which efforts are priorities.

However, there are minimal efforts for sharing information outside the PFOA that should be done, and then there are further efforts that may not be necessary. The first thing to remember is that the needs of the PFOA process should come first. Sharing information with external audiences can be restricted at first to encourage deliberation of difficult issues among the participants. Transparency is essential to a PFOA, but ideally the goal of transparency should not lead to obstructing or diminishing the PFOA. For example, a PFOA group may need time to candidly discuss ideas without fear of having to public defend every observation or opinion. Generally, the way to achieve a balance is through checks on sharing information about the PFOA outside of the process while it is underway. The temporary restrictions on sharing information outside of many legal proceedings, while they are underway, is a guide for these types of checks.

One option for providing such checks, frequently used in multi-stakeholder deliberations, is to require everyone directly involved in the PFOA to agree not to publicly denigrate the positions of others or reveal statements and conversations while the PFOA is underway. This is meant as a temporary restraint against people using information from the PFOA to position themselves in more powerful political advantage relative to others before the process has been able to run its course. During the PFOA, people can be free to speak outside of the process about their own opinions, and these opinions may be different from what is being discussed or is gaining support in the PFOA. However, if people are revealing incomplete or one-sided information to those not directly involved in the PFOA, such as the media, before the process is complete, it is more likely to undermine the process than help it.

There are also some other options for providing checks on information sharing during the PFOA. One possibility is that

**Box 5.28: How will information be communicated and managed outside of the PFOA?**

- A public website can be a cost-effective and efficient means for communicating with parties outside of the PFOA.
- There will need to be frequent communication with ERA scientists and other external government parties in order to support the PFOA.
- Confidentiality during moments of the deliberation are essential, so agreements have to be made about when and how information is shared; the best model is to produce common statements that are agreed to by all the parties in the PFOA group.
- Stakeholder representatives have to take an active role in informing and reporting back to their sectors.

while the PFOA is underway, only the agency responsible for the PFOA can engage in external communication. A weakness of this is that it threatens the overall transparency of the PFOA by concentrating the control of information about the process. Another possibility, which helps to address this weakness, is that any official external communications must obtain some degree of mutual consent from participants.

Checks are intended to temporarily protect the abilities of everyone in the PFOA to openly explore ideas and achieve a shared understanding with one another. When the external flow of information is temporarily restricted, participants are provided with periods of time where they are not under direct scrutiny from the outside – fears about how actions in the PFOA will be perceived by those outside of the process are temporarily removed. Instead participants can focus on the work of the PFOA.

Transparency will sometimes take precedence over the possible benefits of using checks to control information flowing out of the PFOA, though. Some countries have public meeting laws that will necessitate all PFOA proceedings being fully open to public view. Other countries have laws that limit the amount of restraint that can be used in withholding information, even temporarily.

Another important consideration relating to efforts involving information sharing outside of the PFOA is the audience. As was noted above, there are different types of groups external to the PFOA but for whom the process is directly relevant. These include the government decision-makers that will be receiving the results, members of the stakeholder sectors being represented, the media, government agencies and interest groups not directly linked into the PFOA, and the general public.

The foremost of these groups is the government decision-makers that will be receiving the results of the PFOA. Regardless of how much information is being shared externally during the process, whether the PFOA is fully open or partially closed, the agency managing the PFOA will likely need to provide ongoing reporting to government parties outside of the PFOA about the outcomes of the process at various stages. This will generally serve to keep others abreast of the proceedings, but it will also help decision-makers anticipate possible results, output, and outcomes that might emerge from the PFOA. In turn, having



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some foresight into potential conclusions that the PFOA might reach will help decision-makers in their preparation and planning for when they must take on the GMO issue at a policy level. If the PFOA is a highly iterative process that regularly interacts with ERA scientists, this reporting mechanism may already be built into the PFOA.

Members of the stakeholder sectors represented in the PFOA are another important group with whom information about the PFOA is likely to be shared. PFOA participants need to provide ongoing updates to and hold consultations with the stakeholder sectors they represent. However, there is some caution necessary, as PFOA participants will need to find a balance between what is occurring in the PFOA and what their respective sector wants to be happening.

The responsibilities of representatives to the stakeholder group whose interests they represent versus their responsibilities to the PFOA process itself can sometimes be incongruent. The PFOA requires participants to explore new possibilities, and sometimes this means representatives will be exploring possibilities that members of their sectors would be opposed to. Yet, to explore new possibilities fairly and completely requires a certain degree of openness, which some members of stakeholder sectors, being external to the process, may have a hard time understanding. Thus, on the one hand, those representing stakeholders must be open to input from members of their sector and should frame their participation so that they can best represent the concerns and worldviews of that group. On the other hand, representatives must also be open to examining possibilities beyond the concerns and worldviews of their sector. There are dangers if this balance is not found. For example, the understandings of representatives are likely to change as the PFOA group undergoes shared learning. If representatives do not adequately communicate these new understandings back to their sectors, their sectors may not buy into what is emerging in the PFOA or may end up feeling alienated by the process once it is complete.

The media is another group outside of the PFOA with whom information will likely be shared (Box 5.29). This includes classic media vehicles such as radio, newspaper, and television, but also newer media outlets such as the Internet. The media can minimally serve as the public gateway for the sharing of information about the PFOA with those outside of the PFOA – particularly for those who are not well-linked into the process. The media can be informed about

#### Box 5.29: Possible Media Guidelines for PFOA

- Media members are welcome as observers in public meetings but do not participate in the process.
- Partial sessions may be closed to media observation upon request by stakeholder participants unless this is prohibited by law.
- All communication with the media concerning the official PFOA outcomes will be by agreement of the group.
- Everyone will be mindful of the impact their public and private statements will have on the climate for the PFOA.
- No participant will attribute the suggestions, comments, or ideas of another participant to the news media or other non-participants.
- The media can conduct interviews with participants about their personal ideas and opinions at the discretion of individual participants.



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the PFOA using press releases and by providing updates about the process. Members of the media might also be invited to participate in the PFOA as observers (see page 92). The government agencies involved with the PFOA likely already have some procedures set up for working with the media to share information, and these can be used whenever possible. The main weakness of sharing information through the media is that some of the control of how and when the information is shared can be lost. Furthermore, extensive media campaigns have the potential to be expensive.

Another group outside of the PFOA with whom information should be shared include the general public and government agencies and interest groups not directly linked with the PFOA. It is possible that the minimum needs of these groups may be sufficiently served by sharing information through the media. Extensive transparency of the PFOA to these other groups is desirable, but it may be okay if information sharing efforts must be limited to media vehicles. PFOA needs to serve those most closely linked with the process first. The general public and groups not somehow directly linked into the process are secondary in this sense and should be served once the needs of the primary groups are met.

However, if the resources are available and the desire exists, a PFOA has the potential to be used as a basis for providing society with broader public education about GMOs and related issues. At a minimum, using a public website to post information about PFOA can often be the most cost-effective and efficient way of reaching broad audiences, including the general public and other government or non-government groups. More extensive efforts are also possible if resources are available. One possibility would be to hold local discussions and conferences that are tied to the PFOA and focus on the same issues as the PFOA. Such meetings would be more informal than the PFOA. If held at the right times in relation to the PFOA, though, such as before the PFOA begins or as it nears completion, these sorts of meetings could be an excellent resource by informing and providing feedback to the process. Another possibility would be for the PFOA to make use of the extension efforts of agencies and ministries that have some connection with the PFOA. Often agencies that revolve around environmental, health, and agriculture issues have such systems in place.

These sorts of additional efforts at sharing information with the broader public have the potential to benefit both the

PFOA process and society as a whole. However, because they can be time and resource intensive, they might be best as part of longer term plans for information sharing efforts once the PFOA is underway, or in the future with other PFOAs. In general, the potential size of the investment required means you will want these sorts of outreach efforts to serve longer term goals.

### **M. How will you evaluate the PFOA? (Box 5.30)**

Evaluation of the PFOA has two objectives: 1) to assure that using PFOA continues to achieve the desired goals, and 2) to improve the process of each individual PFOA. For the first objective, a country should periodically evaluate how they are using the PFOA in environmental risk assessment of GMOs. This requires a review of the original goals and whether these need to be modified. It will be necessary to reflect on how the context within which PFOA is being conducted has changed and whether this change has strengthened PFOA or restricted the ability to conduct a PFOA. Of particular importance is whether its linkages with the ERA and the decision makers remains strong as well as whether it has enhanced science, deliberation, participation, transparency, accountability, and decision making in regard to GMOs. Finally, you evaluate to clarify the strengths and weaknesses of the PFOA – how the methodology itself can be improved. In the end, you learn from the evaluation in order to revise the process and its relationships to ERA and governance.

Who should evaluate the PFOA? Certainly those charged with oversight and those who participated in a PFOA as well as those who use the PFOA information. This would include participants, the planners, partner scientists, and decision makers. It would be wise to develop a process that includes internal and external reviewers. This way the internal evaluation can provide a context rich analysis by those involved, while the external review can provide a more detached perspective based on universal standards. A broad evaluation can be conducted approximately every five years, as part of a strategic planning review of environmental risk assessment for GMOs in general. The evaluation results should be publicly available.

For the second objective, improving the process of each individual PFOA, organizers should end each process by asking participants to review specific characteristics as

#### **Box 5.30: Evaluating your PFOA process:**

Evaluation of the PFOA has two objectives:

- to assure that using PFOA continues to achieve the desired goals
- to improve the process of each individual PFOA.

**For a suggested evaluation form to provide to participants after you have conducted the PFOA, see Appendix E.**

**Box 5.31: Providing feedback on the PFOA Handbook:**

- See Appendix E for an evaluation form to provide feedback on the PFOA Handbook.

feedback on the ERA/PFOA for a particular organism.

Organizers can use this feedback to improve the next PFOA, to serve as data for an external review, and to learn so as to improve over time. A basic qualitative evaluation defines a list of important characteristics, identifying their strengths, weaknesses, and suggested modifications to improve.

Possible characteristics can include: preparation materials, participant diversity, facilitation, information sharing, scientist contributions, representative involvement during the deliberation, conflict management during deliberation, decision making, recommendation development and PFOA decisions, among many others. PFOA organizers can do this evaluation as a group and then check their perceptions against the participant evaluations to see where there are common insights and where there might be differences in opinion between the organizers and participants. An evaluation summary should be provided to the participants to increase transparency and accountability.

In general, all components of environmental risk assessment, from regulation to lab science to PFOA, can be improved if participants learn from evaluation and respond by revising their practices in order to achieve their goals.



# CONDUCTING A PFOA

This chapter explains and demonstrates, step-by-step, how to conduct a PFOA. We walk through the entire process of what needs to be done during a PFOA, where we explain the various tasks involved at each stage, examine specific techniques/tools available for accomplishing those tasks, and where applicable, illustrate the possible usage of them within the terms of a hypothetical scenario. Web resources for the various methodologies highlighted in this chapter are included in Appendix F. This chapter explains:

- A. Preparing for a PFOA Meeting: Process & Tools**
- B. Hypothetical Scenario**
- C. During a PFOA – Step-by-Step: Process & Tools**
- D. After a PFOA: Process & Tools**

## A. PREPARING FOR A PFOA MEETING: PROCESS & TOOLS

- Facilitation
- Case System Analysis & Background Report
- Stakeholder Analysis
- Information Management
- Communication & Reporting

See Appendix F for website resources on the various techniques discussed throughout this chapter.

### FACILITATION

The facilitator plays a critical role throughout the entire PFOA process. For this reason, we emphasized the questions of “Who will facilitate the PFOA?” and “What are the roles and responsibilities of the facilitator?” in Chapter 5 (See Chapter 5, page 82). Facilitation is a science and an art all of its own, and facilitation training is beyond the scope of this Handbook. Presumably, whomever you choose as a facilitator will have some previous experience running meetings and facilitating groups, and if they do not, they may want to study the supporting materials. Below we suggest a number of websites that can serve as excellent starting points in this regard. Additionally, even if you will not be acting as a facilitator in a PFOA, it is still useful for everyone involved with a PFOA to have some sense of what the facilitator will be doing. Thus we also present several key components of facilitation below. Finally, for those readers that will be acting as a PFOA facilitator, we discuss preparing participants for the PFOA prior to the first meeting.

#### *Web-based Resources about Facilitation*

If the person chosen to facilitate a PFOA needs training or additional assistance on how to be a facilitator, there are numerous web-based resources available. A few websites on facilitation are available in Appendix F (See page 230) that can be immediately helpful and that users can review as they move forward in their training and development of techniques. Our primary selections focus on free material provided by a public institution or professional society. Additionally, we list a few other sites that may also be of interest. Many of these sites also link to for-profit sites. We do not endorse any of these for-profit sites, nor have we evaluated them; however, it may be useful to visit them to get some insight into the types of products available.

#### *Key Components of Facilitation*

To those who will not be acting as a facilitator in a PFOA process but will be involved either directly (e.g., as a



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participant) or indirectly (e.g., as personnel in the agency administrating a PFOA), it is still important to have some basic understanding of the tasks, characteristics, and responsibilities of a facilitator. Following is a list of key components of facilitation to provide such an overview.

The facilitator is a **legitimizer** for the PFOA and the ERA. The facilitator:

- Explains the PFOA meeting processes and people's roles in them, the objectives and intended outcomes for the PFOA, and how the PFOA will contribute to the ERA;
- Defends the rights of everyone to participate and the desire for the full diversity of knowledge and opinions to inform the deliberation;
- Acts with integrity and builds trust between his/herself and the participants by treating everyone fairly and providing them with the opportunity to voice their ideas and have an opportunity to influence the PFOA recommendations;
- Avoids judgmental comments or decisions that could be interpreted as manipulating or dominating the process.

The facilitator is a **process monitor** that ensures:

- Each participant has the chance to express his/her opinions;
- Safe dialogue continues (i.e., participants are speaking, listening, identifying common understanding, summarizing agreements);
- Everyone is treated with respect and discussion is conducted in a civil manner;
- People have adequate time to make their contributions;
- Ideas are clarified, encouraged, or developed when necessary or appropriate;
- Deliberation is kept on track and tasks are done within the time allotted;
- The group ends with a recorded summary of what was done/agreed upon and what the next steps will be.

The facilitator is a **trainer** that:

- Explains the process as well as educates people that may not have skills in listening, asking clarification questions, negotiating, etc.;
- Finds someone who can explain specific information if the group is confused;
- Does not provide answers, but guides the group to learn how to work together and achieve their goals;
- Is prepared to make suggestions but flexible enough to let the group modify the process;
- Responds to participant's concerns and managing conflict;
- Models composure and respect.

The facilitator is a **problem explorer** that:

- Asks clarifying questions when the group is working with superficial or ambiguous statements;
- Probes when the group is trapped in a very narrow understanding of a problem or on specific details.

The facilitator is an **agent of reality** that:

- Challenges the group if they are omitting important topics or stakeholders in their considerations;
- Pushes the group to see if they can come to an agreement;
- Reminds them about their goals and objectives when they wander off on tangents or add endless lists of requirements to a task.

The facilitator is a **scapegoat** that:

- Listens when a participant expresses frustration;
- Does not become defensive if participants blame the process for a lack of progress but instead asks for helpful suggestions to get the group on track so they can achieve their objectives.

The facilitator is a **leader** that models a transparent, respectful approach to facilitating the PFOA.

### *Preparing Participants for the PFOA*

The facilitator needs to help ensure all participants have an initial understanding of and can competently participate in the PFOA process. This can be accomplished by providing participants with introductory materials and conducting introductory interviews with them prior to the first meeting.

Introductory materials help everyone become better informed and prepared. We recommend that facilitators minimally provide all PFOA participants with the following in advance:

- Preliminary goals for the PFOA: General explanations of why the PFOA is occurring and what objectives it is aiming to achieve.
- Information about actual PFOA process: Information about what the PFOA process is, how it works, and what the process will look like over the course of its proceedings.
- How the PFOA deliberation will be used in the ERA: Explanation of where the PFOA fits within the broader ERA process and how the information generated by the PFOA will be used in the ERA.
- Stakeholder Reflection Exercise (See page 218): A preliminary questionnaire listing PFOA questions to be addressed at each stage of the process. Reviewing the PFOA questions and trying to answer some of them before the PFOA begins helps each participant organize their thoughts and begin reflecting about the individual perspectives and positions of the sector(s) they represent.
- Ground rules: Explanations of behavioral guidelines and participant rights and responsibilities intended to help maintain a respectful and productive meeting environment.
- Case System Background Report: Accessible overview of key information about the case system with which the PFOA will be concerned. This will be a product of the case system analysis discussed below.
- PFOA timeline and agenda for first meeting: A calendar of the full PFOA process. This might include initial agendas for each meeting, but it should minimally include an agenda for the first meeting.



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- **Participant list:** List of who will be participating in the PFOA, including names, relevant organizations, and the stakeholder sectors each is representing.
- **Communication contact information:** Contact information for how to reach the facilitator, relevant agencies and personnel, and each of the participants.

Introductory interviews between the facilitator and each participant serve to establish initial relationships and begin building trust. These can occur in person or over the phone. These meetings allow the facilitator and participants to go through introductory materials together and clarify each other's roles in the PFOA. Participants have the opportunity to ask questions and express any concerns or thoughts on an individual basis. The facilitator can get clearer understandings about each participant and the stakeholder sector they will be representing.

### **Case System Analysis & Background Report (Box 6.1, 6.2)**

Prior to convening a PFOA, it is important to have an overview understanding of the full case system into which a GMO is being considered for introduction. This overview understanding is called a case system background report and it is produced through a case system analysis. A case system background report helps everyone involved in the PFOA begin the process with basic information and discuss issues in an informed manner. Below we discuss conducting a case system analysis to create a case system background report and examine some important considerations about compiling the necessary information.

The case system for a PFOA encompasses the major components of the natural and societal systems that play a significant role in or have the potential to be affected by the introduction of a GMO.

A case system analysis should make the context for a GMO more understandable and manageable. Conducting a case system analysis consists of compiling and synthesizing existing information about the different components in the system and what considerations are relevant. The hypothetical scenario provided in the next section of this chapter (see Box 6.5) includes examples of the type of information that could be found in a case system background report.



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A case system analysis for a PFOA is closely associated with information gathered during the preparation for an environmental risk assessment (See Chapter 5, page 103). The same categories of consideration (See Box 6.1) and types of information (See Box 6.2) identified in Chapter 5 can be used to guide a case system analysis.

When compiling information for a case system analysis, start with the information that already exists. Much of it can likely be obtained from various institutional sources. Scientists will have information gathered to begin an ERA. Proposals and reports about the proposed GMO will contain relevant information. Government agencies and academic research institutions are sources for national level agronomic, economic, environmental, and social data.

It is unlikely that you will have time to conduct original research for a case system analysis. Therefore, you will need to use secondary sources.

When compiling information from any source for a case system analysis, a key task will be judging information quality and identifying information gaps (See Chapter 5, page 107). In terms of information quality, you should consider how recent the information is, who obtained it and how, and applicability of the information for your specific concerns. For example, a country might have annually updated data mapping out specifically where local varieties of a crop are grown, or a country may only have informal approximations, based on the personal experiences of its scientists and extension workers. In the case system background report, identify what information is missing or if there are gaps in data. For example, perhaps there is reliable plant survey data for only one region of the country. You will also need to determine what information is missing or inadequate to formulate a useful understanding about any particular component of the case system. The GMO technology application may have extensive information on science components, such as the genetic characteristics of the GMO, but you will have to look elsewhere for information on things such as cultural traditions or religious values that may be affected by introducing a new technology.

### Stakeholder Analysis (Box 6.3, 6.4)

In Chapter 5, we discussed who will participate in a PFOA (See page 86) and suggested that conducting a stakeholder analysis will assist in deciding what stakeholder sectors

#### Box 6.1: Six categories of consideration relevant to a case system analysis:

- The GMO as a technology
- The GMO as a plant or animal species
- The GMO in the agroecological or aquatic production systems
- The GMO in the broader ecosystems
- The GMO in terms of industrial production and distribution systems
- The GMO in terms of sociopolitical systems

#### Box 6.2: Types of information relevant to a case system analysis:

- Biological science
- Ecological science
- Social science
- Culture and values
- Spiritual concerns
- Ethics

**Box 6.3 – What is a stakeholder sector?**

A stakeholder is any sector of society that stands to be affected positively or negatively by a decision (i.e., those who have an interest in the outcome of a decision) Stakeholder sectors are the individuals and groups that share some common interest in relation to a specific issue.

**Box 6.4: A stakeholder analysis helps you to:**

- Identify stakeholder sectors that capture the diversity of sectors.
- Classify each sector according to how critical each is to the PFOA deliberation.
- Decide whether any sectors share interests or are similar enough that they could be represented by a single stakeholder representative.
- Choose stakeholder representatives that can participate in the deliberation on behalf of each sector or grouping of sectors.

should be involved in the PFOA (see Box 6.3). A stakeholder analysis involves determining the range of sectors that have an interest in an issue, identifying the people who could represent those sectors, and evaluating the nature of each sector's interests (See Box 6.4). Here we provide further guidance about conducting a stakeholder analysis, including information on tools and techniques to assist with the process.

*How Extensive to Be*

There are varying degrees of effort that can go into conducting a stakeholder analysis. Minimally, a stakeholder analysis needs to provide a broad but concrete sense of who the stakeholders are and what their interests are in relation to the GMO issue. For a stakeholder representative who will participate in the PFOA, you assess the knowledge they will contribute, organizational affiliation(s), and ability to work collaboratively.

*Stakeholder Analysis Process*

A stakeholder analysis has five steps: brainstorming, profiling, interviewing, analyzing, and inviting.

Brainstorming is the first step in conducting a stakeholder analysis. For a PFOA, this involves creating a list of all of the different sectors that could potentially be affected by and affect the introduction of a proposed GMO (i.e., stakeholder sectors), and then identifying individuals who could act as representatives (i.e., stakeholder representatives) for each of the sectors. When brainstorming, it is important to think broadly and “outside the box” to ensure a more complete list. You want to identify not just the obvious stakeholders, but also the ones that could easily be overlooked. There are many good techniques to help with brainstorming (See page 150). Another helpful strategy is to conduct brainstorming with a group of people, or at least discuss your list with multiple people. In addition to helping to ensure a more complete list, involving others in the process will help eliminate potential bias. Once you have an initial list, members of the sectors you identify as stakeholders can often be excellent resources for identifying additional stakeholders.

The next step to stakeholder analysis is profiling the stakeholders you have identified. Profiling involves using a set of criteria or a series of questions to gather information about each stakeholder. This provides a basic understanding of each stakeholder and helps to prioritize and group similar

interests of different stakeholder sectors. The profile can be initiated by the PFOA organizer and then checked with members of the stakeholder sector. The following questions could be used to profile stakeholders for a PFOA:

- What are the characteristics of the stakeholder sector?
- What interests does the stakeholder sector have in relation to the proposed GMO?
- What is the current position(s) of the stakeholder sector regarding the proposed GMO?
- How is the stakeholder sector likely to be affected by the proposed GMO?
- What knowledge (e.g., legal, scientific, agricultural) and/or resources (e.g., financial, political) will the stakeholder representative bring to the PFOA?
- What organizational affiliations does the stakeholder representative have?
- Has the stakeholder representative worked collaboratively across sectors before?
- Will the stakeholder representative be willing to engage in a PFOA deliberation?

The third step in a stakeholder analysis is interviewing. Interviewing involves talking with members of the stakeholder sectors you have identified as well as the individuals you have identified as potential representatives for the sectors. Interviewing helps you ensure you have not forgotten any sectors. It helps you identify and learn about the legitimacy of a potential stakeholder representative to speak on behalf of a sector in a PFOA. It also allows you to gather additional information for your stakeholder profiles that you may not have been able to completely determine on your own. Interviews can be done in person or by phone to reduce costs. An important point about interviewing is that it will often be the first interaction members of the different stakeholder sectors have with the PFOA and so it plays a role in establishing the legitimacy of the PFOA among the members of the various sectors.

Analyzing is the fourth step in stakeholder analysis. Analyzing is taking all of the information you gathered in the first three steps and using it to make determinations about what stakeholder sectors to involve in the PFOA and who should participate as stakeholder representatives in

the process on each sector's behalf. While analyzing, you make decisions about what stakeholder sectors can be grouped together because they share common interests or positions. Furthermore, you determine what individuals are most qualified and can legitimately represent different sectors and groupings of sectors. For example, qualified representatives need to have some knowledge of the GMO issue, or the ability to acquire it, and should have a willingness to deliberate with representatives that may have diverse perspectives. And for representatives to be legitimate, each one needs to have some power and stature among their sector – this includes having the ability to communicate and work with others within those sector(s).

The final step is inviting stakeholder representatives. Based on the determinations made in the previous four steps, you formally invite stakeholder representatives to participate in the PFOA on behalf of stakeholder sector(s). Often this is a simple step, but it can be complicated by certain outcomes. If the individual you identified declines your invitation, you will need to return to your information and analysis and find an alternative. If there are protests about the person you have chosen to represent from within the sector, you will need to evaluate the validity of those protests and how they will interfere with the PFOA's legitimacy in order to make a determination about seeking an alternative



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#### *Web-based Resources about Stakeholder Analysis*

There is information available online to assist with and further explain how to conduct a stakeholder analysis in a community-based or project-based natural resource program. Most of the websites do not address a national level, multi-stakeholder group that is part of the regulatory system. But many of their insights can be used or extrapolated for a PFOA. We have identified a few selected sites available in Appendix F (See page 231) that can be immediately helpful.

#### **Information Management**

Information management is an important part of conducting a PFOA, as was indicated in Chapter 5 (See “How will information used in the PFOA be communicated and managed within the PFOA?” page 112). During the PFOA, participants will be making use of a lot of information as well as creating new information. This information needs to be managed so participants can access, navigate, and understand it in a timely manner. Three important tools that can assist with this process are electronic databases, summaries and syntheses,

and meeting recorders. Here we provide a brief overview of each.

### *Electronic Databases*

An electronic database is a collection of information organized in a systematic way on a computer to facilitate access and retrieval. It is essentially a virtual filing system. However, the advantages of an electronic database over a physical filing system are that it can be customized to your needs, made widely available for user access, and retain considerably more flexibility for changes that can arise over time.

Electronic databases have a number of features that can be customized to help serve your information management needs. These include defining categories for how information is organized, constructing mechanisms for linking and cross-referencing related information, setting standards for how information is input, and integrating search and sort tools for navigating the information.

Electronic databases can also help make information widely accessible for users. Information sources are stored digitally, which simplifies transfer and replication of information in a database. Electronic databases can be made web-based so they are remotely accessible through any Internet connection.

Additionally, electronic databases are capable of retaining flexibility for dealing with change. This can include keeping users aware of additions and changes being made to the information contained in the database. Or it can include being able to modify the structure or function of a database without causing major disruption.

There are different options for creating and administering a database. Various software applications are available (e.g., Microsoft Access™, Filemaker Pro™, MySQL), or a database can be custom-designed specifically for your purposes either by a hired consultant or internal personnel. Whatever you do, making sure that some qualified individual is assigned to administering an electronic database will help to ensure that the database is always functioning correctly.

### *Summaries and Syntheses*

Summaries and syntheses help to make information more useful and accessible for everyone involved in a PFOA. A summary provides users with an overview of the information

contained in a source without reviewing the entire source. A synthesis establishes a current state of understanding about a topic, theme, or issue by incorporating key points and findings from a collection of relevant sources to provide users with access to a baseline understanding without having to review every source individually. Earlier we discussed conducting a case system analysis; this process summarizes and synthesizes information about the case system a PFOA is concerned with in order to provide an entry point for understanding the case system. Equivalent entry points at the level of individual sources and collections of sources used in a PFOA are of similar benefit.

Summaries and syntheses are especially helpful to a PFOA because of the diverse ideas and concerns to be considered by a collection of people likely having widely disparate backgrounds and knowledge. For example, raw data alone is not likely to be appropriate or sufficient for a PFOA because the full audience for the data is not likely to have the particular expertise or time necessary to make adequate sense of it. Communicating information in summarized and synthesized forms better serves the diverse needs of everyone because the amount of information requiring review and the amount of review necessary to gain a baseline understanding of any particular topic are both reduced. For the same reasons, summaries and syntheses are equally relevant for information coming into the PFOA, such as from ERA scientists, and for information produced over the course of the process, such as requests for information and recommendations made to those not directly participating in the PFOA.

The most important step in making summaries and syntheses useful for a PFOA is establishing rules and guidelines for the practices ahead of time and then enforcing and following them. For example, in the case of summaries, there could be a requirement that all individual information sources be accompanied by a summary that gives users an overview of the information contained in a source without having to review the entire source. As for syntheses, key topics, themes, or issues of importance to the PFOA could be defined and then explanatory documents could be created that synthesize all relevant information from available sources pertaining to each. Web resources for writing summaries and writing syntheses are available in Appendix F (See page 232).

### *Meeting Recorder*

In preparing for the PFOA, decide how you will record meeting minutes. A meeting recorder is a designated person responsible for recording and managing information from meetings. The tasks of a meeting recorder in a PFOA are nothing more complicated than what one would traditionally think of with regard to recording and managing information for a meeting. However, we emphasize meeting recorder tasks here because they are an important part of an effective meeting and, as basic and obvious as they may seem, these tasks are frequently forgotten or overlooked when people begin talking in meetings.

Meeting recorder tasks include:

- Visibly keeping track of information as it emerges during a meeting so participants can refer to it
- Keeping records, or minutes, of what occurs in a meeting
- Providing meeting reports, or minutes, to participants and other relevant parties
- Maintaining meeting information and areas of agreement for future use

Different meeting recorder tasks can be the responsibility of a single person or they can be divided among multiple participants with one person organizing the material.

### **Communication & Reporting**

At different points before, during, and after a PFOA, it will be necessary to communicate with and report information to various audiences outside the PFOA. Chapter 5 addressed the question of how information will be communicated and managed outside the PFOA in some detail (See “How will information be communicated and managed outside the PFOA?”, page 114). Here we elaborate on planning communications for audiences outside the PFOA and provide details on a few recommended tools that will be important to these activities.

#### *Planning for Communication and Reporting*

Planning is an important part of ensuring that communications with audiences outside the PFOA will be effective. Three basic, interrelated considerations can help guide communications planning: purpose, audience, and communications strategy.



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When communicating with audiences outside the PFOA, purpose is the reason or motivating factor behind the communication. Purpose is what should or needs to happen as a result of the communication. The purpose for communicating with an audience outside the PFOA might be to educate them about the process, to provide a status update, to request additional information or support, to inform policy, or to initiate some action. It may be that there are multiple purposes. As you plan any communication with audiences outside the PFOA, think ahead about its purpose. Defining purpose(s) in advance will help to keep the material focused while ensuring adequate and essential information is included.

The audience for a communication is the person or people for whom a communication is intended. Audience determines what information is important and relevant. The various audiences outside the PFOA include government decision-makers, scientists outside the ERA, members of the stakeholder sectors being represented, the media, the general public, and government agencies and interest groups not directly linked into the PFOA. Each of these audiences will have different needs and be interested in different types of information and degrees of detail. As you plan communications, ask yourself who the audience is and what interest they will have in the information contained – try to take the point of view of your audience to think in terms of what they will need to get and what they will expect. Let the audience determine what information is included in a communication.

Communications strategy refers to how information is conveyed. In other words, how information is organized and the format and design used. To communicate with audiences outside of a PFOA, you may need to employ a variety of different communications strategies. For example, considerations relating to communications strategy have to do with how the material is structured, how the audience is directed through the material, and what information is highlighted. Format and design considerations refer to communication genre (e.g., report, media release, public meeting), communication medium (e.g., print, electronic), and the different elements (e.g., written word, graphics, document layout) to be used in a communication. As you plan communications, aim to align communications strategies with what is most appropriate for your purpose and audience. For example, decision-makers might be most interested in the recommendations coming from a PFOA and so in

communications going to them, it would be important to emphasize this information up front.

### *Communication and Reporting Tools*

The amount of communication and reporting that occurs with audiences outside the PFOA will vary from one case to another and one country to another depending on contextual factors (e.g., PFOA goals and design, existing procedures and regulations, available resources). However, three tools that will be important for communicating with and reporting to audiences outside the PFOA are communication coordination procedures, memos, and reports.

Communication coordination means having a person/people and procedures in place for overseeing how communications are created and distributed. In the context of a PFOA, this means defining and delegating responsibilities relating to communication with audiences outside the PFOA. Having mechanisms for communication coordination in place facilitates the exchange while ensuring that information being delivered is appropriate, ready, and correct. The purpose and needs of communication coordination for a PFOA are not necessarily any different from communication coordination for any project or organization. In fact, existing requirements and processes for communication coordination are the best guide to shaping communication coordination for a PFOA. We make note of communication coordination mostly as a reminder that it is something to think about.

Memos are correspondence documents. In the context of a PFOA, they serve to maintain and facilitate communication between parties outside of the direct PFOA process. Memos tend to be shorter and less formal in nature. The audience for memos is likely to be those more closely connected to the PFOA process; for example, scientists and government agencies rather than the general public. Their purpose can be to keep people informed and up-to-date about the PFOA or to make a request for information needed for the PFOA. Additionally, memos also provide an ongoing record of the PFOA.

Reports are summative documents. In the context of a PFOA, they serve to provide more terminal accounts of the process and recommendations that emerge from it. Reports can vary in length and tone depending on purpose and audience, but they tend to be longer, more formal, and more focused in nature compared to memos. Reports will minimally be used

for communicating the recommendations of the PFOA to decision-makers, but they can be tailored for communicating with any audience outside the PFOA, including the media or general public. The purpose of reports in a PFOA is primarily to convey summative information and results from the process. To this end, it is important that reports be complete yet focused on the needs of their audience. Web resources on communication and reporting are available in Appendix F (See page 232).

## **B. HYPOTHETICAL SCENARIO**

This chapter uses a hypothetical scenario to help explain the different stages of the PFOA process and the different tools/techniques that can be used at each stage. An explanation of this scenario follows and throughout the next section of this chapter, “During a PFOA – Step-by-Step: Process & Tools”, we will refer back to it to illustrate points and provide examples of how various stages might proceed. The scenario is developed around a problem that may cause a nation to consider a GMO as part of the solution. In practice, an ERA is often driven by an applicants requests to import or begin research on a GMO. Finally, the handbook scenario is fictional and meant for demonstrative purposes only. See Box 6.5 on the following page.

**Box 6.5 - Hypothetical Scenario**

Suppose that you are a government official in Zilnamya, a hypothetical country, and you are responsible for conducting a PFOA within an environmental risk assessment (ERA) to consider a genetically modified version of matton, a hypothetical crop. Zilnamya is a country with a moderately sized population and geographic area located in the tropical latitudes. Matton is an important crop grown throughout the world as a food and for the materials that can be derived from it. Zilnamya is one of the largest producers and consumers of matton in its region. In recent years, some farmers in Zilnamya have experienced yield reductions as a direct result of unprecedented infestations by an insect pest known as mattonbug. Efforts to control mattonbug thus far have had varied success. Alternative strategies are now being considered. One proposed strategy is the use of a genetically modified matton that was developed to resist relatives of mattonbug and is currently being used in other countries. Preliminary tests of the effectiveness of the genetically modified matton on controlling mattonbug in Zilnamya show promise. The Zilnamyan government has decided to conduct an ERA for the genetically modified matton and will begin the PFOA.

**About the Country**

Zilnamya is a country situated in the tropical latitudes. Its population and geographic area are both of moderate size, approximately 3 million people. It is bounded by four neighboring countries and an ocean. The climate of Zilnamya is mostly tropical with some temperate areas at higher elevations. Terrain in Zilnamya varies. Flat and rolling plains cover more than half the country and the remainder is divided between hilly and mountainous regions containing networks of rivers and lakes.

**About the Crop**

Matton is an important crop grown throughout the world for various purposes. It is most frequently grown for its use as a food and is an important staple in many countries. Matton is also grown for the materials that can be derived from it. Matton oil has widespread uses in cooking and industry, and there is a moderate international market existing around it. A less frequent reason people grow matton is to produce cloth from the plant fiber. Cloth made from matton is not of high quality; however, it is relatively easy and inexpensive to produce locally at small scales.

**Matton Production in Zilnamya**

Zilnamya is one of the largest producers and consumers of matton in its region. Matton produced as food makes up the largest portion of the total production in Zilnamya and most of this is consumed domestically. On average, 15-20% of a Zilnamyan person's total calorie consumption is matton-based. The other major driver behind matton production is matton oil, which is a significant export for Zilnamya. A portion of the matton oil produced is used domestically but most is exported. Finally, there are many farmers in Zilnamya who grow matton to produce cloth at local scales.

### Matton Production Areas and Climate

Matton production in Zilnamya can be divided into four agro-ecological zones that coincide closely with the geography of the country. These are the Southern Grasslands, the Eastern Savanna, the Northern Highlands, and the Western Hills.

#### Zone 1 – Southern Grasslands:

- Location: Plains region extending across the south of Zilnamya from the coast inland;
- Average yield: High;
- Altitude: Low and flat;
- Precipitation: Moderate and reliable;
- Misc: Largest and most dominant matton production region – responsible for approximately 75% of Zilnamya's matton with about two thirds of the total production area.

#### Zone 2 – Eastern Savanna:

- Location: Plains region in the east to northeast of Zilnamya;
- Average yield: Low and variable;
- Altitude: Low, but with regular variance creating plains that are more rolling than flat;
- Precipitation: Driest of the four production zones; normal precipitation generally follows a wet and dry season; the only production zone that regularly experiences drought – usually about once every 6-8 years;
- Misc: Low precipitation; recurring drought causes occasional crop failures of more than 50%.

#### Zone 3 – Northern Highlands:

- Location: Mountainous region in the west to northwest of Zilnamya;
- Average yield: Moderate;
- Altitude: Variable but high overall – region as a whole contains the highest parts of Zilnamya;
- Precipitation: Variable but reliable;
- Misc: Arable land in this region is of limited availability and occurs in pockets, some of which are quite remote; climate is mildly temperate.

#### Zone 4 – Western Hills:

- Location: Hilly region in the west of Zilnamya; situated between the mountains and the plains;
- Average yield: Moderate with occasional variability;
- Altitude: Variable – notably higher than the plains but lower than the mountains;
- Precipitation: High – contains some of the wettest parts of the country; reliable throughout the year, although one part is significantly wetter than the rest; heavy precipitation can sometimes exceed the water needs of matton;
- Misc: High biodiversity in the area creates competition for resources; 15% of matton produced in this area.

### **Farm Size, Farm Distribution, and Farming Practices**

The majority of individual farms in Zilnamya are small landholdings with production for the immediate region. Small farms are scattered throughout all four of the agro-ecological zones, although they are less common in the Southern Grasslands and make up the great majority of farms in the other three regions. As a group, small farmer households in Zilnamya tend to have lower incomes and this is reflected in their farming practices, which are more subsistence based and less mechanized than those of larger landowners. Small farms tend to grow a moderately diverse selection of crops, about 3-5 different crops is the norm, and they rarely if ever practice monoculture. Most small farmers also raise at least some livestock. The majority of small farm equipment includes tractors that are owned or on loan, but beyond that mechanization varies. Some of the medium-sized farms have additional machinery and infrastructure, while some in the most remote areas of the Western Highlands and Hill Tropics still rely heavily on animal labor, particularly for plowing graded areas. The farming practices of farmers with small landholdings tend to be more traditional and culturally based.

Large landholding farms make up the minority of individual farms in Zilnamya but are responsible for approximately 70% of the country's annual matton harvest. The majority of large farms are found in the Southern Grasslands region but they exist in all four regions. Most of Zilnamya's matton harvest surplus is produced by large farms and so the large farms serve much of the trade and food security roles of matton production. For example, large farms are almost exclusively responsible for the country's matton oil trade and domestic supply shortages for urban populations are usually satisfied by the large farms. Large farms generally have extensive mechanization throughout the production process, inputs of pesticides and fertilizers, and practice monoculture agriculture.

### **Supporting Infrastructure**

Zilnamya has seed distribution systems and exchange networks in place, but the success and usage of them varies by region and farm size. Farms in the Southern Grasslands and Eastern Savanna are the greatest benefactors because of their overall accessibility. Most farms in these regions rely on national distribution systems and plant the commercially and nationally produced hybrid seeds. Large farms in these two regions plant the hybrids exclusively. Smaller farms here tend to use hybrids whenever they are located close enough to a distribution point that doing so remains convenient and affordable, but this is not always the case. The situation is different for farms in the Northern Highlands and Western Hills because of less consistent accessibility. These farms are not serviced by national distribution, but rely on local and regional seed distribution and exchange networks of local seed varieties. The seeds distributed through these networks can lack some of the quality and reliability offered by the national hybrids, although the local varieties are usually better suited for the particular needs of the micro-climates where they are used.

Transportation and processing systems for matton follow a similar pattern to that of distribution and exchange. Transport availability follows material availability, so transport systems best serve the areas with the greatest production and accessibility, which conform approximately to the locations of large farms and the predominant agricultural zones. Initial processing of matton usually occurs regionally. Yield not intended for local use is then transported to the primary industrial center for matton in the Southern Grasslands region. There the pre-processed raw materials are converted into food products and matton oil and shipped out for domestic and foreign destinations. Products for domestic usage are transported by road, rail, and barge to their locations. Products for international trade, mainly matton oil, are shipped to one of two major ports for international distribution – a rail port serves continental trade transport to nearby countries and a sea port serves all other trade transport.

### **Mattonbug Problem in Zilnamya**

In recent years, mattonbugs have become a growing problem in Zilnamya. Mattonbug is an insect species that exists in a variety of climate conditions around the world and uses matton and its relatives as a primary food source. In small numbers they cause negligible damage to crops, but in large populations they can devastate a matton crop. Mattonbug is an exotic species in Zilnamya. The first reports of mattonbug in Zilnamya occurred a few decades ago in a single region of the Southern Grasslands near the coast. Over time, mattonbugs became increasingly more widespread further inland. Now mattonbugs are found throughout the Southern Grasslands and in some areas of the Eastern Savanna. Even as the range of mattonbugs has grown, though, they have usually posed only minor problems for farmers in Zilnamya. However, a few years ago many farms in the Southern Grasslands, particularly larger farms, began experiencing unprecedented mattonbug infestations.

Since the infestations began, the country as whole has seen increasing yield reductions. Currently the infestations are mainly occurring in the Southern Grasslands. Although there is evidence that the problem may be expanding into the Western Hills as above average mattonbug populations are now being observed. The Zilnamyan government has been working closely with affected farms to control the mattonbug problem using some of the most effective pesticide methods. However, these efforts have so far had varying effect. There has been some localized success, but the geographic scope of areas experiencing infestations, along with the number of individual farms being affected, has only continued to increase. It has become clear to the Zilnamyan government that alternative strategies for dealing with mattonbugs need to be considered.

### **Zilnamya and Genetically Modified Matton**

One proposed strategy for dealing with the mattonbug problem is the use of a genetically modified matton. The genetically modified matton was developed to resist relatives of mattonbug and is currently being used in other countries. Preliminary tests of the effectiveness of the genetically modified matton on controlling mattonbugs in Zilnamya show some promise.

Interest in and concerns about the genetically modified matton vary by region. The main interest in the genetically modified matton occurs in the Southern Grasslands, where the mattonbug infestations are mainly occurring. Large farms there are largely in favor. Small farms are mixed. Some are in favor but worry about affordability. Others have cultural reservations about the genetic modification of crops.

In the Eastern Savanna, farms have not yet experienced significant mattonbug infestations. However, the area already has marginal matton production with occasional crop failures and so there is concern about the added effects that mattonbug infestations could cause here. Large farms and many small farms that use national distribution systems tend to be in favor, whereas small farms that utilize regional distribution of local seeds are concerned about the various ways that they could be impacted.

The situation for farms in the Northern Mountains and Western Hills is the most complicated. It is these regions where the greatest risks for gene flow exist because there are several wild relatives of matton that may be capable of cross-breeding. These areas do not yet have any significant mattonbug presence, but mattonbugs are biologically capable of becoming established in the climates of these regions. Seed usage in this region is also the most diverse. Most farms rely on regional distribution networks of local seeds but some are served by the national distribution systems of hybrid seeds. This region also is also home to many of the more traditional communities most likely to be negatively affected by adverse impacts on their environment.

A PFOA will be conducted as part of the ERA for the genetically modified matton.

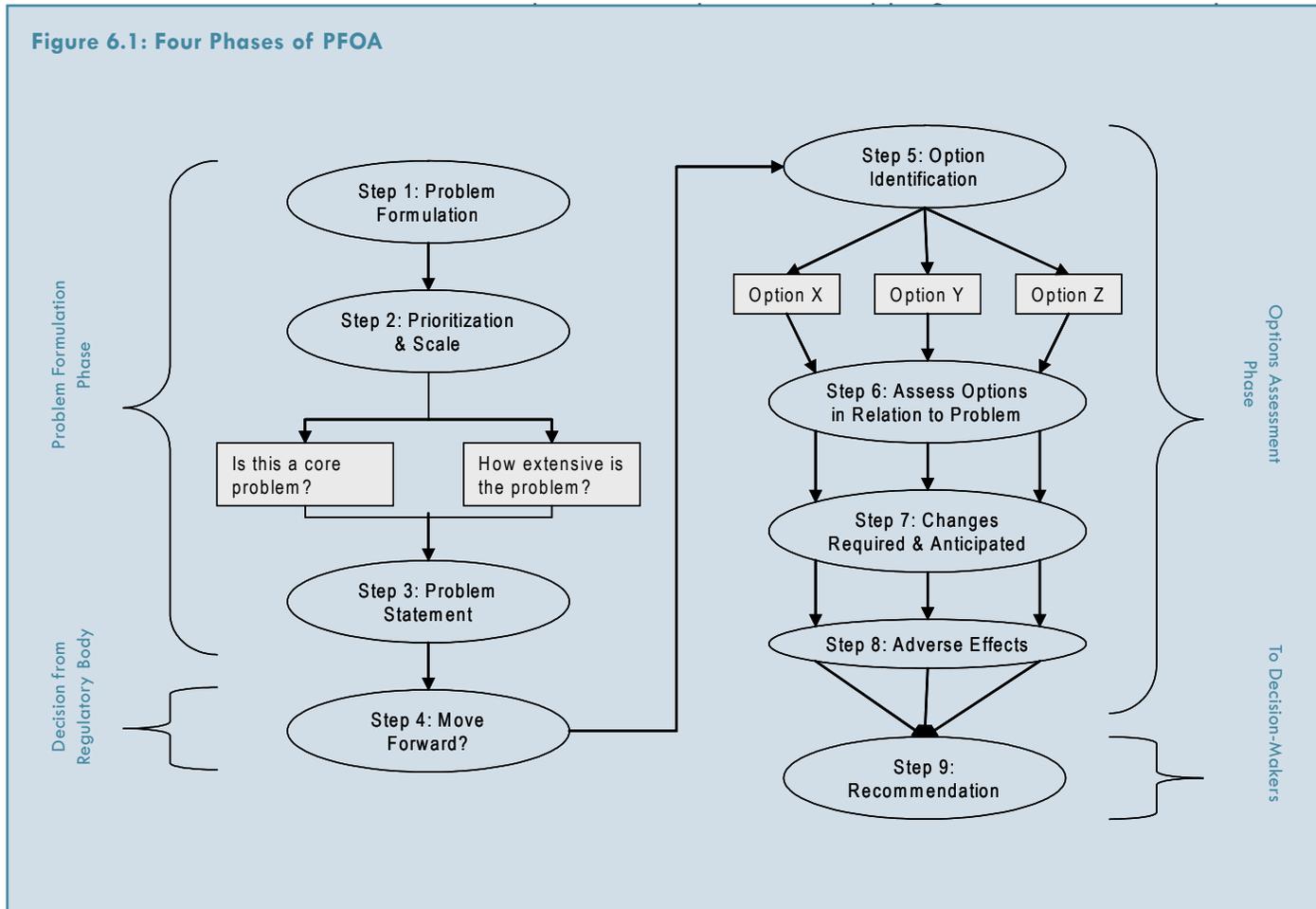
### C. DURING A PFOA – STEP-BY-STEP: PROCESS & TOOLS

This section discusses how to conduct a PFOA process, from beginning to end, with information on tools that can be useful in each step.

There are nine distinct steps that occur in the PFOA process. However, since some steps in a PFOA occur together and others have distinct intervals that must occur in-between them, for the purposes of this section, it can help to think of the way these nine steps separate into groupings of steps (See Figure 6.1, following page). Considering the PFOA in this way, steps can be grouped into four phases: a problem formulation phase (steps 1-3), a phase requiring a decision from a regulatory body based on the information from the problem formulation phase (step 4), an options assessment phase (steps 5-8), and lastly the phase of recommendations from the PFOA going to the decision-making body (step 9).

The text is written with the expectation that the same group of participants will conduct each PFOA step in sequence, but

Figure 6.1: Four Phases of PFOA



at different points in their national biosafety framework with different participants. For example, a country may choose to have their research and development agency use the PFOA methodology in the ‘problem formulation phase’ but use the ‘options assessment phase’ during the environmental risk assessment for a specific GMO.

Planning the full PFOA requires an anticipation of the number of meetings and how long each phase will take to complete. As always, the length of time a PFOA will take depends on many factors; for example, the extent of the discussion, cultural norms for how long participants take to present their ideas, and how efficiently the meetings are run.

Based on the methodology, a **basic PFOA** would require two meetings amounting to a minimum of three to five full days over the course of the different phases. The problem formulation phase (Steps 1-3) would take a minimum of one day and then there would be a period of waiting for the regulatory decision to continue with a risk assessment (Step 4). The options assessment phase (Steps 5-8) could

be conducted in two days prior to the experimental period in the risk assessment process. While these experiments are being conducted, a draft PFOA recommendations report could be prepared, and once the risk assessment experimental findings exist, PFOA participants could meet for a final day to review their recommendations in light of new information from the findings. Based on this review, the group would complete the final report and send their recommendations to the decision-making authority (Step 9).

Another approach is a **highly interactive PFOA** that follows the general structure of the basic approach but is much more interactive in task force meetings with the scientists doing the environmental risk assessment. This approach would add meetings between sub-groups of the PFOA and/or scientists at critical points in scientific decision-making; for example, when the scientists are identifying the system within which the GMO will be used or when they are identifying adverse effects. These interactive meetings could vary in the topics addressed and increase the number that occur depending on the specific interests in each country. In most cases, these interactive meetings would occur during the options assessment phase (Steps 5-8). A highly interactive PFOA would increase the amount of time spent in the PFOA, but it could also enhance the science and the PFOA discussions therefore contributing to improved decision-making. For example, a highly interactive PFOA could be designed to expand participation and consultation, starting as a national level meeting that covers Steps 1-3 and then regional consultation sessions to discuss what the national representatives produced. This could also be done with Steps 5-8, where the national PFOA deliberation from the first meeting could be shared at the regional or state level and groups could provide feedback on the report. This regional feedback could be considered during the last national level meeting and incorporated into the final report. Another approach would be to enhance the interaction between PFOA participants and ERA scientists. Depending on the objectives for this interaction, visits to the labs or field trails could expand discussion between the scientists and PFOA representatives about the systems that might be affected. Or PFOA participants could become more involved in defining the long-term research agendas for GMO monitoring or short-term identification and prioritization of potential values at risk that require further investigation.



Thomas Isler

## Before Step 1: Introduction and Warm-up

### General Introduction

When the PFOA is first convened, begin with a general review and discussion of the process that everyone is about to take part in. The extent and amount of introduction that is appropriate or necessary will depend upon how much pre-meeting preparation was conducted (e.g., materials sent out, stakeholder interviews, training). However, regardless of how much preparation occurred, there are some key introductory tasks that should occur before moving to step 1 in a PFOA process:

- Personal Introductions
- Review PFOA process, timeline, and agenda
- Review and discuss goals
- Review and discuss ground rules
- Allow time for questions

A PFOA should always begin with the participants and the facilitator introducing themselves to one another. The group is going to be working together and to do so effectively, everyone must minimally know everyone else in the group. Personal introductions can be quite simple or more extensive (i.e., personal introductions could be integrated with a warming up technique, as discussed below). At the very least, though, we suggest that everyone go around and indicate:

- Who they are by name;
- Who the stakeholder sectors are that they will be representing in the PFOA;
- Why they, personally, are interested in working in a PFOA.

Before the actual PFOA process begins, the facilitator should review the process, timeline, and agenda. Presumably, all participants will be somewhat familiar with all three of these things as a result of pre-meeting preparation (e.g., meetings, interviews, mailed materials). Nevertheless, it is useful to walk through the process, timeline, and agenda for the PFOA before it begins just to confirm that everyone understands and is in agreement about each aspect. If there are any conflicts or concerns that have not already been dealt with, this could be the time to discuss them as a group to determine if any modifications may be necessary.

Likewise, after reviewing the structure of the PFOA, the facilitator should also guide the group through a review and discussion of the goals for the process. It is best for

the group to have clear definitions of the goals both for the PFOA as a whole and for each individual phase in the process. Some of these goals will have already been determined and discussed prior to the meeting. These should be reviewed to ensure everyone knows and understands the basic obligations. This will help everyone stay focused on what it is they are all working toward – especially in helping people get back on task if tangents emerge – and allow people to feel successful as they complete specific tasks and achieve particular goals. Beyond the basic obligations inherent in the PFOA process itself, a group may also decide to set additional goals for themselves to help further guide the process. The beginning of the PFOA is the best time to discuss any goals the particular group may want to add to the list or modify.

Similarly, the ground rules for the PFOA should be reviewed and discussed. Everyone should know them from pre-meeting work conducted by the facilitator (e.g., interviews, meetings, preparation materials), but now the rules are actually going to be used and people are going to need to abide by them, so it is important that everyone understands them. The facilitator should review the rules and make sure they are visually available to everyone – perhaps by hanging them on a wall or passing out a handout to participants. Additionally, participants could have objections or additions to the rules that they would like to raise with the group. If that is the case, this is the best time for such discussions to occur. Again, addressing and discussing any desired modifications now, before the PFOA has even begun, is much easier and will go much more smoothly here than in the middle of the PFOA process. Finally, there needs to be time for questions. This can occur throughout the introductory process, or at the end of it once everything has been reviewed.

### *Warming Up*

When you first convene the PFOA, the stakeholder representatives are most likely going to be coming together for the first time as a group (unless you have held some sort of pre-PFOA training or meeting that everyone attended). Some of these individuals might already be acquainted with one another, but some may not know each other at all. In a PFOA, all of these individuals are going to need to work together and function as a group. Warming up exercises are an important practice used to help groups function more effectively.

There are two ways in which warming up exercises can be helpful to a PFOA. First, when a PFOA initially convenes, warming up exercises are a way for group members to get to know one another better, both as individuals but also as a group. Groups function much more effectively when members have at least some familiarity and knowledge about each other. Warming up exercises are a means of providing some neutral ground for all group members to begin forming relationships around issues and discussions that are not of central importance to the PFOA. Used in this way, warming up exercises can be an effective way to build everyone's comfort level beyond what can be achieved through standard introductions alone (although those are still important). Additionally, they help the group get focused on the specific tasks at hand; it rarely works to jump right into a task before everyone is focused on the relevant issues and materials.

Second, as a PFOA occurs over a series of meetings, participants will occasionally need help re-focusing, maintaining focus, or refreshing energy levels – warming up exercises can help with this. Between meetings, everyone is dispersed and off thinking about other things and when a PFOA reconvenes, it is important for people to get back on topic. Also, over the course of a single meeting, a group's energy levels can begin to wind down as a consequence of the time and effort involved. The standard way to improve focus and energy levels during meetings is to provide breaks (e.g., a ten minute coffee or tea break). Breaks can provide a moment to refresh as well as allow for informal negotiation and clarification among participants. Another thing that can be quite effective at achieving similar ends is a short 5-10 minute warming-up exercise, either used in conjunction with or in place of a break. Used at the start of a PFOA meeting, when people's minds may be distracted, a warming up exercise can help a group re-focus on the objectives of the PFOA. Used sometime during a PFOA meeting, a warming up exercise can help participants to relax and re-energize, or to help bring participants back together after a break.

A key point about using warming up exercises is that they should never become a dominating component of the PFOA. Warming up exercises should be kept:

- Short – usually about 5-10 minutes.
- Clean-natured and comfortable: This is

something that you will need to make a context specific judgment about. It can be okay to push against the boundaries of what participants might expect in a formal group meeting (e.g., a warming up exercise could involve humor or a game) as long as it ultimately helps the group function better. But a warming up exercises generally shouldn't leave any participants feeling uncomfortable or offended after the exercise is complete.

- Fun and light-hearted – for example, a short game might help to shake a group up a little, or an exercise that involves getting up and moving around might help to get people re-energized.
- Neutral – the content of the exercise should not be divisive; for example, warming up exercises generally should not relate directly to what is occurring in the PFOA.

All groups have their own unique formation that must be attended to in order to keep it functioning effectively as a group. This is important to consider in choosing what warming up exercises to use and when to use them. There are literally hundreds of different warming up exercises that exist for use in meetings. Additionally, you could come up with your own. Examples of warm up exercises that could be used in a PFOA are available in Appendix F (See page 233).

### **After Breaks Between PFOA Meetings: Review**

Throughout the PFOA whenever the group is re-convening after a period apart it is helpful to do some review for participants. This is especially true if several weeks or months have passed since the group last met. This review could include going over what occurred at the last meeting, noting where the group is within the PFOA process, and sharing any relevant developments that may have occurred since the last meeting. There does not need to be a lot of time devoted to doing review. The facilitator could spend a few minutes reviewing information as a way to open the meeting, or such information could be delivered in a handout given to people as they arrive.

## Problem Formulation and Options Assessment (PFOA) Steps

### STEPS 1-3: PROBLEM FORMULATION PHASE

For a handout of the PFOA questions, see Appendix E.

Together, the first three steps of a PFOA result in an articulated understanding of the problem a GMO is being proposed to address. Steps 1 and 2 - “Problem Formulation” and “Prioritization and Scale” - are performed in tandem, and Step 3 - “Problem Statement” - is the product of those steps.

The first step of PFOA is to begin formulating the problem. This is the initial and central component of PFOA that must be done by a multiple stakeholder group in an open deliberation of diverse perspectives. For the purposes of PFOA, a problem is defined as an **unmet need that requires change**. Basic human needs are most commonly identified as food, shelter, and safety. Other human interests are stakeholder specific, such as enhanced economic opportunity, positive social interactions, and cultural richness. For example, individuals have the basic need for a certain amount of calories per day or the security that their children will continue to live healthy lives as a minimum foundation for well being. Once the needs for food, shelter, and safety are met, an individual can expand their interests to include numerous options for well being. These interests will differ from one individual to another and from one group to another.

In formulating the problem, an initial task can be to consider two questions: whose problem are we addressing (the positive question), and whose problem should we be addressing (the normative question). There may be more than one “who” identified here. The next task in formulating the problem is to focus on the negative effects of the problem to determine the needs of the identified people that are not being fulfilled by the present situation. For example, a shortage of water could result in a reduction in yields that results in hunger, or the unmet need for a minimal amount of food available for the region’s citizens. Finally, identifying the causes of the shortage of water helps the group think about potential solutions. Changing the present situation to meet unmet needs is a statement of the “solution” to the problem.

The second step of PFOA – Prioritization and Scale – consists of using the problem formulated through deliberation to

clarify the relative importance of this problem as compared to other problems or issues. All the stakeholder sectors should be involved in formulating the problem and providing perspective on its priority and scale. This is particularly true for those groups whose needs are not being addressed or for whom the problem is most relevant. This allows these groups to provide perspective on the relative need of their group. This is accomplished in PFOA by each stakeholder representative presenting their sector's perspective on the problem formulation and prioritizing. Other public actors can also share their perspective on the relative importance of this problem in relation to scale, impact, and uncertainty.

Through the deliberative processes of the first two steps, the needs of each stakeholder group will be clarified and a shared assessment of the problem will be developed.

The key questions to be answered during the first two steps of the problem formulation phase are the following:

#### **PFOA Step 1: Problem formulation**

##### **Relevant Questions**

1. What needs of the people are not being met by the present situation?
  - Whose need is being addressed and whose need is not being addressed?
  - What is the unmet need = the problem?
  - What are the causes of the problem?
  - How do these causes rank in their influence on the problem?
  - Whose problem is it? What are the effects of the problem?
  - What aspects of the present situation must be changed to meet the needs?

#### **PFOA Step 2: Prioritization and Scale**

##### **Relevant Questions**

1. Is this problem a core problem for the people identified?
  - Do the people recognize the problem as important to their lives?
  - What are the potentially competing needs of these people?
  - How do the needs identified rank in importance to these other competing needs?
  
2. How extensive is the problem?
  - How many people are affected?
  - In what part of the country are these people located?
  - How large an area is affected by the problem?
  - How severe is the problem (local intensity)?

During the first two steps of the problem formulation phase, the PFOA group can use three primary techniques to answer the questions: brainstorming, conceptual mapping, and ranking.

### *Brainstorming*

Brainstorming is a process for helping the group to generate a broad list of ideas. It is used throughout the PFOA whenever the group begins to answer a question. At first, brainstorming will be a formal process, but as you move through the PFOA, it can become less formal as the group gets more comfortable.

To begin brainstorming, the facilitator can ask participants to individually reflect on a question and write down two or three brief ideas in response. Next, the facilitator should go in order around the circle and ask each participant to provide one idea to share with the group. As each responds, the facilitator or meeting recorder should write the ideas on a list that can be read by the whole group. If participants have more ideas after everyone has contributed once, a second round of idea sharing may be necessary.

An option for a less formal brainstorming process is for the facilitator to have the group move through the questions together and allow everyone in the group to freely provide brainstormed responses, which the facilitator or meeting recorder then writes down on a list visible to the whole group. This informal approach can save time and be effective when all the members are respectful of diverse opinions.

One caution for a less formal approach is to guard against dominant voices in the group providing all of the responses with the majority of participants not contributing. If the facilitator sees this happening, they could:

- Ask members who have not contributed yet if they have any comments;
- Ask everyone to reflect on the questions and write down a few ideas – some people need to think before they speak – this can improve the overall contributions;
- Return to a more formal process, discussed earlier, and give everyone a turn to speak if one or two people are really dominating the brainstorming.

Brainstorming is not a time for extensive discussions about ideas being shared. There may be brief clarifying questions, or a participant could note their support or agreement around an idea that has already been listed. However, too much discussion at this point can get people off track – it is best to hold off on longer discussions to keep ideas coming forward. The goal is to get an adequate list of ideas generated so that the group can begin to see different possibilities and considerations they may not have thought of on their own while beginning to see where people share agreement.

After the list has captured all the responses, the group can begin to discuss the brainstormed ideas generated. This is the time for more extensive clarifying questions, insights about relationships between different responses, suggestions for grouping responses that are similar, etc. Several web resources on brainstorming are available in Appendix F (See page 233).

#### EXAMPLES FROM HYPOTHETICAL SCENARIO

In a PFOA for our hypothetical scenario, participants would begin Step 1 by brainstorming ideas in response to the questions presented. For example, what problems exist for the ‘matton’ situation in Zilnamya. Going around the table and asking each of the stakeholder representatives for ideas might result in a list of possible answers:

- A representative for farmers in the Eastern Savannah might state the problem as an occasional drought that results in reduced harvests and crop failures.
- A representative for the matton oil industry might state the problem as an unpredictable supply of raw material because increasing mattonbug infestations are reducing matton yields in the Southern Grasslands.
- A representative for consumers might state the problem as fluctuating prices for food and not being able to get reasonably priced products throughout the year because of seasonally-reduced matton yields.
- A representative for the government might state the problem as increasing mattonbug infestations in the Southern Grasslands reducing the viability of matton as a national crop.



Thomas Isler

### *Conceptual Mapping*

A conceptual map is a drawing of relationships between a problem and its causes and effects. In a PFOA, it can be helpful for the group to have a visual map of these relationships because people don't have uniformly similar concepts of case systems. Drawing out a conceptual map helps the group come to a shared understanding as well as identify where there are differences of opinion. The conceptual map can assist in developing the problem definition by allowing the group to discuss what key items are important and see how they relate to each other.

The facilitator guides the PFOA group through drawing a conceptual map of the problem, causes, and effects. Using questions, the facilitator asks the group to identify characteristics of the map and relationships between distinct components. If a power imbalance between members of the group would significantly stifle the ability of some participants to express their ideas, then the facilitator could ask everyone to develop a basic conceptual map individually and then the facilitator organizes all the conceptual maps into a common document for discussion. The advantage of this approach is that you start with the greatest diversity of ideas and the facilitator can help the group consider all 'voices.' A potential disadvantage is that it will take more time and you could lose the emergence of common ideas that can happen when a group builds the conceptual map together.

This technique can be used as a very general tool to visualize relationships or it can be enriched with ranking decisions and quantitative information. Early conceptual maps may be very messy, hand drawn words and possible relationships (Buzan and Buzan 1994). For example, the group will rank problems based on their importance to threatened cultural values or after reviewing scientific studies that provide quantitative assessments of an impact, such as percent yield loss attributed to different factors (see the ranking discussion next in this chapter).

There is an inherent link between the process of brainstorming answers to the PFOA questions and the process of developing a conceptual map of the relationships between answers. The brainstormed answers provide a basis and structure to help with answering subsequent questions. For example, if the group identifies a problem, in subsequent questions they will brainstorm possible effects and possible

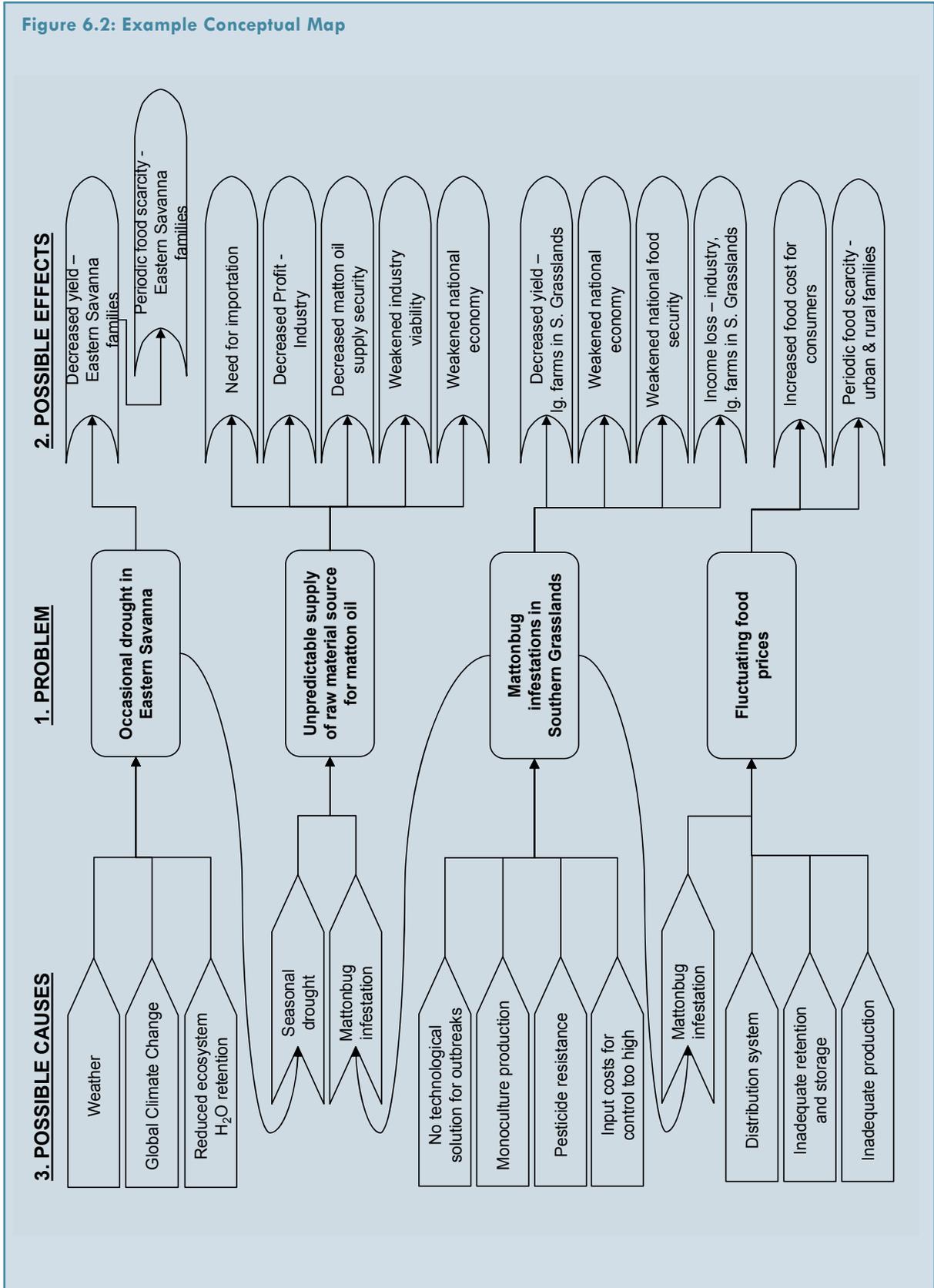
causes of the problem identified. Some relationships become apparent through the answering, and in this way the beginnings of a conceptual map are automatically being created throughout the brainstorming process.

How a group goes about answering the PFOA questions will affect how a conceptual map takes form. For example, a group might approach the questions by brainstorming a list of answers to each question individually, or they might identify one problem and then, before trying to brainstorm any others, immediately try to brainstorm possible effects and causes relating to that problem. Either strategy is valid and groups will probably have a tendency to do some of both; however, to make brainstorming as productive as possible, we recommend trying to stick to one PFOA question at a time. For example, first work on identifying a list of problems, then identify possible effects of the brainstormed problems identified, and finally identify causes of the problems. This can help a group stay focused and better able to see connections across and between different brainstormed problems, effects, and causes. Although, there will be modifications of previous responses as the group sophisticates their analysis of the relationships. Web resources on conceptual mapping can be found in Appendix F (See page 234).

#### EXAMPLES FROM HYPOTHETICAL SCENARIO

In the PFOA for our hypothetical scenario (See Box 6.5, page 137), assume that the group brainstormed the list of problems presented above and then moved on to brainstorm a list of possible effects for each problem and a list of possible causes for each problem. If they were to then create a conceptual map by drawing out the relationships between the items in each of these lists, it might look something like Figure 6.2.

Figure 6.2: Example Conceptual Map



### Ranking

Ranking techniques help the group come to a common agreement on the relative importance of various answers based on the insights of the PFOA members. In most cases, a simple qualitative ranking allows the group to see which of many good ideas are considered to be the most important by the group. For example, after brainstorming the complex causes of “reduced yields,” each group member could select what they consider to be the three most important, thereby producing a simple vote tally for what the group thinks are the most important. Discussion after a ranking exercise focuses the group, narrowing their problem analysis, and assists with coming to a common understanding. Often there are one or two responses that everyone agrees on. Minority opinions can be expressed so that the group understands that there can be different perspectives and then considers these opinions in the analysis.

In PFOA, ranking occurs after a conceptual map has allowed participants to see the relationships between problems, effects, and causes, and the group has then been able to dig into these relationships to discuss the severity and extent of problems, effects, and causes in comparison to one another. Discussions of severity and extent are important to ranking because they increase and clarify people’s understandings. This better understanding enables participants to make more informed choices as the group’s attention turns to ranking and prioritizing what issues will be at the center of the problem statement and thus the focus of the PFOA going forward.

The time to rank becomes apparent when the group thinks they have identified all the major problems, effects, and causes, and articulated to the best of the group’s ability what is known and what may be unknown about these issues. If questions exist at this time, seeking an outside opinion from ERA scientists for confirmation can be appropriate. Web resources on ranking techniques are available in Appendix F (See page 234).

### EXAMPLES FROM HYPOTHETICAL SCENARIO

Let’s assume that after creating a conceptual map such as Figure 6.2, participants from the PFOA in our hypothetical scenario held discussions that better specified the severity and extent of the different problems, effects, and causes. During these discussions the following information emerged:



Areca Treon

- Drought in the Eastern Savanna occurs about every three years and causes 100% crop loss for small scale farmers in the region with no irrigation systems and results in a 5% loss in national production. This population includes farms with 1-20 hectares – approximately 200,000 families.
- Unpredictable supplies of raw material source for matton oil causes increases of 15% in production costs. Rising production costs generally have the greatest affect on regional producers served by areas with decreased yields (i.e., Eastern Savanna during drought years, Southern Grasslands during mattonbug infestations); national producers, although better able to fend off rising costs because of their diversified sources, are also affected depending on how much they rely on a particular region for source material.
- Mattonbug infestations in the Southern Grasslands cause a 20% loss of yield in the areas afflicted but the farms affected account for 60% of national production. There are generally only about 200-400 farms afflicted by infestations, but since their collective holdings account for about 500,000 total hectares, the loss of yield has a disproportionate per farm impact on national production.
- Fluctuating food prices means reduced calorie intake for citizens generally. The population affected includes millions of citizens throughout the country, with people in urban areas feeling the greatest impact because of limited ways to augment their food supply when they can't afford matton.

Using this information, participants can make decisions about what issues are most important. The main goal here would be to get a general sense of common areas where people agree. There is bound to be differences of opinion, but patterns can emerge as participants rank issues they think are most important. If there is even distribution, it can suggest that further information or discussion is required, but if many participants all identify a particular issue as most important, then some sense emerges of what issues should have the greatest priority.

There are many different ways to go about ranking. One way that participants in our scenario could rank the issues is to just pick the top 2 or 3 issues from those listed, providing no greater emphasis amongst the issues chosen. Another way would be for each participant to pick the top 2 or 3 issues, but then rank them from 1 (more important) to 2 or 3 (less important). If these numbers are compiled, issues most frequently identified as most important might emerge as priorities.

Ranking should be followed by discussion to allow participants to understand why different people might rank issues differently. People can change their ideas about what is most important once they have a chance to hear someone else's opinion or ideas. For this reason, the advantage of the first method mentioned above is that it doesn't create a false impression that the most important issue has already been identified before discussion has begun.

### **PFOA Step 3: Problem Statement**

A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people.

The task of the third step of PFOA is to articulate this shared assessment in a problem statement.

After the deliberative processes of the first two steps, the group has the raw material to write a problem statement about the unmet societal need. They have the rich list of responses to each question and have a general conceptual map of the relationships between the questions, or at least responses organized by causes, problem, effects (scale/priority), and changes. Additionally, they have some idea about how different group members think the various problems compare to one another in importance.

One way to write a problem statement is to break-up into groups of 3-5 people and draft multiple problem statements for consideration. Form the sub-groups with stakeholders who have different interests to encourage listening across different voices and integration of ideas in a smaller group. This first drafting should be done in a relatively short period of time (e.g., 20-30 minutes). This allows many members to be actively involved in working through the creation of a problem statement but reduces the time spent on considering each word. The groups should be cautioned that they are not coming up with the correct and only definition that will "win"

approval from the whole group; rather, they are producing creative drafting of the group agreement on a problem. The problem statement is a brief, clear description of the problem, causes, and effects that everyone can agree on.

Before presenting their problem statement to the group, each sub-group should write their draft on newsprint so the whole group can see the different drafts. Using a blank sheet of newsprint, the facilitator asks the group to identify common areas of agreement in the language stating the problem and to make proposals for the final draft. Discussion continues through all the components of the problem statement to create proposals for the final language. When there is a strong disagreement, the issue is usually best noted and set aside in order to keep the group moving forward. A sub-group can be charged with developing a final statement based on the rough draft, issues for negotiation, and group discussion. Later, the sub-group then presents the final problem statement to the whole group for minor revisions.

In finalizing a problem statement, a consensus is the optimal final agreement, but the group can vote. If drafting the statement is highly contentious, the group can use a voting technique called “the fist of five” to identify the level of support a statement has:

- 5 fingers = full support
- 1 finger = a bare minimum of support
- A fist = a blocking or non-support

The degrees of support can be reported with documentation about what the range of support is based on.

There are numerous approaches for conducting the writing of the problem statement. The key to all of them, though, is that writing a problem statement is not just creating a summary of what the PFOA group listed – a problem statement should be more precise and concise than a write up. Decision-makers are going to need to be able to look at the statement and make a determination about whether to proceed to the next phases of the PFOA, and they may have limited time and background to examine the full proceedings of the PFOA. Web resources on problem definition writing are available in Appendix F (See page 235).

### EXAMPLES FROM HYPOTHETICAL SCENARIO

Writing a problem statement is not a process that can be effectively replicated here, so we are not going to provide an actual problem statement for the scenario. Rather, we will elaborate some on how the PFOA group from our scenario might go about writing a problem statement and refer you back to the problem statements from the trial runs of PFOA as examples for what a final one might look like.

Let's assume that after ranking the issues in the scenario, participants discussed why they ranked issues the way they did. Looking back at the rankings, the group would now take what emerged as priorities to construct a problem statement. In this case, let's say mattonbug infestations emerged among the group as seeming to be the biggest problem because of resulting drains on the national economy and effects on food prices and food security. However, let's say the drought problem and its effect of 100% yield loss for some farms was deemed a problem that could not go unaddressed, perhaps it is just the second priority. In a case such as this, where two problems emerge as needing to be noted in the problem statement, the problem statement would just need to embed the multiple problems and their relationships to one another into the actual statement. Rather than focusing on just one problem, for example, the statement could note a primary problem and a secondary problem.

Assuming our hypothetical PFOA went through the problem statement writing process described above, or something similar, the group might produce a statement along the lines of what was produced in Kenya and Brazil during the trial runs (Nelson 2006).

Kenya:

*Current maize varieties are susceptible to stemborers and under high infestation suffer heavy damage reducing yields and lowering profitability.*

Brazil:

*During periods of high infestation, Lepidopteran pests cause yield reductions in cotton, increasing the number of insecticide applications and consequently increasing the cost of cotton production, possibly affecting the health of farmers and people who are involved with the crop, also causing environmental pollution in the soil and water systems. Reduced stability of yield makes planning more difficult and risky.*



Pierre Silvie

*In the Northeast for small-scale farmers, the boll weevil damages cotton during the rainy season (March-May). Lepidopteran pests are not a major problem.*

*In the Midwest and Meridian regions, Lepidopteran pests are a moderate to major problem.*

The problem formulation phase of the PFOA ends with a commonly agreed upon written problem statement and a discussion of the merits in continuing the process or not proceeding further.

#### STEP 4 – DECISION PHASE

At this point, a decision should be made by the appropriate regulatory authority:

- Should the PFOA process advance to develop the options assessment in relation to addressing this problem or not?

Reasons for not proceeding may be based on the limited scale of the problem, the unimportance to stakeholders, or the unclear need for change, among others.

#### PFOA Step 4: Recommendation to Move Forward

If through a deliberative process the stakeholders can identify a high priority problem and they receive legitimating authority from the appropriate regulatory group, they will proceed with the options assessment. This is an essential prelude for characterizing the context for a full risk assessment.

#### Relevant Questions

1. Does PFOA move forward to identify options and conduct an options assessment?

#### STEPS 5-8: OPTIONS ASSESSMENT PHASE

The Options Assessment phase in PFOA (See Box 6.6) promotes deliberation about technological solutions for the problem defined in the Problem Formulation phase. It is an organized process for:

- Identifying options that could address the problem in the future (Step 5), which includes the GMO under consideration;
- Defining the options' characteristics for problem solving (Step 6);
- Understanding the systems changes that will be

- necessary to enhance the benefits and reduce the risks of each option (Step 7);
- Defining the adverse effects that the participants identify within the production system and for external ecosystems, these can be thought of as potential problems created by using the technology.

**Box 6.6: Option Identification and Assessment Chart**

Option Identification and Assessment Chart				
Step 5	Step 6	Step 7	Step 8	
Options	Characteristics	Changes	Effects on the System	
	For problem solving	Required/ Anticipated	Internal	External
			(social, environmental, economic)	
Option A				
Option B				
Option C				
Etc.				

**STEP 5: OPTION IDENTIFICATION**

Option Identification requires brainstorming possible options for addressing the problem and then narrowing the list to a manageable set of options that the group would like to discuss during the PFOA (Step 5). These options should be considered future alternatives; that is to say, any option that could be implemented in place of what presently exists. This includes modifications of technologies in use at the present time, technologies that exist but are not widely used, and new technologies, such as the proposed GMO.

When brainstorming an options list, you want to be as specific as possible. By technology we mean any management system or product that will address the problem or parts of the problem and reduce the unmet needs within society. For example, in agriculture, many production systems use pesticides alone, integrated pest management (IPM), or organic management methods. All of these ‘technologies’ or ‘technological packages’ are used to reduce a pest problem. When a PFOA group is brainstorming possible options for comparison, it is best to focus on options that specifically address the particular problem. For example, the GMO being assessed may have a particular toxin that kills an insect pest, thereby reducing the negative effect of a pest population on crop yields. Other options that would be good

as a comparison should be defined specifically for the target pest. For example, listing organic production is too broad because the group will have problems answering questions in the options assessment. Instead, the group should articulate the particular techniques within the organic production of the crop that reduces the specific pest population and its affect on yields. A hypothetical example could be that five years without pesticides results in reduced pest outbreaks, and that combined with crop rotation and early planting by 1 week collectively minimize the negative effect the pest has on yields.

The key question to be answered during Step 5 in options assessment is the following:

#### **PFOA Step 5: Option Identification**

##### **Relavant Questions**

1. What are the options for solving the problem?

#### **DELPHI TECHNIQUE**

You can use a Delphi Technique to identify and select the options. This technique allows all the participants to provide option ideas but then the group works to narrow the number of options that will be considered in Steps 5-8. The narrowing happens based on mutually agreed upon criteria and in a transparent manner. A Delphi helps a group organize a many option ideas into a few agreed upon options to use in the PFOA assessment.

There are different ways you can conduct a Delphi. You could use it to 1) establish a list and select options in the first session of the meeting, or 2) identify and select options for comparison before the meeting, using email or postal exchanges. The first suggestion is the most basic approach, which is to ask participants to come prepared to make suggestions for options that the group should consider. This list can be augmented by options identified by scientists. The benefit of this approach is that everyone has ample opportunity to discuss the options and clarify ambiguities. The second suggestion is to prepare for the Option Assessment meeting by identifying the options beforehand using a Delphi method through email or postal exchanges. The benefits of this approach are that scientists, staff, and participants can prepare supporting materials for the meeting discussions, enriching the exchange of information and deliberation. The disadvantage is that there may be some confusion about the particular options because participants have not been able to talk. Some time will still be needed to review the options



Areca Treon

selected and ask clarifying questions when the participants meet. Web resources on the Delphi Technique are available in Appendix F (See page 236).

### EXAMPLES FROM HYPOTHETICAL SCENARIO

In the PFOA for our hypothetical scenario, for the purposes of demonstration, let's assume the group decided the primary problem needing to be addressed is mattonbug infestations in the Southern Grasslands because of the cascading effects at multiple levels of society.

Going forward in Step 5, the group could use some form of a Delphi Technique to help them reach agreement about what options to focus their attention on as possible pathways toward dealing with the mattonbug infestations. Brainstorming might produce a large list of possible options – perhaps too many to reasonably consider given the time and resources available for the PFOA. To help narrow down the list, at this point the group might have some interaction with the ERA scientists. The purpose being to help the group choose the best of similar options and decide upon a smaller number of options that seem most feasible and likely to be effective. This selected list would then become the focus of PFOA steps going forward. This consultation with scientists can be augmented by each PFOA member selecting the three options they believe are the most promising, tabulating the votes, and selecting the three options with the most votes from the participants.

There are many different options available for helping to deal with the mattonbug infestations, but let's assume that after consulting with the ERA scientists and voting, the PFOA group from our scenario decided to pursue the following:

- **GMO matton:** This option is to use a genetically modified strain of matton that produces a toxin within the plant that can control mattonbug.
- **Modified use of Pesticide X:** Pesticide X is a pesticide currently being used to control mattonbug, but under existing practices it is having reduced efficacy because of increasing mattonbug resistance. This option involves implementing different strategies of application that are less likely to increase pesticide resistance amongst mattonbug.
- **Combination of organic practices:** This option involves using a combination of crop rotation,

companion planting of another crop with matton, and insect traps to capture adults.

### STEP 6: ASSESSMENT IN RELATION TO THE TECHNOLOGY AND THE PROBLEM

Step 6 is a discussion about the attributes and characteristics of each option. It encourages exchanges between PFOA participants and scientists as well as among the participants themselves. At a minimum, it helps the PFOA participants understand what the technologies are and how they work. During this step, the group reviews the basic attributes/ characteristics of each technology option. For example, for a GMO, this includes the gene being used, how it is constructed, and how it affects the target pest. Or, for crop rotation to control a pest, this includes the recommendations for rotation cycles, types of crops for a good rotation that would reduce the target pest, and the ecological reasons that populations decline. This definition and clarification of what a technology is and how it works helps participants begin to understand and evaluate the similarities and differences between options. It also allows the group to talk about different characteristics of the technology and its use; for example, economic issues such as cost, toxicology issues such as efficacy, ecological issues such as the ability to travel through water systems, or ethical issues about the manipulation of food sources.

Understanding the characteristics of the options lays the foundation for later discussions by helping the group clarify what we know about the technology and what we don't know. It brings all the members to a similar, basic understanding that can reduce uncertainty due to misinformation or misunderstandings. It also prepares the participants with the best available science and clarifies where our knowledge about these characteristics comes from, whether it is field trials, extrapolations from work with other species, observations from farming over the years, or educated approximations.

The list of characteristics considered is flexible. The questions below suggest important characteristics but others can be added depending on the specifics of your case.

The key questions to be answered during Step 6 in options assessment are the following:

**PFOA Step 6: Assessment in Relation to the Technology and the Problem****Relevant Questions**

## Technology Attributes:

1. What are the characteristics of the technologies involved?
2. What is the efficacy of the “technology” on the target?
3. What is the cost of the technology within the production system?

## Sociopolitical Attributes:

4. What social and economic organization will be required?
  - What is the range of production systems and what is the geographic region the option is likely to be used in or have an effect on?
5. What laws, regulations, policies or programs currently exist that would regulate the option?

## Production Attributes:

6. What current advantages do we have for implementing this option?
7. What barriers to use exist? i.e., is the distribution system in place; can the potential solution be integrated into present production; can the farmers afford the potential solution?
8. How does this option fit with current practices? (expanded in Step 7)
  - How might the use of the option change production practices, such as use of other species, tillage systems, pesticide use (including impacts on non-target pests)? What useful practices are reinforced by the potential?

## Summary of how the option might solve the problem:

9. What is the current state of information and science related to this option?
  - What sources of baseline data are available on the agricultural system? What information is needed to show that the changes are likely to occur?
10. How confident are we that this option could successfully solve the defined problem?
  - How will anticipated changes in practices affect the needs identified in Steps 1 and 2?

There are several ways the PFOA group can prepare for and move through the deliberation in Step 6. An efficient way to prepare is for staff members and scientists to develop responses to these questions for each option. This can be done if the PFOA group identifies the comparison options before they meet to discuss Step 6-8. If a short report cannot be prepared in advance, staff members and scientists could be present to answer questions the PFOA group has about the options. If the information is not available, this should be clearly identified.

A suggestion for considering the information in this step is to discuss all the responses for one option and then proceed to the next option. Once all the options have been discussed, the group can begin to evaluate differences and similarities between the options, as well as missing information or areas

of conflicting interpretation. Presenting the information in a table can help a group view a characteristic across options more easily. One caution for everyone is to be very patient during this discussion. The information may be presented in words or ways that is not familiar to all the participants. For example, scientists have to clearly and carefully explain what “efficacy” means when evaluating toxic effects of a technology. Or participants familiar with the legal requirements may have to remind the group about how laws interact to influence how a technology can be developed or used.

Overall, Step 6 builds a shared understanding about the options and how they address the problem. In addition, it identifies areas for research in risk assessment due to missing information, contradictory findings from previous work, or important concerns expressed during the discussion. There are many possibilities for customizing the options assessment process. The web resources available in Appendix F (See page 237) provide just a few possibilities for how to develop more elaborate and/or quantitative procedures for doing options assessment.

#### EXAMPLES FROM HYPOTHETICAL SCENARIO

The PFOA group from our hypothetical scenario have decided to pursue three options in their deliberations: GM-matton, modified use of Pesticide X, and a combination of organic practices. During Step 6, the group would answer all of the questions in relation to the three options. Then to compare them, they might chart the information (See Box 6.7). For example, for the three options in response to questions 2, 3, and 5 above:

**Box 6.7 Options Assessment from Hypothetical Scenario**

OPTIONS ASSESSMENT			
Technology	Efficacy	Cost	Policy and Programs
GM-matton	Assumption is that the efficacy for the GM-matton is 100%, but we do not know. Waiting for lab and field trials to be completed by ERA scientists.	Some cost, X, for seed per hectare	Biosafety laws and international treaties related to GMOs
Pesticide X	Data over time from Department of Agriculture shows that efficacy drops off over time. In the early years of use, efficacy was at 80-90% but has dropped to 40-60% because of increasing resistance.	Some cost, Y, per liter per hectare	Health and labor policy regulating application.
Combination of organic practices	80% efficacy has been demonstrated in field trials at international research centers.	Some cost, Z, per hectare for pheromone traps	Crop rotation = no policy, but strong recommendations are attached to credit in order to prevent soil erosion. Organic certification required for marketing, labeling.

**STEP 7: CHANGES REQUIRED AND ANTICIPATED**

Step 7 allows the PFOA group to explore how a technology option would or should change the way things are done at multiple levels of the social and natural system. It is this step that helps the participants think about the future, answering the hypothetical questions, “What would change if we used this technology?” and plan for “What should change?” In this discussion, there is no right answer because the group is reflecting about the future, and interpretations of this future can vary among participants as well as be based on tremendous uncertainty with theoretical arguments about what might happen. Participants deliberate in order to achieve a common understanding of possible changes and where there is consensus or divergent interpretations of what might happen.

The objectives for Step 7 are to anticipate changes that will be necessary to make the technology more effective in meeting societal needs, as well as anticipate changes that will be necessary to reduce risks inherent in using the technology, thereby contributing to sound risk management strategies. This step goes beyond the classical risk assessment by broadening the discussion to societal considerations. An



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important technique used in this step is to focus on changes at multiple levels. For example, in the case of a crop technology, start with changes in farm management and then broaden the discussion to other levels such as the community, regional government programs and production systems, and national considerations, such as distribution systems. Finally, through these discussions, participants are able to compare and evaluate the changes required by different options.

The key questions to be answered during Step 7 in evaluating system changes required and anticipated are the following:

### **PFOA Step 7: Changes Required and Anticipated**

#### **Relavant Questions**

1. What changes in management practices might contribute to the solution?
2. What changes in the local community might contribute to the solution?
3. What changes in government support might contribute to the solution?
4. What changes in the structure of production might contribute to the solution?
5. What other changes would likely be needed to facilitate widespread use of this option?
6. How do the options compare in the extent of the changes required or anticipated?

For example, at the farm level, if the technology is a GMO maize variety targeting a specific pest species, the farmer may have to adjust their pesticide management strategies for other pests. Or, if the option is an intercropping method, the farmer may have to change their planting calendar. Continuing with the same examples, at the community level, for the GMO cotton variety, neighboring farmers who are not using the new technology may have to use strategies to prevent contamination from gene flow. Or, with the intercropping technology, there may be increased demands for labor. For the processing and distribution levels, a GMO cotton variety may require labeling in processing and product distribution systems. Or, for the intercropping technology, new harvesting machines may need to be developed to accommodate a patchwork of planting in space or time. The web resources and tools relating to scenario development are available in the options assessment section in Appendix F (See page 237).

### **EXAMPLES FROM HYPOTHETICAL SCENARIO**

To give a sense of how to think about what sorts of changes might be needed by an option, let's consider how the above questions might be answered in relation to GM-matton (note

that question #6 is omitted since we are only examining one option).

1. What changes in management practices might contribute to the solution?
  - If GM-matton is adopted, then costs for pesticide application may decrease – this includes reduced costs for labor and reduced costs for pesticides. However, a farm might need to develop new mechanisms to ensure that seeds from their crop do not travel into neighboring areas, resulting in gene flow into other, non-modified matton populations. Also, secondary pests may emerge requiring new controls.
2. What changes in the local community might contribute to the solution?
  - There might have to be notification of where GM-matton is being planted so that neighbors can make wise management decisions about their own crops if they want to reduce threats of gene flow. Local businesses invested in pest management may have to convert from supplying pesticide to supplying seed that is genetically modified.
3. What changes in government support might contribute to the solution?
  - Government may need to provide additional assistance with ensuring seed quality and helping with seed distribution.
4. What changes in the structure of production might contribute to the solution?
  - Distribution systems for matton products may need to be modified to ensure that it is known when a matton end-product does or does not contain GM-matton. This might be required by other countries, in the case of export, as well as domestically.
5. What other changes would likely be needed to facilitate widespread use of this option?
  - There may need to be labeling laws so that people have knowledge of when they are using a product made from GM-matton. There may need to be laws about where GM-matton can and cannot be planted in order to protect other values, such as plant biodiversity. There may need to be public education campaigns so that people have correct information about GMOs.

### STEP 8: ADVERSE EFFECTS

Step 8 continues deliberation about the future but narrows the discussion to identifying the important societal values participants want to protect and anticipating potential consequences of using the technology, specifically the adverse effects that may threaten these important societal values. The group identifies new problems that could develop from using the technology and how important societal values might be affected. In the discussion, participants also identify benefits gained by using the technology that would reduce existing problems.



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The deliberation in this step covers the broadest range of societal values, including environmental, economic, social, cultural, legal, and ethical values that could be adversely affected by using a technology. These considerations will be country specific and something that may change gradually over time with changing societal values. Therefore, a society's understanding of risk can change. For example, a multi-stakeholder group in Europe may identify consumer choice, co-existence of non-GM and GM crops, international trade issues, ethics of genetic manipulation, sharing of benefit vs risk, irreversibility of technological change, etc. Environmental risk assessment is designed to provide an improved understanding of environmental factors and possible adverse effects that define risk in relation to important societal values. For example, the GMO ERA project focuses on the selection of assessment endpoints that require balancing and reconciling of criteria. Types of adverse effects arising from environmental change include nontarget and biodiversity effects, adverse consequences of gene flow, and adverse effects from resistance evolution (GMO ERA Project 2007). By guiding the deliberation as a comparison of options using agreed upon criteria, the group creates an improved understanding of possible societal choices.

The key questions to be answered during Step 8 focused on adverse effects are the following:

#### PFOA Step 8: Adverse effects

##### Relevant Questions

1. How might the potential solution affect production systems and their infrastructures?
2. How might the potential solution reinforce poor practices or disrupt useful practices?
3. What are the potential adverse effects/harms of these changes internally and externally to the production system?

4. How will its use affect (both positively and negatively):
  - a. Other nearby production systems (can its use be restricted to a particular system or geographic region)?
  - b. Other nearby ecosystems?
  - c. The conservation of genetic variability of species and other related biodiversity?
  - d. Important social, cultural, economic, or ethical values?
5. What is the scale and importance of the effects for a, b, and c?
6. Are any of these effects difficult to reverse once they occur?
7. How do the options compare in their potential of adverse and irreversible effects?

The group can brainstorm a list of values that they are concerned would be affected by using the option and discuss how the option would adversely affect these important values. Working across categories of values helps the group cover a range of ideas and in the end assess the major areas where important values might be adversely affected. Group members can discuss which categories have many values and which ones have very few. Members can each identify the top three values they think are most likely to be at risk and these can be compiled in order to get a sense of the group’s opinion about the likelihood of an adverse effect. Or the members can each identify the three most important values for society, or for themselves, to get a sense of which values are most important for the group and the adverse effects that could threaten those values. The group can identify which effects might be irreversible, implying that any loss would be a permanent condition. In general, stakeholder groups are best at identifying adverse effects and not as good at estimating the probability of something happening. Comparing all of this information between options allows the group to analyze societal choices to inform risk assessment scientists, policy decision makers, and risk management strategists.

Options	Values at Risk					
	Environmental	Economic	Social	Cultural	Ethical	Other
Option A						
Option B						

**EXAMPLES FROM HYPOTHETICAL SCENARIO**

To give a sense of what to think about when examining adverse effects in different value categories, here are a few hypothetical adverse effects relating to each of the three options being examined in our hypothetical scenario:

#### Adverse Effects of GM-matton:

- **Environmental:** Plants at neighboring farms and in the wild could become contaminated by gene flow. This could result in wild plants gaining the gene modification and related toxins. Also, there could be cascading effects on biodiversity within the field if the GM-matton is so effective in controlling mattonbug that it starts to reduce food availability for other species.
- **Economic:** Neighboring farms could suffer economic loss if they have trouble selling future crops because they have become contaminated with GMO strains of matton. Possible contamination in product distribution systems.
- **Cultural:** the GM-matton might have a negative effect on a wild plant or animal that is important in a cultural system such as local foods, religious ceremonies, etc.
- **Ethical:** Some people may be ethically opposed to genetic modification.

#### Adverse Effects of Pesticide X:

- **Environmental:** Pesticide runoff can contaminate nearby ecosystems and water sources. Non-target pests might be affected and have cascading effects throughout the food-chain.
- **Economic:** Mis-application of pesticide could destroy nearby crops or increase the health system costs for the nation.
- **Social:** Potential negative human health consequences across society because of pesticide exposure.

#### Adverse Effects of a Combination of Organic Practices

- **Environmental:** Non-target insects could be attracted to traps, which could result in cascading effects and a loss in biodiversity. Crop rotation could result in increased soil erosion if done improperly.
- **Economic:** May result in increased costs to farmers for labor required to conduct crop rotation or intercropping.
- **Social:** If the increased labor is poorly paid it could threaten human rights.

## STEP 9: RECOMMENDATION TO DECISION MAKERS

Step 9 is the recommendation from the PFOA participants to the decision-makers supported with documentation of the deliberation during Steps 1-8. These recommendations should be delivered in the form of a written final report (see Step 4 for suggestions about how to produce a group report.). The final report should begin with an executive summary of the PFOA recommendations on the technology options. This summary should be directed toward the decisions the decision-makers will be making about the proposed GMO, as well as provide insights on environmental risk and risk management.

The bulk of the final report documents the PFOA deliberation through the Steps and serves as supporting material for the executive summary.

Achieving the final recommendation and report will require participants to come to agreements and make some decisions. The recommendation summary should clearly reflect how the recommendations were made – by consensus or by a form of majority vote – and whether there is common agreement (see Chapter 5). The weakest possibility for producing the recommendation summary from a PFOA is to simply use the process to produce a summary of what judgments are shared and what judgments are not shared among stakeholders. Producing such a listing as a product from the PFOA would be informative for decision-makers as a summary of what stakeholders think. However, it would provide less guidance on how to resolve those differences or prioritize the importance of different positions than agreed upon recommendations for decisions or actions.

If the agency managing the PFOA has provided ongoing reporting to government parties outside of the PFOA about the outcomes of the process at various stages, then the contents of the final report should not be a surprise. Ongoing reports from the managing agency will generally serve to keep others abreast of the proceedings, but it will also help decision-makers anticipate possible results, output, and outcomes that might emerge from the PFOA. In turn, having some foresight into potential conclusions that the PFOA might reach will help decision-makers in their preparation and planning for the GMO issue at a policy level. The final report can be written by a sub-committee or staff members based on meeting records and previous documentation. However, PFOA participants should be given sufficient time to

review a draft report and make suggestions for modifications before it is given to decision-makers. Acknowledgement of a participant's agreement with the report is often provided with a signature or allowing their name to be included as a co-author of the report. Once this agreement is achieved, the report can be sent to decision-makers and shared with the public.

In the end, the PFOA report informs societal decision making about GMOs. The legitimacy of the delegated government decision makers rests on their ability to reflect the interests of diverse groups within society. Under their Biosafety Frameworks, each nation has identified the particular decision making body for GMO biosafety (UNEP-GEF 2003a/b, Nelson *et al.* 2004, Capalbo *et al.* 2006, Nelson *et al.* 2007, Nelson and Banker 2007). Environmental risk assessment completed with a PFOA encourages the decision makers to continue good governance through transparency, accountability, and participation.



# FINAL THOUGHTS

We end with a few final thoughts about PFOA in the context of changing environmental risk assessment and technology development. PFOA will have to be adaptable as nations develop their biosafety frameworks and environmental risk assessment regulations. The PFOA goals may stay the same, to enhance science for risk assessment and strengthen decision making based on good governance, but how a nation designs the PFOA process may change.

- A. Remain flexible and plan for change**
- B. Transparency helps modify the politics and power imbalance**
- C. Societal risk and decisions will always be with us**

### **Remain Flexible and Plan for Change**

As a nation prepares strategic plans for research and development, the PFOA can assist with policy formation and research agenda setting to target critical societal problems (Steps 1-3). These problems will change overtime, influenced by a range of factors such as global market positioning, climate change, and societal values, to name a few. PFOA can assist in an understanding of emerging problems and how a nation can proceed with technological development to address them.

In addition, PFOA is designed to be flexible enough to respond to a changing national context. If a nation has very few resources, options assessment (Steps 5-8) could be done with only one option, the GMO, as a start. Deliberation over one option is a beginning because the PFOA group is still integrating diverse perspectives and opinions about an uncertain future and its risks. Considering only one option, you lose a comparative understanding of the GMO option in relations to other technology options as well as the ability to differentiate which option would be best. A comparison of options can be added as the technology development programs and risk assessment regulations grow and resources become available. A single option PFOA is never an endpoint but it could be a beginning with a plan to expand to multiple options assessment. A final example of flexibility would be the use of PFOA to develop a risk management program if a GMO is already being used in a country. The PFOA questions are all phrased as if the GMO is being considered for introduction but most of these questions can be modified to evaluate the GMO that is currently in use, and develop recommendations to inform risk management and evaluation of the technology's influence on the problem. In summary, the PFOA can be adapted to respond to the changing national context.

### **Transparency helps modify the politics and power imbalance**

Culture and politics will influence the national approach to deliberation within PFOA as well as societal concerns about risk and new technologies. Some cultures support open public confrontation between interest groups as the accepted approach to governance. Other cultures are more comfortable with delegation of authority to experts or leaders who are expected to have the best interests

of the people in mind when they make a decision. These approaches will influence how participants discuss issues during deliberation, what topics are acceptable for public consideration, and what topics are left to leaders. In addition, societal concerns vary based on values at risk and accepted interpretations of predicting what may happen in an uncertain future. Some societies may be considered “risk-taking,” believing any future problem can be fixed and other societies may be “risk-adverse,” proceeding carefully when the implications of a decision are unclear.

In any political situation, power will influence politics, specifically the use of the PFOA within risk assessment of GMOs. Critics argue that it is naive to host multi-stakeholder deliberations as open processes because powerful interests will ignore the multi-stakeholder recommendations or control their influence by controlling the decision makers. Others caution that powerful interest groups can capture the PFOA process by co-opting the representatives or restricting representative selection. These are serious concerns if a nation wishes to maintain the legitimacy of its science and PFOA for improved risk assessment, but politics and power are always part of national decision making. One way to maintain legitimacy is to strengthen the transparency of the process and how decisions are made. If citizens can watch what is being done they can be aware of how decisions are influenced and express their concern when the broader societal good is not protected.

### **Societal risk and decisions will always be with us**

Finally, PFOA is a flexible method, which can be a transparent assessment of risk and choices, and could be used beyond consideration of GMOs. Today’s discussion is focused on genetically modified organisms but tomorrow’s decisions will focus on nanotechnology and other unknown choices. Risk will always be with us but society has the ability to evaluate some risks, deliberate over uncertainties and values, and make decisions that address the greatest needs and protect the common good.



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# APPENDIX

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## APPENDIX A:

## GLOSSARY OF KEY TERMS

<b>Accountability</b>	The State's responsibilities to its citizens and the degree to which governance processes are open to external oversight and challenge by the public. There is accountability in governance when people are free to examine and ask questions about governance actions and their consequences, and the individuals and institutions behind any given action are bound to such scrutiny.
<b>Adverse effects</b>	An undesired effect.
<b>Benefit</b>	A desired change.
<b>Biosafety</b>	As defined by the Convention on Biological Diversity: "Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Cartagena Protocol on Biosafety, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage."
<b>Cartagena Protocol on Biosafety</b>	An international agreement designed to help protect societies and the environment against potential risks and adverse effects that GMOs may pose. It was adopted by the Conference of the Parties to the Convention on Biological Diversity in January 2000, and as of October 2007 had been ratified by over 143 countries worldwide. The agreement aims to provide safeguards against the uncertainties associated with GMOs, and in doing so, it conforms to the precautionary approach guiding Principle 15 of the Rio Declaration on Environment and Development.
<b>Collaborative approaches</b>	In governance, having stakeholders and State agency representatives work together to reach common agreements and inform decision-making.

<b>Consensus</b>	Agreement and decision-making standard indicating that a group as a whole has reached shared agreement. It suggests a group has actually identified what is common among the diverse views of its members and have together integrated the commonalities into a shared conclusion. Consensus is the strongest form of agreement because it implies the broadest support, but it is also the hardest to achieve.
<b>Database</b>	Collection of information organized in a systematic way on a computer to facilitate access and retrieval; essentially a virtual filing system.
<b>Deliberation</b>	Deliberation is a means by which a group of participants representing diverse interests in a governance process can work together to carefully consider all relevant sides of an issue in order to reach or move closer to a shared conclusion. It is characterized by an open sharing of ideas, listening to others, acknowledgement of diverse views, and a spirit of collaboration.
<b>Deliberative process</b>	A collaborative group process based on using deliberation to move participants with divergent positions closer to agreement. Deliberative processes are structured to allow participants to openly exchange information, clarify their understandings, create new possibilities, and compare options.
<b>Environmental risk assessment (ERA)</b>	The identification and the qualitative and quantitative evaluation of risk posed to humans and/or the environment by the actual or potential presence and/or use of specific stressors, excluding food safety issues which is covered in another assessment (U.S. E.P.A. 2007).
<b>Equity, equitable</b>	The quality of being fair and just. In governance, an equitable decision-making process will seek out and take into account information from the broadest spectrum of society; all stakeholders will have the possibility for voice and influence in the process and decision.
<b>ERA</b>	See “environmental risk assessment”.
<b>ERA Partners</b>	ERA partners are those who participate in the PFOA by way of informing it and/or working in a problem solving partnership. Generally, ERA partners will be scientists involved in the ERA but could also be agency personnel, such as lawyers or regulators, whose presence at some point in the PFOA could help the process. ERA partners may interact with the deliberation occurring between stakeholder representatives, but they do not actually engage in the deliberation.

<b>Facilitator</b>	In a multi-stakeholder process such as PFOA, the person – or people (there can be more than one facilitator) – most directly responsible for guiding the process effectively and efficiently toward its goals. The tasks of a facilitator are concentrated in conducting stakeholder meetings, but facilitators can also play important roles in preparation and planning.
<b>Future alternative</b>	Any available option that could be implemented in place of what presently exists. This can include options that currently exist, options that will exist in the future, and options that may exist in the future whether they have been thought of yet or not.
<b>Future technology options</b>	Future alternative involving technology. See also: “future alternative”
<b>Genetically modified organism (GMO)</b>	A genetically modified organism (GMO), also known as a living modified organism (LMO), is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
<b>GMO ERA Project</b>	Pioneering initiative driven by public sector scientists, most of whom have strong expertise in environmental science, as well as biotechnology and socioeconomics. The project is identifying and developing scientific methodologies and tools that can be used for environmental risk assessment and management of transgenic plants, in accordance with the Cartagena Protocol on Biosafety and other international agreements.
<b>GMO, GMOs</b>	See “genetically modified organism”.
<b>Governance</b>	The activities carried out by individuals and institutions, public and private, to reach their shared goals and manage their common affairs (Bingham, Nabatchi, & O’Leary, 2005; Hemmati, 2002). Often used today to describe different practices intended to promote a working two-way relationship between government and citizens, namely through participation, transparency, and accountability.
<b>Harm</b>	Adverse effect.
<b>Inclusiveness</b>	The degree to which the full range of stakeholder voices, with their different backgrounds and concerns, are included in decision-making processes. Decisions that are inclusive tend to be better informed, more durable, and able to generate greater commitment.

<b>Interest</b>	Something beyond necessity or minimal requirements relating well being; also a right to, stake in, or share of something. Human interests are stakeholder specific; for example, enhanced economic opportunity, positive social interactions, and cultural richness. Interests are secondary to needs.
<b>Legitimacy</b>	Having support, acceptance, or sanction as being valid by relevant parties, such as governing bodies or the public.
<b>Majority votes</b>	Agreement and decision-making standard indicating that some greatest portion of a group has reached shared agreement; used when consensus cannot be reached. Majority votes range in the strength and effectiveness of the agreement they represent. On the strong end are supermajority votes, where upwards of 2/3 of a group support an agreement (for a PFOA we recommend 75%). On the weaker end are simple majority – support from some fraction of the whole greater than half – and relative majority – support from the greatest portion of the whole in comparison to any other portion.
<b>Multi-criteria analysis</b>	Formal methods that people can use to help work through issues that are complex because of the many different factors and competing interests involved in them – many of which cannot be reduced to a common measurement for comparison. Multi-criteria analysis generally involves creating a conceptual model based on stated assumptions about the way different factors work and relate to one another; this allows incompatible factors and interests to be weighted based on assumptions, thereby providing some foundation for comparison.
<b>Multi-stakeholder, multi-stakeholder participation</b>	Including multiple stakeholders in a process to represent their interests.
<b>Need</b>	Something that is necessary; a minimal requirement. Basic human needs are most commonly identified as food, shelter, and safety.
<b>Observer</b>	Parties with an interest in the PFOA and its outcome – such as the media, agency personnel, and government decision-makers – that can be present during the process but who are not involved in the deliberations.
<b>Option</b>	Potential alternatives for addressing a problem. See also: “future alternative”

<b>Participation, participatory</b>	The foundation for a two-way relationship between citizens and the State. Participation means citizens have ways to provide the State with input about their interests and influence decision-making, and the State can continually learn about and respond to the various interests of its citizens. Participation can help ensure the rights of citizens are protected and enable the State to govern more effectively.
<b>PFOA</b>	See “Problem Formulation and Options Assessment”.
<b>Precautionary approach</b>	According to Principle 15 of the Rio Declaration on Environment and Development (1992), “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”
<b>Primary stakeholder</b>	Groups or sectors of society that are absolutely essential to the PFOA deliberation in order for the process to function effectively and have legitimacy.
<b>Principle 15 of the Rio Declaration on Environment and Development (1992)</b>	“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”
<b>Problem</b>	Unmet need that requires change.
<b>Problem formulation</b>	Identifying the societal problem that the technology will address, Discussion focuses on whose problem is being addressed, whose problem should be addressed, and what needs of the people identified are not being met by the present situation. The group assesses whether a problem truly exists based on extent, severity, and relative importance compared to other problems.
<b>Problem Formulation and Options Assessment (PFOA)</b>	Methodology for conducting deliberative formulations of a problem and comparative assessments of future alternatives for addressing the problem relative to the biosafety evaluation of GMOs. A PFOA process helps stakeholders collaboratively analyze and advise on the identification of possible harms and the enhancement of potential benefits within the specific contexts for which a GMO is being considered. To this end, a PFOA relies upon being transparent, inclusive of all appropriate stakeholders, and rationally informed by the best available science.

<b>Risk</b>	Likelihood that an adverse effect will occur.
<b>Risk assessment</b>	Identification and qualitative and quantitative evaluation of risk posed to humans and/or the environment (U.S. Environmental Protection Agency 2007).
<b>Science-based</b>	Based on thorough consideration and accurate interpretation of the most relevant scientific information available (Mills, Quigley & Everest, 2001).
<b>Secondary stakeholder</b>	Groups or sectors whose presence could enhance a PFOA deliberation but who are not central to the process. A secondary stakeholder might be able to make a unique contribution to a PFOA, but their absence would not substantially reduce the legitimacy or results of the process. Oftentimes, the interests of secondary stakeholders could be represented in the PFOA through some other related or larger sector.
<b>Societal need</b>	A need defined in terms of its relevance to a society as a whole (e.g., food security). See also: “need”
<b>Stakeholder</b>	In the context of PFOA, any sector of society that stands to be affected positively or negatively by a decision; i.e., those who have an interest in the outcome of a decision.
<b>Stakeholder representative</b>	Individuals that participate directly in the core deliberation of the PFOA on behalf of the interests of a particular stakeholder sector or grouping of sectors with shared interests. Stakeholder sectors must have their interests represented in a PFOA by a representative because it is not practical or effective to directly involve every individual member in the process.
<b>Stakeholder sector</b>	Individuals and groups that share some common interest in relation to a specific issue or decision.
<b>State</b>	The ruling body of government in a country.
<b>Stressor</b>	An agent, condition, or other stimulus that causes stress to an organism.
<b>Summary</b>	Overview of the information contained in a source; provides users with a scope of a source without having to review the entire source.

<b>Supermajority</b>	Agreement and decision-making standard indicating that some portion of a group greater than two-thirds has reached shared agreement; supermajority is a strong version of a majority vote. In a PFOA we recommend a supermajority to mean support from at least 75% or more of all participants, as is deemed appropriate.
<b>Support personnel</b>	People directly responsible for managing the PFOA, including the facilitator, management staff, clerical staff, etc.
<b>Synthesis</b>	Document establishing an overview of the current state of understanding about a topic, theme, or issue; syntheses incorporate key points and findings from a collection of relevant sources to provide users with access to a baseline understanding without having to review every source individually.
<b>Transboundary movement</b>	Movement across international political boundaries.
<b>Transgenic organism</b>	See “genetically modified organism”.
<b>Trait</b>	A genetically determined characteristic or condition; A physical characteristic brought about by the expression of a gene or many genes.
<b>Transparency</b>	Open communication of information between all parties; in governance, transparency implies that decision-making processes are open to public review and that information is being freely shared between government and citizen. This can occur through a number of different means ranging from observation and reporting procedures to participatory practices that put stakeholders in the same room together with government officials.
<b>Uncertainty</b>	Uncertainty represents a lack of knowledge about factors affecting risk and can lead to inaccurate or biased estimates of risk. (U.S. Environmental Protection Agency 2007).



## APPENDIX B:

# SCHOLARS AND ORGANIZATIONS ASSOCIATED WITH PFOA AND THE GMO ERA PROJECT

The core group involved with GMO ERA Project is made up of over 350 public sector scientists representing over 200 organizations and institutions in over 60 countries worldwide.

Of these, more than 50 members have participated in the development of the Problem Formulation and Options Assessment Methodology.

The work of the GMO ERA Project is guided by the following steering committee:

#### Project Co-coordinators

Dr. David Andow, University of Minnesota, USA

Dr. Angelika Hilbeck, Swiss Federal Institute of Technology ETHZ, Switzerland

#### Steering Committee

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## APPENDIX C:

# ASSOCIATED WORKS OF THE GMO ERA PROJECT

## **Environmental Risk Assessment of Genetically Modified Organisms**

Series editors A.R. Kapusinski and P.J. Schei, GEF Scientific and Technical Advisory Panel

### Published:

Environmental Risk Assessment of Genetically Modified Organisms Volume 1: A Case Study of Bt Maize in Kenya

Edited by A. Hilbeck and D.A. Andow

Reference: Hilbeck, A. and Andow, D.A. (eds) (2004) Environmental Risk Assessment of Genetically Modified Organisms Volume 1: A Case Study of Bt Maize in Kenya. Wallingford, UK: CABI Publishing. ISBN 0-85199-861-5

### Environmental Risk Assessment of Genetically Modified Organisms Volume 2:

Methodologies for Assessing Bt Cotton in Brazil

Edited by A. Hilbeck, D.A. Andow and E. M. Fontes

Reference: Hilbeck, A., Andow, D.A. and Fontes, E.M.G. (eds) (2006) Environmental Risk Assessment of Genetically Modified Organisms Volume 2: Methodologies for Assessing Bt Cotton in Brazil. Wallingford, UK: CABI Publishing. ISBN-10: 1-84593-000-2, ISBN-13: 978-1-84593-000-4

### Forthcoming:

Environmental Risk Assessment of Genetically Modified Organisms Volume 4: Challenges and Opportunities with Bt Cotton in Vietnam

Edited by D.A. Andow, Nguyen Van Tuat, and A. Hilbeck

Reference: Andow, D.A., Nguyen Van Tuat, and Hilbeck, A. (eds) (TBD) Environmental Risk Assessment of Genetically Modified Organisms Volume 4: Challenges and Opportunities with Bt Cotton in Vietnam. Wallingford, UK: CABI Publishing. (forthcoming).

### How to Order:

The Environmental Risk Assessment of Genetically Modified Organisms series is published by CABI Publishing, Wallingford, UK. Copies can be ordered online:

Kenya book link: [http://www.cabi.org/bk\\_BookDisplay.asp?PID=1766](http://www.cabi.org/bk_BookDisplay.asp?PID=1766)

Brazil book link: [http://www.cabi.org/bk\\_BookDisplay.asp?PID=1892](http://www.cabi.org/bk_BookDisplay.asp?PID=1892)

Or go to <http://www.cabi.org>, and go to “Bookshop” > “Plant Sciences” > “Biotechnology, Plant Breeding and Genetic Resources”.

## Other GMO ERA Project Products

### Project Newsletters

Download previous mailing list newsletters here: <http://www.gmoera.umn.edu/public/publications/newsletters.html>

Register with the project to receive newsletters: <http://www.gmoera.umn.edu/public/registration/index.html>

### Teaching Tools

Teaching tools for a course on the project methodologies are currently being developed and will be made available in the future.

For a summary of course content, visit: <http://www.gmoera.umn.edu/public/science/index.html>

## Additional book in the CABI series

Environmental Risk Assessment of Genetically Modified Organisms Volume 3:  
Methodologies for Transgenic Fish

Edited by A.R. Kapuscinski, K.R. Hayes, S. Li, and G. Dana

Kapuscinski, A.R., K.R. Hayes, S. Li and G. Dana (eds). (E. M. Hallerman and P.J. Schei, series editors). 2007. Environmental Risk Assessment of Genetically Modified Organisms Volume 3: Methodologies for Transgenic Fish. Wallingford, UK: CABI Publishing. 310 pp. ISBN 978 1 84593 296 1

## APPENDIX D:

# PFOA TRIAL RUNS

Several trial runs of the PFOA methodology have been conducted. These trial runs played a critical role in evaluating and refining the PFOA, as well as developing this handbook. This appendix provides some illustration of the PFOA methodology in practice through some discussion of what occurred during these trial runs. This appendix is divided into four sections:

- Testing the PFOA Methodology in Three Country-Specific Cases
- Trial Run for the PFOA Model in the Kenyan Case Study for Bt maize
- Trial Run for the PFOA Model in the Brazilian Case Study for Bt cotton
- Trial Run for the PFOA Model in the Vietnam Case Study for Bt cotton



Kristen Nelson

### TESTING THE PFOA METHODOLOGY IN THREE COUNTRY-SPECIFIC CASES

During the initial development, the PFOA Model underwent trial runs during workshops in Kenya, using the case of Bt maize in 2003; Brazil, using the case of Bt cotton in 2004; and Vietnam, using the case of Bt cotton in 2005. During these trial runs, participants evaluated PFOA by discussing its purpose within an ERA, testing questions from each step in the PFOA to experience the type of discussion that might result from a multi-stakeholder exchange (Box D.1), and deliberating over how a PFOA would best fit in each country's regulatory system. Additionally, representatives from multiple countries—Chile, Cuba, Thailand, and China—met in a workshop to consider a PFOA in an ERA for transgenic fish in 2006. The participants discussed possible answers for PFOA questions, but they did not conduct a complete trial run.

Overall, the case studies provided applied insights, allowing everyone to test the questions, modify steps in the PFOA that did not make sense, and think about how a PFOA would work within their system. As participants moved through each step they were constantly working with both process and content, answering questions but also thinking about the process through the eyes of multiple stakeholders. The following section provides examples of how the PFOA was evaluated in three of the case studies—Kenya, Brazil, and Vietnam. Understand that these were not full PFOAs for the respective crops but rather evaluations of the concepts and protocols for the PFOA Model using applied cases. These workshops also built on each other (See Chapter 4): ideas from the first workshop in Kenya resulted in modifications of the PFOA for the Brazil workshop, the Brazil workshop resulted in modifications for Vietnam, and Vietnam resulted in modifications for the more recent transgenic fish workshop. Improvements continue through the writing of this handbook and on to today as regulators, scientists, and stakeholder representatives work with the PFOA in their own country's contexts.

At the time of this writing, a complete treatment of each trial run has been or will be published in other publications of the GMO ERA Project. For the sake of brevity, rather than replicate the full treatments in this handbook, we have instead provided summaries of essential points from each of the treatments, along with reference information for locating them.

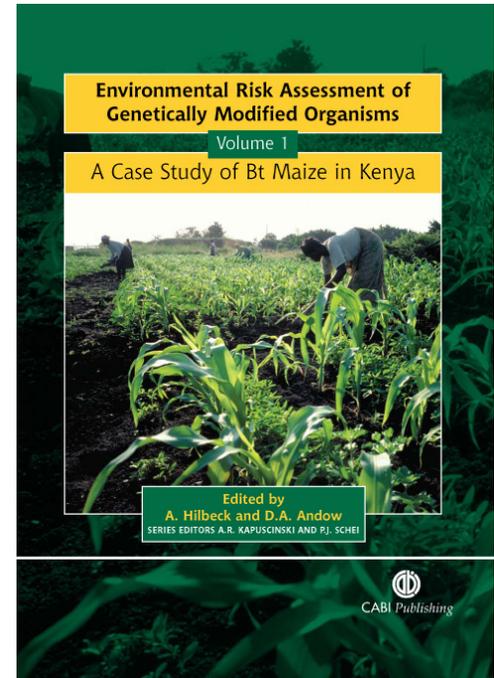
## TRIAL RUN FOR THE PFOA MODEL IN THE KENYAN CASE STUDY FOR BT MAIZE

Nelson, K.C., G. Kibata, M. Lutta, and J.O. Okuro, F. Muyekho, M. Odindo, A. Ely, and J. Waquil.. 2004. Chapter 3. Problem Formulation and Options Assessment (PFOA) for Genetically Modified Organisms: The Kenya Case Study. In Hilbeck, A. and Andow, D.A. (eds) (2004) *Environmental Risk Assessment of Genetically Modified Organisms Volume 1: A Case Study of Bt Maize in Kenya* (pp. 57-82), Wallingford, UK: CABI Publications.

In the Kenya workshop eight participants, representing Kenyan and international scientists, evaluated the PFOA Model by taking it through a trial run. In the end, the group summarized their findings about the PFOA content and process within the context of Kenya's deliberation over Bt maize. Overall the case study provided applied insights, allowing everyone to test the questions, modify steps in the PFOA that did not make sense, and think about how a PFOA would work within their system. As we moved through each step, we were constantly working with both process and content, answering questions but also thinking about the process through the eyes of multiple stakeholders. One of the most striking realizations was that a PFOA could not be done in a single one-day session. In addition, to make this a scientifically based discussion, more consideration needed to be given to how the PFOA steps linked to the other sections of environmental risk assessment as well as the timing of each step.

In Kenya, the initial Steps 1-3 of the PFOA Model proved to be a wide-ranging discussion about the state of agriculture in Kenya, world markets, and pest problems. As we moved through the questions, the group began to focus on the specific problem(s) of maize production and worked to develop a shared problem statement (Box D.1). Throughout the rest of the PFOA steps, we used this problem statement to focus our discussion when we were diverted by tangential discussions and speculations.

Brainstorming the list of potential future alternatives for addressing the problem allowed participants to put anything up on the list without a veto from other participants (Box D.2). This opened up the process and supported creative thinking. In Kenya, we did not use the next technique, which would be to narrow down the list by clearly defining each option as distinct and appropriate for targeting the problem.



Under time pressure, we picked two options to focus on - Bt-maize and the Push/Pull system (Box D.3) - that were of special interest to the participants.

In the following sessions, we used the Option Identification and Assessment Chart (See Chapter 3, Table 3.1, Page 27) to compare Bt-maize and the Push/Pull system. Moving through Step 6 we worked to clarify the technology attributes, possible barriers to its use, and other issues embedded in the questions (Box D.4). In this trial run, we did not insist on answering one question at a time but rather moved through the questions, circling back to expand on our answers as we learned new things. This was the richest time for sharing information, coming to a common understanding of variables, and identifying gaps in our understanding.

In Step 7, we considered the changes required in order to make each option a viable solution (Box D.5). Given the training of the participants it was easiest to discuss the on-farm changes, but working at the macro-scale and considering factors such as the structure of agricultural support gave everyone new insights into what it takes to develop a successful technology.

This understanding of assessment at different scales carried over to Step 8 as we discussed adverse effects of each technology (Box D.6). After two days, we were winding down in the amount of energy we had left for discussion but this step also included the greatest degree of uncertainty. Many of our responses were speculations or educated guesses that would need to be confirmed by research findings produced by the other risk assessment sections.

#### **Box D.1: Kenya Example: Problem Formulation and Options Assessment, Steps 1-3 Trial Run**

##### **Step 1: Problem Formulation**

###### *A. Whose problem is it? Whose problem should it be?*

It is the problem of producers, consumers, and society at large

- a. Food security
- b. Poverty

1. *What needs of the people are not being met by the present situation?*

2. *What aspects of the present situation must be changed to meet the needs?*

Increase yields, reduce costs of production

**Step 2: Prioritization and Scale****A. Is this problem a core problem for the people identified?**

Yes. Information is available in dispersed PRA reports, and the Maize Database (See Muhammad and Underwood 2004)

1. *Do the people recognize the problem as important to their lives?*

Different stakeholders would rank the problem differently but for this case the farmers are considered the direct target while society and consumers are considered the indirect target for food security.

2. *What are the potentially competing needs of these people?*

Depends on the stakeholder. For example, a farmer may have problems with soil fertility or market access.

3. *How do the identified needs rank in importance to these other competing needs?*

There is a need for farmers to do further matrix ranking exercises. More specific information is available in Muhammad and Underwood (2004).

**B. How extensive is the problem?**

Occurs in all major maize growing zones (See Muhammad and Underwood 2004)

1. *How many people are affected?*

All farmers in maize growing zones, to varying extents.

2. *In what part of the country are these people located?*

3. *How large an area is affected by the problem?*

4. *How severe is the problem (local intensity)?*

Infestation may reduce maize yields by between 13-46 %

**Step 3: Problem Statement**

Shared understanding of the unmet need and its relative importance for a particular group of people.

**Context:**

Kenyan maize is not competitive in regional markets, resulting in maize products that are too expensive for consumers.

**Problem Statement:**

Current maize varieties are susceptible to stem borers and under high infestation suffer heavy damage reducing yields and lowering profitability.

**Box D.2: Kenya Example: Options Assessment, Step 5 Trial Run****Step 5: Option Identification**

Brainstorm possible alternatives to solve the identified problem, transgenic organisms would be one option. This step can be completed by the multiple stakeholder group for the initial identification of options. The multi-stakeholder group can do Steps 6-8 or a technical committee can develop a report that covers Steps 6-8 and the multi-stakeholder group can use the document to begin their evaluation and modify the assessment.

Brainstormed list of technology options for maize stem borers, no preference implied by the order listed:

- A. Bt maize
- B. Intercropping/ habitat management: Push – Pull/ crop combinations (See Box 4.3)
- C. Classical Biological Control (*Cotesia flavipes*)
- D. Local Technical Knowledge (LTK)/ Indigenous Technical Knowledge (ITK) – chilli pepper/ash
- E. Classical host plant resistance alone
- F. Synthetic pesticides – systemic/ contact
- G. Biopesticides – Bt alone
- H. Botanicals – Neem, among others,
- I. Cultural Control – time of planting, removal of crop residue, etc.

**Box D.3: Push/Pull System**

The push/pull strategy relies on diversified plantings in and around maize fields to reduce stemborer attack, *Striga* infestations, and erosion losses (Khan et al., 1997a, 2000). The most significant maize stemborers in Kenya, *Busseola fusca* and *Chilo partellus*, feed on many graminaceous host species (Khan et al., 1997b), but prefer Sudan grass (*Sorghum vulgare sudanense*), and Napier grass (*Pennisetum purpureum*) over maize (Khan et al., 1997b, 2000). Stemborer survival, however, is lower on these hosts, due to host plant physiology and/or increased attractiveness to parasitoids (Khan et al., 1997a). Furthermore, other plants, such as molasses grass (*Melinis minutiflora*) and *Desmodium* spp., repel ovipositing stemborers (Khan et al., 1997a, 1997b). Thus, intercropping molasses grass or *Desmodium* with maize would “push” the pests away from maize, and nearby Sudan grass could “pull” them away. The push-pull strategy also confers protection against *Striga*, a parasitic weed with minute seeds, when *Desmodium* is used as the intercrop with maize. *Desmodium* is not a host for *Striga*, and it also exerts an allelopathic effect to kill germinating *Striga* seeds (Khan et al., 2000). Maize fields intercropped with *Desmodium* spp. had vastly lower levels of *Striga* than maize monocultures, and maize yield was significantly increased relative to the monoculture (Khan et al., 2000). Finally, *Desmodium* are nitrogen-fixing legumes that improve soil fertility and provide early season cover, which should reduce erosion and eliminate conditions favorable for *Striga*.

**Box D.4: Kenya Example: Options Assessment, Step 6 Attributes  
Bt Maize and Habitat Management/Push Pull Intercropping Trial Run**

Bt Maize	Habitat Management /Push Pull Intercropping
<p>1. <i>What are the attributes of the option? (characteristics)</i></p>	
<p>Seed-incorporated resistance to stem borer; product; pest specific; easy to adopt.</p>	<ul style="list-style-type: none"> <li>■ Ready for adoption in some zones</li> <li>■ Preferred host “attractant” and repellent plants</li> <li>■ Persistent during the entire cycle</li> <li>■ Integrated technology—addresses soil fertility, two pest organisms (stemborers and Striga), using two or more extra crops. Soil, two pests, two crops.</li> </ul>
<p>2. <i>What is the range of crop production systems the option is likely to be used in or have an effect on?</i></p>	
<p>Bt maize is expected to be effective in all Kenyan production systems where the significant stem borer species are susceptible to the line in question. For Bt hybrids it is likely to be used in those areas where hybrid maize is already widespread, whereas adoption of Bt open pollinated varieties (OPVs) is more likely where farmers usually buy OPVs.</p>	<p>Target small-scale crop and livestock farmers, currently ready for mid-high altitude. Not large maize producers.</p>
<p>3. <i>What barriers exist for the option? i.e. is the seed distribution system in place; can the potential solution be integrated into present production; can the farmers afford the potential solution?</i></p>	
<p>Bt maize is not yet commercially available in Kenya. Social acceptability may be a barrier to adoption. This will depend on public opinion (influenced by international developments and unknown health/environmental effects). Access to markets will be a barrier if those markets demand non-GM produce. Lack of high quality, low-cost seed maize due to limitations in the distribution network may act as a barrier to adoption in remote areas of Kenya.</p>	<ul style="list-style-type: none"> <li>■ Not all farmers can use it</li> <li>■ Farmer knowledge needed, meaning you have to scale up extension</li> <li>■ New technology = adoption curves</li> <li>■ Area used for “trap” can’t be used for maize production</li> <li>■ Increased labour for controlling maize-Desmodium intercrop in the first year</li> <li>■ Limited scientific knowledge about other “trap/host” and repellent species</li> <li>■ Cost and limited supply of Desmodium seed</li> <li>■ Reduction of other intercrop options (beans)</li> <li>■ Limitation of mechanized agriculture</li> </ul> <p>Farmers can afford the technology with some problems associated with initially establishing Desmodium. Napir grass is locally available, cheap, easy to grow; diseases may be a threat.</p>

Bt Maize	Habitat Management/ Push Pull Intercropping
4. <i>How will its use beneficially affect internal and external (nearby) crop production systems?</i>	
<p>Internal crop production systems will benefit from the increased yields resulting from control of stem borer populations. Expectation that input costs of insecticide are reduced. External (nearby) cropping systems may benefit in subsequent seasons from some stem borer control resulting from gene flow of Bt transgenes. Neighboring farmers may in addition be motivated to adopt the Bt technology if they witness benefits associated with its use.</p>	<ul style="list-style-type: none"> <li>■ Refuge for natural enemies of maize stemborers in Napir grass</li> <li>■ “Freeloader” uses his neighbor’s trap crop to reduce stem borer</li> <li>■ Neighbor may adapt after observing the benefit</li> <li>■ Increased source of fodder for community</li> <li>■ Reduced weeding in second year</li> <li>■ Reduced lodging of plants</li> <li>■ Increased soil fertility</li> <li>■ Controls <i>Striga</i></li> <li>■ Soil erosion cover</li> <li>■ Increased soil moisture</li> </ul>
5. <i>Can its use be expanded to other cropping systems or geographic regions?</i>	
<p>The Bt transgene can be expected to spread through the maize population depending on the rate of natural and artificial selection and the rate of use. Farmer selection and insect pressure will result in expansion to other maize cropping systems.</p>	<p>Once the farmer learns the trap crop methodology they may transfer this principle to other cropping systems. It could be modified for use by the same sector of farmers in other regions.</p>
6. <i>How might the use of the option change cropping practices, such as tillage systems or pesticide use (including impacts on non-target pests)?</i>	
<p>The control of stem borers by Bt maize may result in a decrease in insecticide use, or a reduced need for insecticides to be adopted in areas where they are not currently used.</p>	<p>Reduces pesticide use. Encourages minimum tillage in subsequent cropping cycles. It is difficult to integrate this method into large-scale commercial production systems due to limitations on mechanization.</p>
7. <i>What useful practices are reinforced by the potential option?</i>	
<p>If Bt maize leads to increases in hybrid adoption, this could be viewed as reinforcing a useful practice.</p>	<ul style="list-style-type: none"> <li>■ Multiple benefits result from complex management tool</li> <li>■ Increase biological diversity</li> <li>■ Improved human diets with complex system: crop, manure, milk, seed reserve</li> <li>■ Room for farmer experimentation to meet site specific needs</li> </ul>
8. <i>How will anticipated changes in agricultural practices affect the needs identified in Steps 1 and 2?</i>	
<p>Any decrease in pesticide use will reduce production costs (This follows from the problem statement).</p>	<p>Reduce stem borer and <i>Striga</i> infestation resulting in better yields and reduced production costs. It will increase soil fertility resulting in a more robust plant and the possibility of higher production.</p>

Bt Maize	Habitat Management/ Push Pull Intercropping
<p>9. How might the potential solution positively affect the structure of agricultural sector?</p>	
<ul style="list-style-type: none"> <li>■ Agriculture system based on improved hybrids and increased attention to seed quality</li> <li>■ Expansion and possible diversification of the agricultural sector based on maize production</li> </ul>	<ul style="list-style-type: none"> <li>■ Opportunity for local economic development: seeds for income generation</li> <li>■ Increased markets responding to yield increases.</li> <li>■ More diversity in agricultural production, for example milk production</li> </ul>
<p>10. What information is needed to demonstrate that the anticipated benefits are likely to occur?</p>	
<ul style="list-style-type: none"> <li>■ Demonstration plots for farmers “To see is to believe”</li> <li>■ More information on which species are refuges based on location specific data</li> <li>■ Impact on animals - domestic and wild</li> <li>■ Comparative advantage against other options: there is a lot of information on biological control and pesticides. We need more information on Local Technical Knowledge, other local practices, crop rotation (contradictory data now), crop residue infestation.</li> <li>■ Data to reduce uncertainty about impact of Bt maize on environmental and health issues</li> </ul>	<ul style="list-style-type: none"> <li>■ Training for farmers on how to work with the system</li> <li>■ How to produce seed locally</li> <li>■ Demonstration plots - “to see is to believe”</li> </ul>

**Box D.5: Kenya Example: Options Assessment, Step 7 Changes  
Bt Maize and Habitat Management/Push Pull Intercropping Trial-Run**

Bt Maize	Habitat Management/ Push Pull Intercropping
<p>1. What changes in farm management practices might contribute to the solution?</p>	
<p>Bt maize requires an integrated package of pest and agronomic management. For example the use of cultural control and others would enhance stem borer control by Bt maize.</p>	<ul style="list-style-type: none"> <li>■ Increased farmer confidence and ability to manage intercropping systems</li> <li>■ Need crop/livestock systems to take advantage of this technology</li> <li>■ Other control strategies could be added to this technology</li> </ul>

<b>Bt Maize</b>	<b>Habitat Management/ Push Pull Intercropping</b>
<i>2. What changes in the local community might contribute to the solution?</i>	
<p>Local seed distribution sites and farmer training options will need to be established. Special emphasis can be placed on training trainers or community resource persons. On farm demonstrations to build confidence and ownership of the technology to enhance adoption. Well-run local seed banks may assist farmers in distribution and quality concerns.</p>	<ul style="list-style-type: none"> <li>■ Establish local seed distribution sites and farmer training options. Special emphasis can be placed on training trainers or community resource persons.</li> <li>■ On farm demonstrations to build confidence and ownership of the technology to enhance adoption. Well-run local seed banks for trap and repellent species as well as crop species may assist farmers in distribution and quality concerns.</li> </ul>
<i>3. What changes in government support for farmers might contribute to the solution?</i>	
<ul style="list-style-type: none"> <li>■ Government programs will need to support farmers if the farmer is going to benefit from reducing input costs rather than cost savings being passed on to the consumer</li> <li>■ Variety Release Committee will need to expand to include representatives from the Ministry of Health and identified environmental groups</li> <li>■ The extension services need to be strengthened to supply appropriate information</li> <li>■ Seed inspection services will need to be enhanced to increase farmer confidence in the seed. Concerns exit about seed quality and truthfulness in labelling.</li> <li>■ Government evaluation system for seeds supported by scientific data provided by public institutions</li> <li>■ Need a monitoring system for tracking GMO and non-GMO products</li> </ul>	<ul style="list-style-type: none"> <li>■ Need increased resources for extension or farmer-to-farmer education programs</li> <li>■ Need marketing of maize and milk to respond to increased production</li> <li>■ Need back stopping research to understand interactions and validate pest control benefits</li> </ul>
<i>4. What changes in the structure of agricultural production might contribute to the solution?</i>	
<ul style="list-style-type: none"> <li>■ More seed companies will result in healthy competition and improved services</li> <li>■ There may need to be a segregated maize management system if the market requires it. This may be expanded to products that have used Bt maize such as milk, meat, etc.</li> </ul>	<ul style="list-style-type: none"> <li>■ Improved cooperative systems for diverse product processing, distribution and marketing</li> <li>■ Increased support for diverse products coming from this new technology such as milk, new fodder species, etc.</li> <li>■ Local seed producers for trap and repellent systems</li> <li>■ Increased capacity in maize storage and distribution to respond to the increased production</li> </ul>

Bt Maize	Habitat Management/ Push Pull Intercropping
<p>5. <i>What other changes would likely be needed to facilitate widespread use of this alternative?</i></p>	
<ul style="list-style-type: none"> <li>■ There are several changes: improvement of extension services to support Bt maize; training about integrating Bt maize in the system; promotion of Bt maize, seed subsidies especially for small farmers; regulations for seed distribution to ensure quality; strengthen seed quality inspection services</li> <li>■ The general infrastructure of rural Africa will need to be improved to provide the best services for farmers in roads, communication, and distribution options</li> <li>■ Adoption of Bt maize may contribute to increased household income that could be used for better storage structures and other improvements that would be multiplied across the rural sector</li> </ul>	<ul style="list-style-type: none"> <li>■ There are several changes: improvement of extension services to support the technology; training about integrating push-pull in the farm system; promotion of habitat management benefits; seed production of the trap and repellent plants</li> <li>■ A philosophical emphasis on eco-friendly, natural, sustainable production systems focused on habitat management</li> </ul>

**Box D.6: Kenya Example: Options Assessment, Step 8 Impact  
Bt Maize and Habitat Management/Push Pull Intercropping Trial-Run**

Bt Maize	Habitat Management/ Push Pull Intercropping
<p>1. <i>How might the potential solution affect the structure of agriculture or agricultural infrastructure?</i></p>	
<ul style="list-style-type: none"> <li>■ Reduction in the pesticide market</li> <li>■ Increased production may initially result in uneven supply and demand problems</li> <li>■ Difficult task to separate grains if you do not want to contaminate non-Bt maize</li> <li>■ GMO labelling may be needed if demanded by consumers</li> <li>■ There could be a concentration of seed producers, with a loss of small regionally specific producers</li> </ul>	<ul style="list-style-type: none"> <li>■ May contribute to keeping farmers in small-scale production systems. The technology does not directly translate into large-scale production.</li> <li>■ Reduced market for pesticides</li> <li>■ Demand for repellent and trap seeds will require a agricultural supply system</li> <li>■ There will be a shift from monocultures to intercropping</li> <li>■ Increase in integrated crop and livestock production, on the farm or at the community level</li> <li>■ Organization of cooperatives may assist in economies of scale</li> <li>■ Increase in demand for veterinary services</li> </ul>

Bt Maize	Habitat Management/ Push Pull Intercropping
2. <i>How might the potential solution reinforce poor agricultural practices or disrupt useful practices?</i>	
<ul style="list-style-type: none"> <li>■ With Bt maize, farmers could believe they do not have to take care of other production stresses</li> <li>■ Farmers may relax other pest control strategies thinking Bt maize is the “miracle” control option. For example, soil pests, disease vectors, and leaf hoppers.</li> <li>■ Link to farm management: Unknown whether they would stop doing other practices or increase use of other options to protect the new production gains</li> <li>■ There is a potential loss of Local Technical Knowledge with Bt maize</li> </ul>	<ul style="list-style-type: none"> <li>■ Limits introduction of more mechanized agriculture</li> <li>■ It may not be practical to manage such a complex system on a large scale</li> <li>■ Reduces the crop combinations that may be used.</li> </ul>
3. <i>What are the potential adverse effects of these changes internally and externally to nearby crop production systems?</i>	
<ul style="list-style-type: none"> <li>■ Uncertainty about these adverse effects</li> <li>■ Cheaper production of Bt maize may threaten other maize and crop production systems, specifically: markets and plant diversity</li> <li>■ Efficiency of pesticide use may be reduced at the farm level because one primary crop will not be using the equipment, etc.</li> <li>■ Gene flow may interfere with other crops</li> <li>■ Risk of resistance break down in Bt maize may result in higher crop damage</li> <li>■ Non-target species may be affected</li> </ul>	<ul style="list-style-type: none"> <li>■ Possible reservoir for plant diseases and other insect pests (?)</li> <li>■ Link to pest scientists: What is the relationship of other crop borers, disease, legume pests to attractant crop?</li> </ul>
4. <i>Are any of these changes difficult to reverse, once they occur?</i>	
<p>Once Bt maize is part of the system it would not be easy to reverse any impacts. You could stop seed distribution to minimize impact. East African farmers will continue to recycle seeds.</p>	<ul style="list-style-type: none"> <li>■ Unlikely, remote possibility.</li> <li>■ If you use introduced repellent or attractant species it could become invasive.</li> </ul>
5. <i>What information is currently available?</i>	
	<ul style="list-style-type: none"> <li>■ Baseline data associated with the diversity of present IPM practices should be used if it is available.</li> <li>■ There is baseline data on farmers’ opinions about the system</li> <li>■ On farm trial data exists</li> </ul>

## TRIAL RUN FOR THE PFOA MODEL IN THE BRAZILIAN CASE STUDY FOR BT COTTON

Capalbo, D.M.F., Simon, M.F., Nodari, R.O., Valle, S., Santos, R.F. dos, Coradin, L., Duarte, J. de O., Miranda, J.E., Dias, E.P.F., Quyen, Le Quang, Underwood, E. and Nelson, K.C. 2006. Consideration of problem formulation and option assessment for Bt cotton in Brazil, . In: Hilbeck, A., Andow, D.A. and Fontes, E.M.G. (eds) *Environmental Risk Assessment of Genetically Modified Organisms Volume 2: Methodologies for Assessing Bt Cotton in Brazil* (pp. 67-92). Wallingford, UK: CABI Publishing.

In Brazil, the thirteen participants, including scientists and regulators from the major government agencies, evaluated the PFOA Model by discussing its purpose within an ERA, testing a few questions from each step in the Model to experience the type of discussion that might result from a multi-stakeholder exchange, and deliberating over how a PFOA would best fit in the Brazilian regulatory system. The authors then summarized their findings about the PFOA content and process within the context of Brazil's deliberation over Bt cotton.

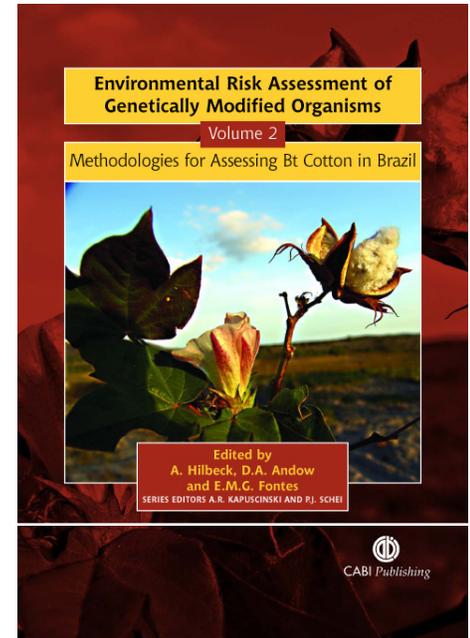
Brazilian participants used the questions as a sampling of the type of discussion possible. After discussing the questions in Steps 1 and 2 in the PFOA Model, the authors came to a consensus on the following problem statement for cotton pest problems:

*During periods of high infestation, Lepidopteran pests cause yield reductions in cotton, increasing the number of insecticide applications and consequently increasing the cost of cotton production, possibly affecting the health of farmers and people who are involved with the crop, also causing environmental pollution in the soil and water systems. Reduced stability of yield makes planning more difficult and risky.*

*In the Northeast for small-scale farmers, the boll weevil damages cotton during the rainy season (March-May). Lepidopteran pests are not a major problem.*

*In the Midwest and Meridian regions, Lepidopteran pests are a moderate to major problem.*

Continuing the trial-run of the PFOA Model, we conducted a brainstorming session about possible options for addressing the problem. The options included Bt cotton, insecticide



Kristen Nelson

applications, biological control with *Trichogramma* wasps, Integrated Pest Management (IPM) packages, and organic packages. We selected Bt cotton, biological control (wasps), and insecticide applications as options used to evaluate questions in Steps 6-8. Overall, our conversation jumped around a great deal but participants developed a sense of the type of discussion produced by the questions and where the difficulties would emerge. The majority of the Brazilian deliberation focused on how the PFOA would fit into the regulatory system.



Thomas Isler

### TRIAL RUN FOR THE PFOA MODEL IN THE VIETNAM CASE STUDY FOR BT COTTON

Nguyen van Uyen, Nguyen van Chi, Nguyen van Bo, Le Minh Sat, Hoang Thanh Nhan, Nguyen Xuan Hong, Le Quang Quyen, Arjen. Wals, Deise M. F. Capalbo, and Kristen C. Nelson. (forthcoming) Consideration of problem formulation and option assessment for Bt cotton in Vietnam, In: Andow, D.A. Nguyen Van Tuat, and Hilbeck, A. (eds) *Environmental Risk Assessment of Genetically Modified Organisms Volume 4: Challenges and Opportunities for Assessing Bt Cotton in Vietnam*. Wallingford, UK: CABI Publishing.

In Vietnam, the twelve participants represented national and international scientists, farmer organizations, Vietnamese Universities, and government agencies. Vietnam depends considerably on imported cotton for its textile industry (90%). With the application of new varieties and modern IPM approaches, the actual area under cotton had reached 30,000 ha in 2005. The main obstacle for further development of cotton production in Vietnam is still the pressure of cotton pests.

In this case study, Step 1 (Problem Formulation) was done by brain storming, discussing, and endorsing the following main insights:

1. Lepidoptera insects attacking cotton cause high yield losses (25 - 30 %)
2. Some Lepidoptera species (*Spodoptera exigua*, *Helicoverpa armigera*) have become highly resistant to most pesticides.
3. Most farmers growing cotton are using a high dose of pesticides, some of which have little or no affect on insect control.
4. As a result, farmers are hesitant to switch to cotton because of the high risk involved.

Step 2 (Prioritization and Scale of Problem) and 3 (Problem Statement) would answer the questions: Who is affected by the problem? At what scale? What losses have occurred?

The group agreed that:

1. Most farmers growing cotton are affected, especially small poor farmers who lack proper pesticide application equipment, money to buy the pesticides, and knowledge of pest control. In particular, farmers in the Central Coastal region of Vietnam are heavily affected.
2. Cotton companies, who sign contracts with farmers (the company provides the means for growing cotton in return for the yields), lose investment.
3. Cotton yield is usually reduced by 25-30%.
4. To protect cotton fields from pests, farmers have to use more pesticides leading to many health problems. In many areas, people suffer from allergies and many other diseases.
5. The quality of life for agricultural workers, farmers, and their families could be reduced.
6. Soil, water, and air in the cotton fields and surrounding areas have been polluted.
7. The ecosystem of the whole region can also be affected.

In Step 5 (Options), different options to alleviate the problem(s) have to be identified and discussed based on scientific data and field testing results. In our case study, several options for Lepidoptera control on cotton field were identified:

- Biological control (including the use of GM Bt cotton varieties)
  - Chemical control
  - Cultivating management system
- Integrated Pest Management (IPM) package =  
Biological control + Chemical control +  
Cultivation management system

Among these, two options were selected for the process of option assessment:

- Option A: Use of Insect resistant GM cotton varieties
- Option B: IPM package = Biological control + Chemical control + Cultivation management system



Ron Wheatley

Step 6, 7 and 8 were for multidisciplinary assessment of the trial run options based on different aspects.

**Option A: Use of insect resistant GM cotton varieties:**

- Characteristics: transgenic
- Regions: all cotton growing areas
- Barriers to technology adoption and efficacy:
  - Seed cost (?) and source
  - Adaptability of new varieties to local conditions
  - Government authorization and intellectual property issues (e.g., risk assessment, permission for distribution and commercialization)
  - Knowledge of farmers and acceptance
  - Trade barriers (e.g., consumer concern)
- Needed or Anticipated Changes
  - Less pesticide use and pest-control cost
  - Larger cotton-growing area, especially in dry season
  - More monoculture of some varieties
- Possible effects of technology:
  - Higher dependence of farmers on foreign seeds
  - Biodiversity loss
  - Dramatic change for non-target pests
  - Break-down of resistance
  - Unforeseen other consequences (e.g., human health...)

**Option B: IPM package = Biological control + Chemical control + Cultivation management system:**

- Characteristics: Integrated pest management (IPM) system
- Regions: Central coastal region of Vietnam and similar regions
- Barriers to technology adoption and efficacy:
  - Difficulty in finding a good biological control measure
  - Low acceptance by farmers to apply IPM
  - Knowledge of farmers on applying IPM is limited
  - Coordination across a region of stakeholders (e.g., farmers, local authorities, extensioners,

- companies) is weak.
- Applying biological control measures is costly
- IPM is rather complex and some farmers may not apply it correctly
- Needed or anticipated changes:
  - Reduce using pesticide
  - Need for labor is increased
  - Need training for farmers on IPM and improve coordination of stakeholders
  - Farmers are more independent from foreign input (e.g., seed, bio-pesticide)
- Possible effects of technology:
  - Working condition of farmers and environment is improved.
  - Sustainable practice.
  - Cost for production might be increased.
  - Knowledge of farmers on IPM is increased.

Hopefully, these examples provide insight into the type of discussion and consideration that may be produced by the PFOA questions. Readers should be cautioned that these are responses were NOT produced by a fully developed PFOA methodology for a specific GMO, but rather suggestions from the workshop participants about the types of answers the question would elicit. After practicing the PFOA methodology, workshop participants went on to summarize their evaluation of the PFOA process.



## APPENDIX E:

# HANDOUTS AND EVALUATION FORMS

### CONTENTS

- Handout 1: Problem Formulation and Options Assessment (PFOA) Process Questions
- Handout 2: Questions to Guide PFOA Design and Implementation
- Handout 3: Evaluating Your PFOA Process: Participant Evaluation and Feedback Form
- Problem Formulation and Options Assessment (PFOA) Handbook User Evaluation and Feedback Form

## **PFOA HANDBOOK - HANDOUT 1: PROBLEM FORMULATION AND OPTIONS ASSESSMENT (PFOA) PROCESS QUESTIONS**

*Questions to use as a guide during the PFOA process, and/or sent to participants in preparation for the PFOA meeting. Organizers can select specific questions they would like participants to reflect about prior to the meeting.*

### **Step 1: Problem formulation**

1. What needs of the people are not being met by the present situation?
  - Whose need is being addressed and whose needs is not being addressed?
  - What is the unmet need = the problem?
  - What are the causes of the problem?
  - How do these causes rank in their influence on the problem?
  - Whose problem is it? What are the effects of the problem?
  - What aspects of the present situation must be changed to meet the needs?

### **Step 2: Prioritization and Scale**

1. Is this problem a core problem for the people identified?
  - Do the people recognize the problem as important to their lives?
  - What are the potentially competing needs of these people?
  - How do the needs identified rank in important to these other competing needs?
2. How extensive is the problem?
  - How many people are affected?
  - In what part of the country are these people located?
  - How large an area is affected by the problem?
  - How severe is the problem (local intensity)?

### **Step 3: Problem Statement**

A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people. This stage of the multi-stakeholder process ends with a commonly agreed upon problem statement and a discussion of the merits in continuing the process or not proceeding further.

### **Step 4: Recommendation to Move Forward**

Do we move forward to identify options and conduct an options assessment?

### **Step 5: Option Identification**

What are the options for solving the problem?

**Step 6: Assessment in Relation to the Technology and the Problem**

## Technology Attributes:

1. What are the characteristics of the technologies involved?
2. What is the efficacy of the “technology” on the target?
3. What is the cost of the technology within the production system?

## Sociopolitical Attributes:

4. What social and economic organization will be required?
  - What is the range of production systems and what is the geographic region the option is likely to be used in or have an effect on?
5. What laws, regulations, policies or programs currently exist that would regulate the option?

## Production Attributes

6. What current advantages do we have for implementing this option?
7. What barriers to use exist? i.e. is the distribution system in place; can the potential solution be integrated into present production; can the farmers afford the potential solution?
8. How does this option fit with current practices? (Expanded in Step 7)
  - How might the use of the option change production practices, such as use of other species, tillage systems, pesticide use (including impacts on non-target pests)? What useful practices are reinforced by the potential?

## Summary of how the option might be solved:

9. What is the current state of information and science related to this option?
  - What sources of baseline data are available on the agricultural system? What information is needed to show that the changes are likely to occur?
10. How confident are we that this option could successfully solve the defined problem?
  - How will anticipated changes in practices affect the needs identified in Steps 1 & 2?

**Step 7: Changes Required and Anticipated**

1. What changes in **management** practices might contribute to the solution?
2. What changes in the **local community** might contribute to the solution?
3. What changes in **government support** might contribute to the solution?
4. What changes in the **structure of production** might contribute to the solution?
5. What other changes would likely be **needed to facilitate widespread use** of this option?
6. How do the options compare in the extent of the changes required or anticipated?

**Step 8: Adverse effects**

Special attention should be paid to the potential adverse effects of the proposed options.

1. How might the potential solution affect production systems and their infrastructures?
2. How might the potential solution reinforce poor practices or disrupt useful practices?
3. What are the potential adverse effects/harms of these changes internally and externally to the production system?
4. How will its use affect (both positively and negatively):
  - a. Other nearby production systems (can its use be restricted to a particular system or geographic region)?
  - b. Other nearby ecosystems?
  - c. The conservation of genetic variability of species and other related biodiversity?
  - d. Important social, cultural, economic, or ethical values?
5. What is the scale and importance of the effects for a, b, and c?
6. Are any of these effects difficult to reverse once they occur?
7. How do the options compare in their potential of adverse and irreversible effects?

**Step 9: Recommendation to Decision makers**

Formulating recommendations and a report about the PFOA deliberation

## **PFOA HANDBOOK - HANDOUT 2: QUESTIONS TO GUIDE PFOA DESIGN AND IMPLEMENTATION**

### **I. PFOA in Governance and Regulation**

- A. What are your goals for PFOA?
- B. Where does PFOA fit into the existing regulatory and legal frameworks?
- C. Who manages the PFOA? Who convenes the PFOA? Who does it report to?
- D. What are PFOA costs and how will they be financed?
- E. How will you evaluate the legitimacy of the PFOA process?
- F. What resistance might you encounter and how might you overcome it?
- G. How do you encourage deliberation within PFOA?
- H. What other multi-stakeholder processes that embody principles similar to PFOA exist in your nation?
- I. How will decisions be made within the PFOA?

### **II. ERA and PFOA**

- A. How should PFOA fit into or be staged within current ERA procedures?
- B. How will PFOA link to Risk Management Science?

### **III. PFOA Design Process**

- A. Who will facilitate the PFOA? What are the roles and responsibilities of the facilitator?
- B. Who will participate in the PFOA?
- C. How many stakeholder representatives should participate in a PFOA?
- D. How will stakeholder representatives be involved in the PFOA?
- E. What happens if stakeholders decline invitation to participate in a PFOA?
- F. How important is the continuity of stakeholder representatives?
- G. What preparation, training, and/or resources will different people need prior to participating in the PFOA?
- H. How will differences in power between stakeholders be dealt with in the PFOA?
- I. What information is needed to conduct a PFOA process? How will you identify the gaps?
- J. How will you evaluate legitimacy of the information used in the PFOA process?
- K. How will information used in the PFOA be communicated and managed within the PFOA process?
- L. How will information be communicated and managed outside of the PFOA?
- M. How will you evaluate the PFOA?



7. Do you have any comments about information access and/or availability in terms of this PFOA having adequate or necessary resources at its dispense?
  
8. How effective and/or useful was deliberation in navigating the issues this PFOA was convened to address?
  
9. Did you feel that your voice and contributions were heard and listened to? Was this PFOA process fair? If so, please provide an example. If not, why?
  
10. What aspects of this process could be improved upon or should be changed for future PFOAs? How and why?
  
11. Is there anything more you would have liked to see the PFOA do that it did not in terms of function, content, or scope?
  
12. How supportive are you of the recommendations the PFOA arrived at?
  
13. Do you think the PFOA process was well integrated or had effective interaction with the rest of the environmental risk assessment (ERA) process? Do you think it did or will make valuable contributions to the ERA process?

14. Do you think the PFOA did or will make valuable contributions to government decision-making?

15. Are there ways you think the PFOA could be more effectively integrated into the environmental risk assessment (ERA) process and/or decision-making?

16. Would you participate in another PFOA and/or recommend the process to other potential participants for future PFOAs? Why or why not?

17. Other Comments:

## **PROBLEM FORMULATION AND OPTIONS ASSESSMENT (PFOA) HANDBOOK USER EVALUATION AND FEEDBACK FORM**

*Based on your experiences using or reviewing the PFOA Handbook, please complete this form and return it by mail, fax, or email to:*

Dr. Kristen C. Nelson  
Department of Forest Resources  
University of Minnesota  
115 Green Hall  
1530 Cleveland Ave. No.  
St Paul, MN, USA  
Fax 612-625-5212  
[kcn@umn.edu](mailto:kcn@umn.edu)

*In advance, thank you for providing comments and suggestions!*

- 1.** Country where the Handbook was used:
- 2.** Type of organization or agency user is associated with (organization or agency is name is helpful but inclusion is optional):
- 3.** Please describe your goals and objectives in using the PFOA Handbook:
- 4.** How well did the PFOA Handbook prepare you to take design, implement, and conduct a PFOA?
- 5.** How well did the PFOA Handbook assist you in meeting a need for your organization or agency?

- 6.** Have you or do you intend to implement a PFOA process:  
\_\_\_Yes \_\_\_NO \_\_\_Unsure \_\_\_N/A
- 7.** Do you have plans to use the PFOA Handbook again in the future, or to have others at your organization use it?  
\_\_\_Yes \_\_\_NO \_\_\_Unsure \_\_\_N/A
- 8.** What did you like about the PFOA Handbook?
- 9.** What did you dislike about the PFOA Handbook?
- 10.**What was most helpful about the PFOA Handbook?
- 11.**What could be improved or needs more explanation, clarity, or elaboration?
- 12.**Chapter 5 covers a series of questions to help guide users through designing and implementing a PFOA. Were there any questions you would have liked to see covered but were not?
- 13.**Chapter 7 contains a hypothetical scenario. How helpful was this scenario? How could it be more helpful?

**14.**Do you have any comments about the organization, layout, or design of the PFOA Handbook?

**15.**If we were to do a revised version of the Handbook, is there anything additional you would like to see included?

**16.**What advice do you have for others considering use of this Handbook?

**17.**Other Comments:



## APPENDIX F:

# WEB BASED RESOURCES FOR CONDUCTING A PFOA

**\*Note about Web Resources**

In this appendix, to supplement the text in Chapter 6, we provide suggestions for web resources that are freely available to the public. The benefit of these sites is that they supply additional support for a concept or other tools that could be used. The limitation is that these are not specifically written for a PFOA and websites change or even disappear over time.

**WEB RESOURCES FOR:**

- Facilitation
- Stakeholder Analysis
- Writing Summaries and Syntheses
- Communicating and Reporting
- Warm up Exercises
- Brainstorming
- Conceptual Mapping
- Ranking Techniques
- Problem Definition Writing
- Delphi Techniques
- Options Assessment

## WEB RESOURCES FOR FACILITATION

### Primary sites of interest:

- International Association of Facilitators <http://www.iaf-world.org>, International professional organization providing opportunities for self-training (From Home page, click “Learning More About Facilitation,” or direct link: <http://www.iaf-world.org/i4a/pages/index.cfm?pageid=3283>: professional development, networking, and finding a facilitator. Also links to a methods database <http://www.iaf-methods.org>, that, after free registration, provides explanations of numerous “tools for creating, leading and following up group meetings.”
- Wageningen UR (Netherlands) MSP Resource Portal – Facilitation Skills section [http://portals.wi.wur.nl/msp/?Facilitation\\_Skills](http://portals.wi.wur.nl/msp/?Facilitation_Skills), Includes a basic overview and tips on being a facilitator along with numerous links to additional resources for developing skills and further study.
- Ontario (Canada) Ministry of Agriculture, Food, and Rural Affairs - Facilitating Group Processes: <http://www.omafra.gov.on.ca/english/rural/facts/01-039.htm>, Brief presentation of a variety of facilitation tools, including a self-assessment scaling tool to evaluate what capacity a person has for facilitation and identifying training needs
- University of Minnesota (USA) – Extension Service: <http://www.extension.umn.edu/distribution/citizenship/DH7437.html>, Provides public access to extensive information and training on basic facilitation and running a meeting in a variety of contexts. The information available directly on the web is only a sample of an eight-volume series on facilitation, but the full series is priced to cover production costs and is relatively inexpensive to purchase.

### Other sites of interest:

- National Coalition for Dialogue and Deliberation: <http://thataway.org>, This site is a public, collaborative effort based on the use of dialogue and deliberation to address societal problems. It deals less directly with facilitation as it is involved in a PFOA, but its resources could be useful to facilitators or to those managing various activities that might relate to a PFOA, such as working with communities on a national level.
- Facilitation Start4all: <http://facilitation.start4all.com>, This site is part of a subject-based index portal linking to a large collection of resources on facilitation and related topics. The site is maintained on a non-profit basis by a volunteer. Although there are links to many useful resources here, our main reason for including it is to highlight its section on “Facilitation Services” and indicate that there are many for-hire facilitation services and products available around the world. However, we do not endorse nor have we evaluated any of the products listed.

## WEB RESOURCES FOR STAKEHOLDER ANALYSIS

### Primary sites of interest:

- Health Reform Series - Guidelines for Conducting a Stakeholder Analysis: <http://www.phrplus.org/Pubs/hts3.pdf>, Good stakeholder analysis article focused on national level policy change. The scale is similar to the PFOA and many of the stakeholder characteristics could be used for a PFOA representative selection. The extent of the analysis, cost and time, in this particular technique is probably too exhaustive for a PFOA. This approach involves developing analysis for a longer-term political campaign and policy change.
- International Institute for Environment and Development – Stakeholder Power Analysis: <http://www.policy-powertools.org/Tools/Understanding/SPA.html> Helpful tool for considering power differences among stakeholders. The PFOA would not use the entire tool because it is not a development project but reading this material would help in considering power dynamics in the multi-stakeholder deliberation. Available in English, French, Spanish, and Portuguese.

### Other sites of interest:

- Bryson, J.M. (2004). What to do when stakeholders matter: Stakeholder identification and analysis techniques. *Public Management Review*, 6(1), 21-53. [http://www.hhh.umn.edu/img/assets/3751/stakeholder\\_identification\\_analysis\\_techniques.pdf](http://www.hhh.umn.edu/img/assets/3751/stakeholder_identification_analysis_techniques.pdf), Good article that provides concepts and tools for stakeholder analysis from the perspective of an organization/group that wants to create a strategic plan. The PFOA uses a concept of stakeholder sector that is broader than specific individuals identified in these techniques. This article could provide ideas for stakeholder characteristics that would be used to select participants, such as power, interest, etc.
- FAO – Stakeholder Groups: <http://www.fao.org/DOCREP/003/W8623E/w8623e05.htm>, Good discussion of the stakeholder concept and how to analyze stakeholders for community level natural resource management. This could provide additional insights into why stakeholder identification would be important. The specific criteria for analysis are not appropriate at a national scale.
- FAO Socio-Economic and Gender Analysis Programme Field Level Handbook – Stakeholder Analysis, p. 12-19 <http://www.fao.org/sd/seaga/downloads/En/Intermediateen.pdf>, Complete handbook for community planning. Not written for a national level stakeholder analysis but it does have many good points about gender considerations in stakeholder analysis.
- University of Wales Swansea Center for Development Studies – Short Guidance on How to do Stakeholder Analysis of Aid Projects and Programmes: <http://www.swan.ac.uk/cds/devres/pubs/rsdp3.htm>, Good description for project level stakeholder analysis. A few ideas that could be used at the national level for thinking about criteria for selecting the PFOA participants.
- Wageningen UR (Netherlands) MSP Resource Portal – Methodologies Section on Stakeholder Analysis: [http://portals.wi.wur.nl/msp/?Stakeholder\\_analysis](http://portals.wi.wur.nl/msp/?Stakeholder_analysis) Good, simple list of seven steps in community project stakeholder analysis. These

steps are similar to the PFOA steps but at a more general level for identifying stakeholder sectors, rather than specific organizations or people.

## WEB RESOURCES FOR WRITING SUMMARIES AND SYNTHESSES

### Writing Summaries:

- Literacy Education Online – Process for Writing a Summary: <http://leo.stcloudstate.edu/acadwrite/summary.html>, Provides advice on preparing to write a summary and writing, revising, and editing a summary.
- San Diego State University (USA) – How to Write a Summary: <http://www.sa.sdsu.edu/htc/summary.pdf>, Provides guidelines on writing a summary and an example based on an included article.
- Columbia University (USA) – Writing Summaries: <http://www.columbia.edu/cu/ssw/write/handouts/summary.html>, List of tips and advice for writing summaries

### Writing Syntheses:

- Drew University On-line Resources for Writers – Synthesis Writing: <http://users.drew.edu/~sjamieso/Synthesis.htm>, Intended audience is students, but this site is a great resource. It provides a comprehensive discussion of synthesis writing, including what a synthesis is, different types of syntheses, and the challenges of synthesizing information. Pearson Longman – A Sequence for Academic Writing – Explanatory Synthesis: [http://wps.ablongman.com/long\\_behrens\\_saw\\_1/0,5312,86473-,00.html](http://wps.ablongman.com/long_behrens_saw_1/0,5312,86473-,00.html), Textbook publisher Pearson Longman’s online resources for one of its books on writing. Intended for students but gives a concise explanation of synthesis writing and strategies for writing one. Also provide links to other sites on synthesis writing.
- Howard University – Writing Across the Curriculum – Tips for Writing: <http://www.cetla.howard.edu/wac/tips.aspx>, Click on ‘How to Write a Synthesis’  
Provides a helpful list of tips for synthesis writing.

## WEB RESOURCES FOR COMMUNICATING AND REPORTING

### Memos:

- Purdue Online Writing Lab – Memo Writing: [http://owl.english.purdue.edu/handouts/pw/p\\_memo.html](http://owl.english.purdue.edu/handouts/pw/p_memo.html), This website, as a whole, is widely recognized for its excellent resources on writing, including this guide to writing memos. Provides a comprehensive discussion of what a memo is, strategies for writing one, and what information to include.
- WikiHow – How to Write a Memo: <http://www.wikihow.com/Write-a-Memo>, Part of a public collaborative writing project. Offers a concise list of steps and tips in writing a memo.
- Oregon State University – Business Communication – Memos, <http://oregonstate.edu/dept/eli/buswrite/memos.html>, Offers good tips on memo writing, including some unique discussions of format and style.

## Reports:

- Middlesex University – Advice about Writing a Report: <http://www.mdx.ac.uk/www/study/Reports.htm>, Comprehensive overview of what a report is, stages of report production, compiling information for a report, and the actual writing and structuring of a report.
- University of Canberra – Academic Skills Program – Report Writing: <http://www.canberra.edu.au/studyskills/writing/reports>, Concise but comprehensive presentation of considerations relating to writing a report. Presents a lot of useful tips and reminders in bulleted form.
- Seattle Community Network – Community Empowerment – Report Writing: <http://www.scn.org/cmp/modules/rep-int.htm>, Comprehensive, multi-topic module on report writing. Written more for organizations working at the community level, but much of the information is still relevant.

**WEB RESOURCES FOR WARM UP EXERCISES**

- Drawing Bricks: [http://www.fao.org/Participation/ft\\_more.jsp?ID=5487](http://www.fao.org/Participation/ft_more.jsp?ID=5487), An “easy, effective and interesting warm-up...it also builds skills, knowledge and understanding.” (FAO Participation Website)
- First Name Introductions: [http://www.fao.org/Participation/ft\\_more.jsp?ID=2941](http://www.fao.org/Participation/ft_more.jsp?ID=2941), Helps participants “learn each other’s names quickly...[and] create a relaxed atmosphere.” (FAO Participation Website)
- Fruit Salad: [http://www.fao.org/Participation/tools/fruitsalad\\_13.html](http://www.fao.org/Participation/tools/fruitsalad_13.html), Helps get a group “active and awake.” (FAO Participation Website)
- Name Game [http://www.fao.org/Participation/ft\\_more.jsp?ID=3105](http://www.fao.org/Participation/ft_more.jsp?ID=3105), Helps everyone “speed up the process of becoming acquainted and...learn the names of their fellow participants.” (FAO Participation Website)

**WEB RESOURCES FOR BRAINSTORMING**

## Primary sites of interest:

- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, This site gives a good general idea about the brainstorming process. See:
  - “Brainstorming”: <http://portals.wi.wur.nl/msp/?Brainstorming>
  - “Nominal group technique”: [http://portals.wi.wur.nl/msp/?Nominal\\_group\\_technique](http://portals.wi.wur.nl/msp/?Nominal_group_technique)
  - “Delphi technique”: [http://portals.wi.wur.nl/msp/?Delphi\\_technique](http://portals.wi.wur.nl/msp/?Delphi_technique)
- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security <http://www.fao.org/participation/>, Available in English, French, Spanish, and Arabic. See:

- “Brainstorming”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=2961](http://www.fao.org/Participation/ft_show.jsp?ID=2961), which provides a general overview of brainstorming.
- “Gathering Ideas”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=5464](http://www.fao.org/Participation/ft_show.jsp?ID=5464), which offers an approach to getting a group started.
- URP Toolbox: <https://www3.secure.griffith.edu.au/03/toolbox/index.php>, See “Brainstorming” [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=29](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=29), good general information.

Other sites of interest:

- Brainstorming.co.uk: <http://www.brainstorming.co.uk>, Everything you need to know about brainstorming - rules, software and free training including a random word generator. Creative and lateral thinking problem solving techniques. This site offers some free access to several brainstorming tools. You can also buy the products as a resource.

## WEB RESOURCES FOR CONCEPTUAL MAPPING

- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, See:
  - “Conceptual modeling”: [http://portals.wi.wur.nl/msp/?Conceptual\\_Modeling](http://portals.wi.wur.nl/msp/?Conceptual_Modeling) – Useful for drawing relationships between different factors
  - “Cause and effect mapping”: [http://portals.wi.wur.nl/msp/?Cause\\_and\\_effect\\_mapping](http://portals.wi.wur.nl/msp/?Cause_and_effect_mapping), Helpful qualitative discussion of building a problem definition based on cause and effect logic.
  - “Interrelationship diagrams”: [http://portals.wi.wur.nl/msp/?Interrelationship\\_diagrams](http://portals.wi.wur.nl/msp/?Interrelationship_diagrams) – This allows the group to discuss the relative influence of each cause on the problem. The qualitative method can be used to narrow the discussion about the causes. Trying to arrive at ‘a single cause’ is not helpful reduction using a qualitative method.
- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security <http://www.fao.org/participation/>, Available in English, French, Spanish, and Arabic. See “Mind-mapping”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=5486](http://www.fao.org/Participation/ft_show.jsp?ID=5486)

## WEB RESOURCES FOR RANKING TECHNIQUES

- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, See “Card technique (metaplan)” [http://portals.wi.wur.nl/msp/?Card\\_techique](http://portals.wi.wur.nl/msp/?Card_techique) - Well-used technique for generating, organizing, and ranking ideas. This technique can also be modified to answer many of the questions in PFOA Steps 7 and 8.
- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security <http://www.fao.org/participation/>, See Delphi Technique <http://www.fao.org/participation/>

org/Participation/ft\_show.jsp?ID=5485 - more good ideas for how to use this technique. Available in English, French, Spanish, and Arabic.

## WEB RESOURCES FOR PROBLEM DEFINITION WRITING

Primary sites of interest:

- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, See:
  - “Cause and effect mapping”: [http://portals.wi.wur.nl/msp/?Cause\\_and\\_effect\\_mapping](http://portals.wi.wur.nl/msp/?Cause_and_effect_mapping) - Helpful qualitative discussion of building a problem definition based on cause and effect logic.
  - “Interrelationship diagrams”: [http://portals.wi.wur.nl/msp/?Interrelationship\\_diagrams](http://portals.wi.wur.nl/msp/?Interrelationship_diagrams) – This allows the group to discuss the relative influence of each cause on the problem. The qualitative method can be used to narrow the discussion about the causes. Trying to arrive at ‘the cause’ is not helpful precision when using a qualitative method.
- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security: <http://www.fao.org/participation/>, Available in English, French, Spanish, and Arabic. See “Problem Statement”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=5508](http://www.fao.org/Participation/ft_show.jsp?ID=5508) – an easy, simple process for building a problem statement. You may need general group discussion before individuals start writing their own problem statement. This may reduce the possibility that participants write problem statements based on misunderstanding of terms or basic information about the system.
- URP Toolbox: <https://www3.secure.griffith.edu.au/03/toolbox/index.php>, See Nominal Group, Methods Section, #7 [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=55](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=55), The purpose is to generate group ideas and the sense of the areas of greatest group agreement. It involves brainstorming ideas and two rounds of voting for the most important by all the group members.

Other sites of interest:

- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, See:
  - “CATWOE”: <http://portals.wi.wur.nl/msp/?CATWOE>, This links into a Soft System Methodology that could generally inform analysis of a case but not be used specifically for any of the PFOA steps.
  - “Historical Analysis”: [http://portals.wi.wur.nl/msp/?Historical\\_analysis](http://portals.wi.wur.nl/msp/?Historical_analysis), Provides a historical analysis for a problem. Currently, this is not a primary question in PFOA but could be included if it is important for a particular case or country.
  - “Locality Mapping”: [http://portals.wi.wur.nl/msp/?Locality\\_mapping](http://portals.wi.wur.nl/msp/?Locality_mapping), Limited help on PFOA problem definition. It would help the group identify the regions where the problem is occurring. They could also color code for intensity of the problem on a map.

- “Problem Tree”: [http://portals.wi.wur.nl/msp/?Problem\\_tree](http://portals.wi.wur.nl/msp/?Problem_tree), Tree method for analyzing problem causes and effects with a diverse group. It is written for a broader development project analysis but the problem definition component can be modified for the PFOA requirements.
- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security <http://www.fao.org/participation/>, Available in English, French, Spanish, and Arabic. See:
  - “Chrice Matrix” : [http://www.fao.org/Participation/ft\\_show.jsp?ID=3041](http://www.fao.org/Participation/ft_show.jsp?ID=3041), Very detailed, helpful handbook for thinking about problem analysis and definition. For PFOA, a review of the question/suggestions in problem definition may help the facilitator with ideas about how to bring diverse problem statements together in one definition. Many more questions than would be possible to answer in a PFOA process.
  - “Base Mapping”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=5492](http://www.fao.org/Participation/ft_show.jsp?ID=5492)
  - “Flow Diagram”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=3061](http://www.fao.org/Participation/ft_show.jsp?ID=3061) This is a technique for understanding the problem and possible solutions. It is more elaborate than the Cause & Effect mapping tool listed above, but still qualitative.
  - “Problem/Objective/Alternative Tree”: [http://www.fao.org/Participation/ft\\_show.jsp?ID=4424](http://www.fao.org/Participation/ft_show.jsp?ID=4424) Tree method for analyzing problem causes and effects with a diverse group. It is written for a broader development project analysis but the problem definition component can be modified for the PFOA requirements.

## WEB RESOURCES FOR DELPHI TECHNIQUES

- FAO Participation Website of the Informal Working Group on Participatory Approaches and Methods to Support Sustainable Livelihoods and Food Security <http://www.fao.org/participation/>, Available in English, French, Spanish, and Arabic. See:
  - “Delphi Technique”: [http://www.fao.org/Participation/ft\\_more.jsp?ID=5485](http://www.fao.org/Participation/ft_more.jsp?ID=5485) – explanation of a basic Delphi method.
- URP Toolbox: <https://www3.secure.griffith.edu.au/03/toolbox/index.php>, See:
  - “Delphi Study”: [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=43](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=43) – explanation of a more elaborate approach to using Delphi; information here can help in seeing how a Delphi might be conducted over email.
- Michigan State University Extension – “Delphi Technique”: <http://web1.msue.msu.edu/msue/imp/modii/iii00006.html>

## WEB RESOURCES FOR OPTIONS ASSESSMENTS

- URP Toolbox: <https://www3.secure.griffith.edu.au/03/toolbox/index.php>, See:
  - “Backcasting”: [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=25](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=25) – Backcasting provides a general tool for considering future alternatives. This site could be consulted to get a general understanding about how starting with a future alternative, as we do in PFOA, allows the group to think about what changes and steps would be necessary to achieve that alternative.
  - “Scenario Testing”: [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=8](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=8) – provides a broader understanding about why you evaluate future alternatives or future scenarios.
  - “Simulation (electronically generated)”: [https://www3.secure.griffith.edu.au/03/toolbox/display\\_tool.php?pk1=21](https://www3.secure.griffith.edu.au/03/toolbox/display_tool.php?pk1=21) – May be interesting for groups who have quantitative capacities for analyzing dynamic systems such as what the PFOA discussion considers for GMO technology.
- Wageningen UR (Netherlands) MSP Resource Portal – Tools section: <http://portals.wi.wur.nl/msp/?Tools>, See:
  - “Scenario Analysis”: [http://portals.wi.wur.nl/msp/?Scenario\\_analysis](http://portals.wi.wur.nl/msp/?Scenario_analysis) – provides a broader understanding about why you evaluate future alternatives or future scenarios.

