# Public Participation and the Cartagena Protocol on Biosafety

A review for DfID and UNEP-GEF



#### Team of consultants:

Dominic Glover James Keeley Peter Newell Rosemary McGee With assistance from Paulo Da Costa, Ana Romo, Miguel Loureiro and Lim Li Lin

### **Overview:**

This study looks at public participation in the development of National Biosafety Frameworks (NBFs). We make the following key observations:

- Public participation in the development of an NBF goes beyond the creation of an NBF document. It inevitably encompasses wider issues about the role of biotechnology, and requires ongoing participation in biosafety processes *after* regulations have been developed.
- Despite the fact that Parties face common challenges, there can be no universal prescription or standard formula for public participation and awareness-raising. What works in some places or in some circumstances will not work everywhere.
- Governments have two roles. The first is to initiate participatory and awareness-raising activities. The second is to create an enabling environment for *others* civil society and business to take the initiative.
- National biosafety processes involve development of a framework, implementation and monitoring. Currently, participatory efforts are not balanced across these stages.
- To date, much more education and awareness-raising work is being undertaken than public participation and consultation.
- There are plenty of participatory tools and approaches that have been effectively used in other policy domains, which are currently underused in biosafety processes.

# 1. Background to the study

This report summarises a study of the ways in which different countries have sought to promote and facilitate public awareness and participation in the design and implementation of their national biosafety frameworks (NBFs). The study documents and analyses the experiences of a representative selection of parties to the Cartagena Protocol on Biosafety<sup>i</sup>, in their efforts to fulfil their obligations under Article 23 of the Protocol. The aim of this study is to assist policy-makers by identifying and assessing a range of tools and approaches that may help to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms.

It is for each party to determine which combination of tools is suitable for their purposes, and which can be realistically applied, bearing in mind the resources available to them and their previous experience with participatory processes. Since what is appropriate in one country will not necessarily work elsewhere, the tools presented here need to be adapted to the unique circumstances in the country where they are to be used.

# **Box 1 - Article 23 of the Cartagena Protocol on Biosafety**

Public awareness and Participation:

- 1. Parties (to the Protocol) shall:
- (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In so doing Parties shall cooperate, as appropriate, with other states and international bodies;
- (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding the living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

# 2.1 Key Challenges of Participation

## **Degrees of participation**

There are different degrees of participation. These range from simple *information-sharing*, a precondition without which none of the higher levels can be achieved, to *consultation*, where views are solicited but without any obligation to act on them, to *joint decision-making* and *citizen-led initiatives*, the highest levels of participation. One level does not automatically lead to the next, nor must a process encompass all steps to be valid. But it is useful to clarify, through prior reflection and continuous reappraisal by all parties, what degree of participation is being sought and what is feasible within given constraints. While most activity in the biosafety area is confined to the first two levels at the moment, there are also examples of citizen-led initiatives, and these are mentioned in the discussions of context and tools below.

## Who creates the space for participation?

Public participation and awareness can be promoted and facilitated by many different organisations besides governments. This study includes examples of both formal and informal, 'top-down' and 'bottom-up' mechanisms of consultation, participation and awareness-raising, that have been used by different Parties. Each has its strengths and weaknesses, and each may perform different but often complementary functions. Governments therefore need not attempt to initiate or lead every participatory process themselves, but can take steps to create an encouraging and enabling environment for others to act.

The box below lays out some of the key considerations that need to be taken into account.

#### **KEY CONSIDERATIONS ABOUT PARTICIPATION**

#### Expectations:

- Often there is insufficient transparency on the part of convening institution(s) as to their expectations and the parameters of process. In particular, governments should be explicit about the following: How strong a commitment can be made at the outset to incorporate inputs made by the public in consultations? Will feedback be given? Where inputs are not incorporated, will explanations be provided as to the reasons for rejecting them?
- The credibility of public participation initiatives is highly contingent on the degree of accountability and responsiveness on the part of the convening institutions. The expectations of participants in the process are therefore also critically important. Often, insufficient attention is paid to investigating interested parties' expectations and reconciling these with the expectations of convening institution(s):
- There is often a lack of clarity over who is accountable for the process and its outputs.

### Timing and notice:

- Interested parties need sufficient notice in order to participate in forthcoming events or processes.
- During the consultation process, there is often insufficient time allowed for genuine consultation, learning or participatory deliberation to occur.

• Information needs to be disseminated in good time for interested parties to prepare their inputs in timely fashion, including consulting with constituencies if they are present as representatives.

#### Information:

- Information sharing among participants is an important precondition for inclusion.
- Information gathering is a vital first step. In order to know what sort of information needs to be provided, in which format, and to whom, information first needs to be gathered about who the interested public is, what its concerns and interests are, and what access it has to different kinds of information or media.
- Information needs to be disseminated widely and in appropriate languages, styles and formats.
- Participants need to have access to alternative, impartial analysis, produced by actors other than the principal institution(s) involved.

## Participation and Representation:

- Who participates? Who selects them, and how? Consultation and participation are usually by
  invitation, using criteria which are not transparent, nor devised on the basis of close knowledge of
  the full range of interested parties;
- It is often easiest to reach well-defined and organised groups such as NGOs or trades unions, which claim to represent particular sections of the population. But who represents whom, how, and by what means were they selected or identified?
- Special efforts may be needed in order to reach specific stakeholder groups directly. Otherwise, inclusion may be restricted to a narrow circle of participants, potentially reproducing social inequalities and limiting the participation of interested groups. Those parts of the population which are hardest to reach the poorest, those in remote areas etc. are rarely represented or included.

#### Follow-up:

- Often there is insufficient provision for follow-up activities with all parties involved;
- Feedback by the convening institutions to those consulted/participating is often insufficient or inadequate.

# 2.2. Key challenges of participation in biosafety regulation

Besides the general challenges associated with public participation and consultation, some *special features associated with biosafety regulation* present unique and special challenges for participation. These include:

- ★ **High science:** Experience shows that citizens are certainly capable of discussing scientific issues using ordinary language and concepts. However, scientific information is often made to seem complex and forbidding to the general public. Promoting public participation therefore means finding ways to make the scientific knowledge accessible and useful to 'non-scientists'.
- ★ **Polarized views:** Controversy over the safety and ethical implications of LMOs has tended to make the debate seem polarised. However, experience suggests that open engagement with different opinions and values helps to reveal a more complex and diverse picture of public attitudes and interests, allowing policy-makers to see ways forward.
- ★ **Commercial confidentiality:** Because of the costs associated with the development of LMOs, biotechnology firms feel they need to keep much of the information they provide to regulators secret. However, secrecy about risk assessment and safety testing can breed suspicion and distrust of the regulatory system.
- ★ International trade laws: The influence of WTO obligations may constrain choices in relation to biosafety regulation. The range of issues the Cartegena Protocol permits for consideration in the design and implementation of a system of biosafety regulation is limited to scientific and technical evaluations of safety and impacts on biodiversity, and socio-economic concerns where they

arise from impacts on biodiversity. However, participatory exercises on biosafety have inevitably raised much wider socio-economic, ethical and moral issues regarding LMOs, and have also highlighted the social values implicit in science-based risk assessment. Processes that are unresponsive to such public demands for a more broadly defined approach to regulation are likely to lack credibility and legitimacy.

## 3. Context matters

Appropriate forms of public participation and consultation need to reflect the different situations, capabilities, and stages of development of each country. Governments therefore have to address a range of choices at each stage of the process. The table below provides an illustrative, but not definitive, check-list of the types of choices, processes and tools available to parties:

Choices	Processes	Tools
<ul> <li>General (all 3 stages)</li> <li>Why are you inviting people to participate?</li> <li>What do citizens know, what are they concerned about?</li> </ul>	<ul> <li>Clarifying the purposes of a process and how people's inputs will be used.</li> <li>Engaging with areas of public concern (rather than assuming what people need to know).</li> </ul>	<ul> <li>Information-gathering surveys.</li> <li>Relevant, targeted information distributed in appropriate media, formats and styles.</li> <li>Stakeholder forums that are accessible and widely advertised.</li> </ul>
<ul> <li>Who should participate in the design process?</li> <li>Are people enabled to participate?</li> </ul>	<ul> <li>Identify key stakeholders, going beyond groups that identify themselves as stakeholders</li> <li>Ensuring adequate legal frameworks (rights to information, access to decision-making) are in place.</li> <li>Ensuring people are sufficiently informed about the issues to engage meaningfully with the process</li> </ul>	<ul> <li>Local and regional consultations to discuss issues and solicit views.</li> <li>Laws enabling public participation and access to information.</li> <li>Decision trails showing how views will be carried forward, follow-up explanations about how and why inputs have or have not been used</li> </ul>
<ul> <li>Implementation</li> <li>How far to include people in decisions about:         <ul> <li>The roles, duties and powers of responsible agencies</li> <li>Mechanisms of reporting, public scrutiny and accountability.</li> <li>The location and design of biosafety trials.</li> </ul> </li> </ul>	<ul> <li>Openness about applications for biosafety review and commercialisation.</li> <li>Openness about the purpose, location and design of biosafety trials.</li> <li>Opportunities for public comment</li> </ul>	<ul> <li>Using risk analogies with which people are be more familiar.</li> <li>Public registers of applications under review, with opportunities for public comment and obligations to respond to public comments.</li> </ul>
<ul> <li>Monitoring</li> <li>How to involve people in reflection and evaluation of the adequacy of the existing NBF framework?</li> </ul>	Sharing and explaining findings of trials, creating feedback mechanisms and procedures for acting upon these	<ul> <li>Non-specialist involvement in advisory and review committees</li> <li>Local level evaluations with opportunities for public comment.</li> <li>Constructing mechanisms for ongoing participatory (re)evaluation of the biosafety system</li> </ul>

A range of different factors affect the choices a country can make about processes and tools for framing, implementation and monitoring of biosafety. These include factors such as; available resources, political culture, government capacity, the nature of the legal system, and demand from civil society. In the case study countries looked at for this study, some of the following differences are evident.

In Denmark, for instance, there is a *strong tradition* of extensive participation at all levels of society, and critically there are *resources and capacity* to match this. This is reflected in the indepth consultative activities carried out by the Danish Board of Technology. In other settings, the UK for example, there has been a *lack of trust* in official science, and so it has been important to make plenty of information available and to invite reflection on the Farm Scale Evaluations. In Brazil, exercising *legal rights* has been a key way in which civil society has attempted to widen participation in biosafety assessment. This might not work in all places. In India there has been legal engagement, but intense *media activity and NGO demonstrations* have reflected a sense that not enough has been done to engage with the concerns of a wider range of stakeholders. In Kenya and Zimbabwe, while there have concerted attempts to engage civil society in the development of biosafety frameworks, reflecting traditions of participation in these countries, resource and capacity constraints are serious issues. In China, attempts to widen reflection on biosafety issues have occurred more within the bureaucracy than with civil society and this is generally where tools have been applied.

# 4. Tools and mechanisms for public participation

Below we group tools that can be used for participation and consultation and for education and awareness-raising under separate headings. In practice, however, they are intrinsically linked. Participation is impossible without information being shared effectively. Sharing information and raising awareness invites participation because it enables citizens to consider issues and form opinions on them. To understand whether these tools could help in the design of your NBF, it will help to refer to the full report which explains the context in which they were used, and for what purpose.

# 4.1 Tools for Participation and Consultation

**Enabling legal frameworks:** Laws on public participation, such as in Bolivia, or on rights to information, as in Norway, facilitate meaningful public involvement in biosafety decision-making.

**Routine opportunities for public comment:** In many countries, applications for regulatory approval are published in a register with opportunities for public comment as a matter of routine. Examples include the Netherlands, the United Kingdom, and Canada. In Canada, public comments on aspects of the NBF were compiled and presented at a multi-stakeholder consultation.

**Multi-level consultations:** In some countries, public consultations on different aspects of the biosafety framework have taken place at local, state/regional and federal/national level. In Denmark, public hearings may be organised by local authorities for all regulatory approvals, and consultations have also been organised at neighbourhood and workplace level. In the United Kingdom, the locations of farm-scale evaluations were selected following local consultations.

**On-going oversight and evaluation:** Stakeholder bodies, such as the African Biotechnology Stakeholders Forum, can be set up to review biosafety procedures on an ongoing basis.

**Independent Advisory Committees.** Examples include the UK's Advisory Committee on Releases to the Environment (ACRE) and the Independent Scientific Steering Committee. The authority and credibility of such bodies depends heavily on their independence from government and industry, as well as the extent to which they include the perspectives of non-scientists and their ability to represent a broad range of stakeholders. In the United States, the Advisory Committee on Agricultural Biotechnology was effectively disbanded following the transition from the Clinton to the Bush Administrations.

**Independent Public Enquiries:** These can be independent bodies with broad mandates that produce recommendations. In New Zealand, a Royal Commission looked at the risks and benefits of the technology, broad public interest issues including human health, and the adequacy of regulatory processes. It was also able to target the particular needs of indigenous groups such as the Maori through workshops as well as convening 'youth forums' to hear the views of young people.

**Bottom-up participatory processes:** Participatory processes facilitated by credible and experienced NGOs can help to include stakeholders who risk being left out of government-led consultation processes. Examples include citizens' juries facilitated by NGOs such as ActionAid and ITDG in Zimbabwe, Brazil and India.

## 4.2 Tools for Information and Education

**Surveys of communication needs:** In New Zealand a benchmark survey of a representative cross-section of the population was undertaken to assist the government in the development of a public information campaign.

**Communicating about science and risk:** Using analogies to risks people are already familiar with provides one way of addressing this. Communicating risk is also improved by asking groups what they want to know rather than presuming what they need to know. Science communication is also enhanced by being honest about areas of uncertainty.

**Information Dissemination**: Leaflets, websites, advertising and telephone helplines can be used to explain the regulatory process and how people can be involved in decisions. Information can be disseminated more widely and effectively if it is translated into local languages, distributed widely and free of charge. Establishing councils, bureaus and networks to communicate with the public, as in Brazil, Poland and Canada, can be effective, but to be credible these bodies need to be independent. Kenya's Interlink Rural Information Service and The Biotechnology Trust of Zimbabwe play important roles in disseminating biosafety information to rural areas, raising awareness and facilitating debate.

**Using the media:** Newspapers, radio and TV provide useful routes for informing the public about biotechnology, biosafety regulations, applications for regulatory approval, and opportunities for public comment and participation. Journalists may benefit from support and training on biosafety issues, as has taken place in Kenya and elsewhere. However, the information provided to journalists will lack credibility if it is perceived to be biased or too closely associated with the opinions of interested parties such as industry groups or NGOs. Openness and cooperation with journalists is likely to improve the quality, accuracy and usefulness of the information presented to the public.

**Awareness-raising about participation:** Advertising events and meetings in local media is key to this. Making the public aware of forthcoming government meetings is also important to encourage people to submit comments. In Brazil, for example, although meetings of CTNBIO take place behind closed doors, agendas for the meetings are posted on the web site before the meetings, so that groups can raise issues before the meeting.

### 5. Reflections and lessons for the future

The study which this report summarises has drawn attention to four key observations:

**Firstly**, there is an imbalance in most countries' approaches to their Article 23 obligations, in favour of fairly basic public education and awareness-raising exercises rather than the more challenging and fundamental process of enabling effective public consultation and participation.

**Secondly**, the range of mechanisms and processes being applied by different countries to date is rather limited. There is significant scope for countries to make more creative and extensive use of the many innovative and effective tools that exist for enabling public participation and education.

**Thirdly**, we found few examples in which public participation was being effectively promoted across all three stages of the design and adoption of an NBF (framing, implementation and monitoring). Although we found examples of public participation at each of the three stages in different countries, it is rare to find a country in which citizens are pro-actively included in all three. This is particularly true if only formal or government-sponsored processes are considered.

**Fourthly**, we observed that the credibility, legitimacy and effectiveness of any process or initiative depended strongly on the extent to which it enabled the public participants and key stakeholders to help frame the issues to be considered. Broad, open-ended, dynamic and responsive processes were better able to accommodate the range of concerns which citizens had. Inevitably, these included moral, ethical and social issues because biosafety risks cannot be assessed separately from social evaluations of the potential benefits of LMOs. Processes that succeeded in accommodating this diversity were more likely to command public credibility and respect.

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<sup>&</sup>lt;sup>i</sup> Brazil, Canada, China, Denmark, Estonia, Ethiopia, India, Kenya, Malaysia, Mexico, Namibia, New Zealand, Norway, the United Kingdom, the United States and Zimbabwe. (Although the US is not a party to the Biosafety Protocol, it was decided to include it in the study because of its status as a key actor in the biosafety negotiations and the trade in LMOs.)