African Biosafety Network of Expertise



# ABNE Guideline: Communication for Biosafety Regulators

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# **Executive Summary**

Biosafety communication is considered the third pillar of biosafety, a structure that also includes risk assessment and risk management. Together, these three components form the basis of an effective biosafety regulatory process. This guideline provides information on communication related to the day-to-day activities of an office responsible for biosafety regulation. It is designed to expose biosafety regulators to communication principles and provide a background to effective biosafety communication.

The purpose and goals of biosafety communication are discussed within the scope of regulating the products of modern biotechnology -i.e., transgenic organisms, also called genetically modified organisms. The importance of devising a biosafety communication strategy is emphasised with guidance on how to develop this strategy. Establishing communication timelines is covered to help ensure that important aspects of communication are prioritised and that the best use is made of available funding. Potential pitfalls in biosafety communications are presented.

This guideline can be used as a training resource for new biosafety officers or as a reference document for biosafety offices, especially those initiating new forms of communication or revising existing communication processes. Countries are encouraged to adapt the guideline to reflect their national regulatory requirements and situations.

The guideline attempts to cover a wide scope of communication activities that could be required by biosafety regulatory officials:

- The purpose of biosafety communication;
- Principles of communication;
- Communication strategy development;
- Channels and tools for communication;
- Information for applicants;
- Communicating biosafety decisions;
- Media interaction;
- Addressing challenges and concerns;
- Public participation;
- Emergency communication protocols;
- Agency-specific communication;
- Monitoring and evaluating communication; and
- Communication capacity strengthening.

As with all the guidance documents made available by the NEPAD Agency's African Biosafety Network of Expertise (ABNE), this document is 'a work in progress'. It will evolve as national biosafety offices provide feedback to ABNE and as new examples of working communication components enhance the case studies available for consideration by national biosafety regulators. Please share your experiences with this guidance document and with biosafety communication in your country by contacting us at abne@nepadbiosafety.net.

# Terminology

**Target groups:** Groupings of biosafety stakeholders whose needs regarding biosafety communication are similar.

**Transgenic**: "Genetically modified", "genetically engineered" and "transgenic" all refer to the products of modern biotechnology that have new or altered genes or have altered gene expression as a result of gene modification in a laboratory.

**Stakeholders**: People interested or affected by biosafety and the implementation of regulations for transgenic organisms.

# **1. Introduction**

Biosafety communication focuses on the communication required by a national biosafety office as it carries out its day-to-day biosafety responsibilities. The legal requirements for biosafety communication are laid out in the national laws on biosafety and these should form the basis of any biosafety communication strategy. A large portion of this responsibility is to provide key stakeholders with information about the activities that fall within the mandate of the biosafety authority and the processes to follow to stay compliant with biosafety regulations. To be transparent and effective, the biosafety office must provide information for raising public awareness on national biosafety regulations and enable public participation in the development of policy that will support the regulatory role of the national biosafety authority.

Biosafety communication is much broader than just regulation. There are four major groups who speak about biosafety. These are government regulators, product developers (both public and private), activists and the media. Government biosafety communicators who act as regulators of the safety of transgenic products and implementers of biosafety policy are the focus of this communication guideline. Product developers communicate in terms of new transgenic products, risk management measures to improve safety and to lessen liability. Activist communicators raise their concern about activities with transgenic organisms and the products they oppose. The media look for stories that sell and understand the power of controversy and fear. Concerns and risks are often used by communicators to attract readers.

Much of biosafety communication covers communication about risk, risk assessment and risk management. This is frequently called 'risk communication'. The U.S. National Research Council Committee on Risk Perception and Communication describes risk communication as follows:

"An interactive process of exchange of information and opinions among individuals, groups and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management."

This definition notes a number of important factors that are true for both risk communication and biosafety communication. Both must enable a two-way movement of ideas, from the regulators and to the regulators. Biosafety communication covers risks and concerns about risks. It includes mechanisms to identify, address and manage these concerns. The nature of biotechnology products, and the human and environmental impacts associated so closely with risk from all sources, means that much of biosafety communication is scientific and technical. An essential part of biosafety communication is maintaining a high level of scientific accuracy while using simplified language to ensure easy comprehension by target groups.

The target groups for biosafety communication are the interested and affected parties; *i.e.*, those people and communities that are involved in biotechnology at some level, whether as developers, testers, regulators or end users. Identifying this diverse group of people is important to focus public awareness strategies so that the needs and concerns of these people are clearly identified and addressed.

Concerns are not only about environmental and health risks; concerns about social and economic impacts are included. For years, regulators have focused their attention on health and environmental risk, leaving social and economic impacts to be addressed by natural assimilation and market forces. The more recent inclusion of social impact assessments and economic impact assessments in biosafety decision making has significantly widened the scope of transgenic regulation and strained the resources and expertise of safety regulators. For example, transport and mobile phone regulators have focused for years on the safety aspects of these technological products but have not had to make decisions regarding the impact these devises may or may not have on the social and economic welfare of local communities. Similarly, for decades plant breeders have focused on improving the planting material available to farmers without needing to assess the social and economic impact these new plants might have on the communities that buy, market and use them.

Those noting the largely hesitant adoption of transgenic crops could argue that biosafety communication has not been effective. However, a review of the events leading up to the mainstream, overly precautionary reception to transgenic products in regions such as the E.U. and Africa, indicate that this situation is more obviously the result of very effective opposition communication that took scientific and regulatory bodies by surprise and left them ineffectual in counteracting much of the misinformation on which these campaigns were based. This reinforces the importance of having a transparent and efficient biosafety communication strategy, which includes a plan for rapid response to misinformation, in each national biosafety system. Failure in this respect could cost local farmers and industry access to improved technology in the future.

The primary focus of biosafety communication should be to improve the general understanding of the thoroughness of safety assessments for transgenic products, as well as the effectiveness of the national biosafety framework to ensure access to safe products and control of unsafe products. Good communication of well-informed decisions should build confidence in the biosafety process and help to influence the public acceptance of approved products. Unfortunately, decision-making is not always well informed and good communication of a poor decision does not enable access to improved products!

It is not always straightforward to obtain country decisions on specific transgenic products. Some established biosafety offices, such as in Canada and Australia, have websites that provide relatively easy access to most of the documentation about regulatory biosafety activities. Other biosafety offices, such as South Africa, have lists of approved activities but no access to the applications, safety recommendations or the decision documents. In terms of building public awareness, the understanding of biotechnology and transgenic products is low outside of the technology development community (public research institutions and private companies). Yet, acceptance levels are high in some countries and low in others even with fairly similar levels of biotechnology awareness, such as Australia and the European Union.

The scope of regulatory biosafety communication is broad, and includes communication on:

- The status of biosafety policy in the country and any proposed changes to policy;
- The scope of the policy and what activities require biosafety approval;
- Application and review processes;
- Risk assessment for food safety and environmental impact, including both the process and the risk assessment recommendations;
- Risk management for specific products or activities;
- Compliance requirements; and
- Public participation, including processes for consultation and opportunities to comment on specific applications.

As such, biosafety communication requires largely nontechnical dialogue and information that is accessible to a wide diversity of stakeholders and interested public. However, in addition to communicating about specific applications and approvals, the regulatory biosafety communication must explain how risk is evaluated to distinguish between real impact and perceived risks and

# Examples of perceived vs. real risk

Cell phones:

There is a concern that radiation from the hand held cell phones will cause brain damage.

Data from a hazard assessment of the radiation produced by cell phones indicates that there is close to zero risk of brain damage from cell phone usage. This evaluation is supported by the high adoption rate over the last two decades that has not correlated with any observed increase in brain damage associated with people who use cell phones.

Conclusion: The risk of increased brain damage with the use of cell phones is not a real risk, but a perceived risk.

#### Electric cables:

There is concern that people will be electrocuted by touching bare electrical wires.

A hazard analysis indicates that electrocution is a real risk for many electrical cables. However, electricity has many benefits, so rather than banning electric cables, regulators manage the risk by requiring that these cables are well insulated. This risk management measure allows communities safe access to the benefits of a potentially high risk technology. how potential for real risk is addressed – a very technical discussion. Biosafety communication attempts to clarify the difference between real and perceived risk and to identify the potential consequences of undertaking certain activities by evaluating available hazard information.

Importantly, all activities carry risk. Whether we eat, walk, drive, sleep, work or even breathe, we are taking a risk. Nothing is risk free or has zero risk. Thus, "risk free" and "zero risk" are relative terms that mean approximately 98 per cent safe. This is why risk communicators do not speak of zero risk. They use terms like: "as safe as conventional food", "as safe as conventional planting material", or "safer than existing insect control measures". Biosafety communicators need to keep reminding the public and stakeholders about this.

# 1.1. Purpose of biosafety communication

The goal of biosafety communication is to keep stakeholders well informed about the national process and to address concerns that are raised about specific activities and products. This communication can be used by regulators to detail how and why decisions are made, as well as to acknowledge and address any concerns raised by stakeholders and the public.

There are two major areas of biosafety communication:

- Communication about the regulatory processes; and
- Communication about the safety of biotechnology and its products.

Communication about the biosafety regulation includes providing information on how biosafety policy is developed, what the national biosafety policy is, how stakeholders are able to participate, and how the application processes are accessed. Public awareness communication attempts to increase public understanding of how risk assessment is carried out and how safety, benefits and risks are reviewed by the regulatory authorities. Process-related biosafety communication also provides information on national and international regulations and guidelines that are used for assessing risk and making decisions regarding the use, release and transboundary movement of transgenic organisms.

Biosafety communication about biotechnology products focuses on which products are regulated, how decisions are made, what decisions have been made, and what information is used in arriving at regulatory decisions on transgenic activities and products. Here it is important to focus on risks, concerns and risk management and to cover benefits only in the context of how they are used in decision making. This aspect of biosafety communication mostly deals with specific transgenic organisms for specific applications in a specific location, *i.e.*, it is focused on local adoption and use of a transgenic product, rather than on global product safety statements. None the less, the safe use of products in one or more countries is an important component of safety assessments for use in any other country.

#### 1.1.1. Legal responsibilities

The national biosafety office needs to communicate clearly about its legal mandate to undertake biosafety assessments and issue approvals or refusals for the use of transgenic organisms in the country. The policy that supports these actions should be clearly presented in all communication and in every decision document. These legal mandates may come from national regulations and from international agreements to which the country is party, *e.g.*, the Cartagena Protocol on Biosafety.

Where policy requires the regulators to ensure public participation in specific activities and to promote public awareness of biosafety, these mandates are important components of the biosafety communication strategy of the national biosafety authority. Similarly, where the legal mandate of the biosafety regulatory authority is to review and approve activities with transgenic organisms, then the communication strategy must include clear information on how applications can be submitted for consideration and what information is required for these submissions.

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The movement of transgenic organisms across international boundaries through trade, research or informal activities is regulated in many countries under the auspices of international agreements. Communication is essential if the public are to be aware of the regulatory requirements for such activities. For example, the first approval for planting of transgenic cotton seed in South Africa came with a requirement for a farmer agreement that clearly stated that the transgenic seed and harvested seed could not be carried across international boundaries. This was deemed necessary because of regular informal movement of *conventional* seed across these boundaries. The farmer agreement was identified as the most effective means of communicating this regulatory requirement to the people most likely to move transgenic seed.

#### 1.1.2. Awareness and visibility

Government departments, including the national biosafety authority, are responsible for public awareness and raising the visibility of their activities so that citizens see how public interest is being upheld and how public money is being spent. Thus, biosafety communication must aim to raise public awareness of the regulatory requirements for working with transgenic organisms, as well as the importance and function of the biosafety regulatory authority and collaborating agencies in other ministries.

#### 1.1.3. Information sharing

The biosafety office receives applications, processes these, obtains decisions and interacts with stakeholders in the country, the region and internationally. All of these activities generate information that is of interest to various stakeholders at different times. Access to this information should be easy and cost effective. While electronic information systems are well suited to dealing with most information sharing, it is important to address the information needs of interested and affected public who do not have access to computers or who are not literate. This can be a costly process, requiring printed materials and human resources for outreach and response to enquiries. Working within established government communication systems will help minimize the costs of non-electronic information sharing.

#### 1.1.4. Engagement

Communication is not just about handing out information. It encompasses an important 'listening' component which ensures the two-way flow of information. Biosafety communication strategies must enable stakeholders and interested and affected citizens to provide input into policy development and into decisions that will affect their lives. Some countries engage in wide stakeholder consultation during the development of policy, using public dialogue through citizens' conferences, for example. Once the policy is representative of the needs of the citizens, government departments implement the policy with minimal additional public engagement. Further public engagement is undertaken only when there is an identified need, not for every new decision taken under the approved policy. Other countries consult on new policy *and* consult on each decision taken in the implementation of the policy. Although this is very transparent and inclusive communication, it can be costly and time consuming.

# 1.2. Responsibilities

As with information sharing, the responsibility for engagement with stakeholders and citizens lies with the biosafety office. The biosafety policy determines the triggers for stakeholder and public engagement, and this outreach needs to be implemented by the biosafety office as and when it is required. While the biosafety office may use existing government channels for public engagement, it is up to the biosafety office to determine the purpose, content and timing of public engagement activities to ensure that they meet the needs of stakeholders.

# 1.3. Building trust and credibility

To be effective, biosafety communicators need to be trusted and credible. Good communication is valuable in

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building trust and credibility for the biosafety policy and the offices that implement components of the biosafety regulatory process. This is supported by establishing a clear separation between communication about the beneficial applications of transgenic organisms and the biosafety and risks associated with their use. While balanced communication must address both the benefits and the risks of a new product, it is important for biosafety regulatory communicators to remain focused on regulating safety and not on promoting biotechnology. In the past, some national regulatory offices have combined biosafety functions with biotechnology promotion and this quickly brought the regulators' impartiality into question. In most countries, different government departments/ministries deal with implementing biosafety regulation and promoting the adoption of new technology. While both the development of transgenic organisms and the need to regulate their safety may stem from a single national strategy document on biotechnology, the role of safety regulation should be kept independent of activities to develop and adopt biotechnology.

Similarly, public awareness information can be considered promotional if it focuses on the benefits and applications of the products. Biosafety public awareness communication should focus on the regulatory process, and how concerns expressed by the public are addressed within the national and international biosafety frameworks.

When both biosafety communication and promotion of biotechnology come from one government office, the impartiality of the regulators can be questioned.

This guideline will detail the components of effective communication for biosafety officers to adopt, adapt and modify the components that best suit their environment and national framework.

# 2. Principles of communication

Communication principles that have been established for other technology applications are equally applicable for biosafety (Koch and Massey, 2011). As such, a review of communication related to food safety, energy, transport and environmental impact are just some areas where guidance can be sought for biosafety communication. Communication principles identified for these technologies provide the following important pointers:

#### 2.1. Communication is a two-way process

As mentioned earlier, communicating is not only about handing out information or responding to requests for information, it provides an opportunity to obtain feedback from interested and affected stakeholders and the public. This feedback helps to ensure that the biosafety office is aware of the needs and concerns of stakeholders and that the policies and their implementation are addressing these needs and concerns. To be effective, the biosafety office needs to devise appropriate mechanisms to receive feedback and to analyse and use the information. Feedback enables regulators to identify and address the concerns of stakeholders and the public. It may result in revisions to the way biosafety is implemented, or changes to the communication strategy to make it more effective.

Experience indicates that:

- Listening is important in communication;
- Listening to concerns helps to address them;
  - o repeating a concern shows you have heard it. This alone addresses 70 % of the need; and
- Being able to address the concern completes the process for the concerned stakeholder.

### 2.2. Know the audience's needs

For effective communication it is important to tailor the content of the information to the needs of the targeted audience. These needs vary between stakeholder groups and there should be a good understanding of what information is required by each group. Understanding the particular needs, concerns, knowledge level, opinions and preferred mechanisms for receiving information for each target group helps biosafety offices to design effective communication. The needs of stakeholder groups can be ascertained through consultation with them. The biosafety office should customise communication in the style, content and delivery to ensure that the relevant information is provided in the most effective way to each target group.

### 2.3. Define the purpose of the communication

Because the communication needs of a wide variety of stakeholders can be vast, it is important to plan communication with particular goals in mind. For communication to have the desired impact, it needs to be focused on achieving a specific purpose. If this is not done, the communication may prove too vague, too detailed or irrelevant to many of the audience, leading to frustration and wasted resources. It is important to ensure that all communication focuses on the areas of greatest importance to the audience. For example, the food industry is generally interested in food safety, labelling and approvals of food crops. This stakeholder group should not be burdened with large amounts of information on environmental safety assessments or requirements for management of confined field trials. If they need this information they will access it or attend communication meetings that are specific to this need.

Swamping stakeholders with unwanted or irrelevant information may deaden their receptivity to important communication for which feedback and input may be required.

# 2.4. Know the subject

The people chosen to prepare and deliver biosafety communication need to have a good grasp of biotechnology and biosafety, including the issues that are being addressed. While this seems common sense, the delivery of communication cannot be left to junior members of the biosafety office until they have a good understanding of the biosafety policy, the functioning of the biosafety system and the concerns and needs of the stakeholders.

The drafting team for new communication output should have easy access to technical expertise and all communication should be checked for technical accuracy before it is disseminated. Similarly, the drafting team members need to have a good understanding of biosafety policy and regulations, and be able to describe these clearly and accurately. They also need to consider how information or implementation will impact on the different stakeholder groups and anticipate concerns that can be addressed when any announcement is made. This requires understanding the potential impact of decisions beyond their immediate application.

# 2.5. High quality information

Quality information is communication that is accurate, accessible, balanced and sufficient (not too much and not too little). Obvious inaccuracies lower the credibility and usefulness of biosafety communication. However, inaccuracies in biosafety communication are most often unintentional, resulting from poor wording and insufficient editing. Inaccuracies may occur when technology descriptions are simplified, but it is important to balance detailed descriptions with the need for clarity and accuracy. For example, public awareness talks may state that "all cells in a living organism contain a complete set of the DNA needed to make up that organism". This helps the layperson understand how a single plant or animal cell can be regenerated into a whole new organism. However, in fact, germ cells contain only half the DNA needed to make the whole organism and some mature cells lose their DNA altogether, such as red blood cells. In the interests of clarity, it is not necessary to mention these exceptions when the aim of the communication is to improve public understanding of biotechnology. Many would agree that this simplification does not impact on the credibility of communication materials.

Instituting mechanisms and procedures to edit and check all biosafety communication information before it is released greatly reduces the likelihood of inaccuracies.

In the current standoff between those that support biotechnology and those that do not, a large amount of "biosafety communication" has been issued that is filled with intentional inaccuracies (misinformation). Some of these ideas have spread so far that they are believed to be fact by a wide range of like-minded or ill-informed readers. Knowledgeable experts are able to identify and debunk these ideas. For example, many people have been led to believe that a "terminator" gene is present in all approved transgenic crops. This gene supposedly prevents farmers from keeping back seed for planting in the next season. There are no approved transgenic crops on the market that contain 'terminator technology'.

The Internet is a primary source of inaccurate information, and activist websites can be used effectively to disseminate ideas that have not undergone sufficient testing or review. However, the Internet is also an excellent source of very good information. The secret to using the Internet effectively is in being able to distinguish between sites that are poor sources of factual information and those that are sources of reliable information. For science-based information the source should have undergone peer review, although experience tells us that even this may not always eliminate poor science. Where there is doubt, a review by local scientists who hold a neutral view of biotechnology is a useful mechanism for regulators to evaluate the quality of new information.

Providing sufficient information means striking a balance between providing too much or too little information. The correct balance can be achieved by considering:

• The purpose of the information;

- Understanding the target audience
  - their interests and knowledge level;
  - o their time constraints; and
  - o their preferred mechanisms for accessing information.

It is possible to decrease the volume of biosafety communication by providing contact details for obtaining additional information, thereby eliminating the use of detailed and wordy formats. Some agencies, *e.g.*, the Canadian Food Inspection Agency, use decision documents to provide ongoing public awareness. This is achieved by including an outline of the national biosafety process in the introduction in order to put the decision into a clear context.

# **2.6. Neutrality**

Biosafety offices strive to produce information that neither promotes nor negates biotechnology, but instead provides a neutral assessment of the facts and the decisions that are made. In aiming for neutrality, regulators focus their communication on the policy that supports the biosafety process, the process itself, risk assessment, risk management and biosafety compliance. Achieving neutrality in biosafety communication is a real skill. It is best developed through careful consideration of wording and proactive drafting of key messages and templates for notifications and decisions. In some countries the biosafety policy requires the inclusion of benefits in decision making, and these can be added without compromising the neutrality of the regulators.

# 2.7. Make information accessible

Biosafety communication information must be accessible to stakeholders and interested parties if they are to read it and remain informed. Internet is the most commonly used method of communication for national biosafety offices. This provides a convenient and inexpensive mechanism to provide easy access to national biosafety information. However, access to the internet can be restricted, intermittent or unreliable, especially in developing countries. Where the internet is not a good source of information for interested and affected stakeholders it is best to use existing channels for government communication and to supplement these with a website. The existing methods of communication could be published updates, such as a government gazette and radio updates, where these are already in common use. While the government gazette is an official communication channel, it is not widely read or distributed and it may not reach all stakeholder groups.

If Internet is not a source of information for all stakeholder groups, the biosafety office needs to identify other working communication mechanisms that could be used as needed. Newspapers and printed information are both expensive, thus should be carefully considered. Complex distribution mechanisms to a wide section of the population are also too costly and time constraining to implement on a regular basis. The Philippines was aware of the high cost of printed information and so required public information meetings in communities where confined field trials would be run. This worked effectively for the first few trial sites, but became too onerous and expensive when multiple trial sites were being approved at multiple locations. Also, attendance at these meetings dropped off when understanding in target communities increased. Therefore, by not realizing these constraints when the policy was being drafted, the regulations had to be changed to remove the requirement for the public meetings for all confined field trial applications. Had the initial policy required public consultation when this is deemed necessary, the revision of the regulations would not have been needed.

### 2.8. Maintain transparency

Transparency provides a framework for openness and access that helps to build public confidence in the regulatory system and in the ability of the regulators to uphold the interests of the affected stakeholders. It is established through good communication and a mindset that aims for openness and disclosure. Biosafety

offices should strive for transparency in:

- How policy is established;
- What policy changes are coming up for consultation;
- How the biosafety process is implemented;
- What decisions have been made; and
- The rationale for these decisions.

Transparency is supported by forward planning. A well planned communication process enables regulators to react openly, clearly and quickly to questions and issues as they arise.

# 2.9. Consistent terminology

Terminology needs to be standardised across all communication coming from the biosafety office. The starting point for terminology definitions is the biosafety law. Terms defined in the law should be used consistently in subsequent communication, and it will be necessary to define additional terms as new activities are included in the decision making process. The development of a terminology list is a valuable resource from which terms can be taken to build document-specific terminology definitions.

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# 3. Strategy development

A well-planned biosafety communication strategy has a multi-pronged approach; is focused on the specific needs of specific stakeholder groups; is timely in terms of message delivery; is designed to obtain feedback; is proactive; and is prepared to be reactive. The value of a carefully outlined and planned communication strategy cannot be over emphasized. The scope of biosafety communication is wide, and there are rarely enough resources to do all the activities believed to be important. Preparing a communication strategy is the best way to ensure that maximum impact is achieved with the available resources.

The strategy planning process begins with a clear understanding of the purpose of communication initiated by the biosafety office. Biosafety communication includes access to information on the biosafety mandate and processes, increasing public awareness, and public consultations. Once the purpose of any communication is clear, it is necessary to identify the targeted stakeholder groups who should receive the information and participate in communication activities. The needs of these target groups must be understood to ensure they are clearly addressed in any outreach. It is useful to identify how various stakeholders prefer to receive information and which communicators have the most credibility with specific groups.

Proactive preparation of key messages helps ensure that there is consistency in the information that is issued verbally or in writing. These messages also prepare staff to address questions and concerns that may be raised. A communication work plan will help to ensure that the communication has an impact and that resources are used effectively and efficiently.

A communication strategy ensures that the biosafety office has a process to implement effective communication in a timely and cost effective manner. There are three major questions covered in biosafety communication:

- The first one deals with whether transgenic crops and foods are safe, and whether they are being effectively regulated. This question focuses on safety, but also raises non-safety issues, such as the socioeconomic impact of new products, and how decisions are made.
- The second questions which products are transgenic and raises issues of choice and the right to know what one is eating. This answer requires some understanding of the technology and how it is used in the context of biotechnology.
- The third question focuses on the biosafety process, what the requirements are for specific activities in the country, and the requirements for trade and export of products that may contain transgenic organisms or ingredients.

Two types of information address most questions directed by stakeholders and the public to a biosafety office:

The first is information on the regulatory process. This includes information on the national process for approvals; the requirements for different activities with transgenic organisms; how applications are reviewed; how decisions are made and who is involved; the available mechanisms for public participation; information on approved activities and products; and access to regulatory decision documents.

The second is general information on biotechnology that can be used to increase awareness and understanding of biotechnology and genetic engineering. This includes background information on the products already approved. To maintain a clear distinction between regulation and promotion of biotechnology, it is best to provide this information through links to technology sites in government, the public sector research organisations, academia and the private sector. These links could include academic sites that expand on the risks and benefits of adopting transgenic organisms and products derived from these.

On a day-to-day basis biosafety offices need to respond to questions, queries and challenges about the biosafety policy, the processes used by the office and the decisions that have been made or are under

consideration. As a continuous background communication process, the biosafety office needs to provide information that will raise public awareness. For this aspect of the communication strategy there are three key elements that will help to capture the public's attention:

Information on biosafety should be:

- Easily available;
- Easily understood; and
- Interesting (but not embellished!).

The delivery of information depends on the culture and infrastructure of a country, but may include one or more of the following tools:

- Television;
- Radio (especially in rural areas of developing countries);
- Print, especially newspapers and magazines;
- CDs/ DVDs
- Internet (some countries); and
- Public workshops and seminars, including field visits.

Understandable information requires that the biosafety office considers the most appropriate language or languages to use, as well as the literacy rates in the targeted stakeholder groups. Understandable information needs to be free of scientific jargon and should have clearly simplified scientific or technical details. Ensuring that the format and layout of the information is uncluttered with large print increases the clarity of messages. It is important to take care not to overburden any message with unnecessarily detailed information. Unbalanced information that promotes, clearly or subtly, or denigrates biotechnology will also be picked up by the reader and may cause them to stop reading or listening.

Creating interesting information is always a challenge when writing about regulation and compliance! Dull, lengthy expositions will not capture anyone's attention long enough to impart any knowledge. Biosafety communication needs to be in an attractive format with captivating pictures and short, punchy content. Use links to direct interested readers to more detailed information. Regarding the content, it is valuable to include what is immediately relevant to the reader and, where possible, to illustrate the relevance with real-life stories of people's experiences.

Accessible communication needs to be targeted to specific stakeholders to meet their specific needs and it should be well timed to ensure relevance and effectiveness. Generic information is less effective at meeting the specific needs of different stakeholders. It should be available for interested stakeholders who are looking for less specific answers and more general background.

# 3.1. Key features of a communication strategy

Developing a communication strategy is a simple process that can be outlined and completed in a short space of time. The key components of the strategy development process are:

- Determine the purpose/goal of the communication;
- Identify the stakeholders and group them according to information requirements;
- Consult the stakeholder groups on their biosafety communication needs;
- Establish the key messages about the biosafety process;

- Create a timeline and work plan for the delivery of critical communication;
- Identify effective communication tools for specific components of the biosafety communication strategy;
- Identify the best communicators for specific stakeholder groups;
- Establish protocols for emergency communication, and
- Implement the communication strategy within resource constraints.

#### **3.2 Stakeholders**

The stakeholder groups identified by country biosafety communication strategies have included some or all of the following:

- Relevant government ministries, departments;
- Members of parliament and portfolio committees;
- Industry (agriculture, forestry, fisheries, energy, food, health, industrial, etc.);
- Scientific community;
- Extension officers, health workers and NGOs that can disseminate information to growers;
- End users (farmers, consumer groups, *etc.*);
- The media; and
- International and regional groups active in biosafety, trade, environment, health and development.

Each of these stakeholder groups will have specific requirements with respect to the information they wish to receive, the format in which it is received and who best to deliver the messages.

The value of developing biosafety communication to meet the needs of specific target groups is undisputed. This targeted approach will help achieve judicious use of resources and ensure that communication is effective and efficient. By understanding the specific needs of primary stakeholder groups, the biosafety office can ensure that their communication is welcome, informative and has the desired impact.

#### 3.2.1. Conducting a needs audit

The basis of any communication strategy must be a good understanding of the stakeholders who are interested in and affected by the biosafety policy and regulatory implementation. In addition to knowing who these stakeholders are, it is important to understand the communication needs of various groups within the pool of stakeholders. Thus, prior to establishing a communication strategy the regulatory office must identify the key stakeholders and undertake a needs audit with members of these groups to determine their specific information needs.

Needs audits are best undertaken by talking to representatives of each stakeholder group. It is rarely necessary to organise a meeting to audit the specific communication needs of stakeholders, as these groups will have many reasons to meet on biosafety issues during the establishment of the policy and the implementation of the regulations. Thus, they are already known and can be easily contacted by email or telephone, or spoken to informally at other biosafety meetings. The biosafety office will use the audit to identify how best to contact specific stakeholder groups, who the group would want to hear from on biosafety issues, and which biosafety activities and decisions are of particular interest to each group. Identifying and using existing communication mechanisms within the groups can help to facilitate information dissemination. For example, sector newsletters or listservs offer existing communication routes for dissemination to groups associated with

agriculture, animal husbandry, health, food, forestry, etc.

#### 3.2.2. Prioritising needs and using timelines

While it is commendable to want to address all the communication needs of all the stakeholders this is rarely feasible because of financial and human resources limitations and the complexities of reaching some stakeholder groups in rural communities in Africa. To have an effective communication strategy it is necessary to prioritise communication according to the greatest impact in meeting the legal responsibilities of the biosafety regulators, building awareness of the biosafety process, sharing essential information with affected stakeholders, and building the public's trust in the ability of the regulators to protect the interests of the public and forward the economic development agenda of the country.

The development of a communication strategy for the biosafety office helps to ensure that communication is both efficient and effective. Effective communication meets the needs to the stakeholders. Efficient communication is well timed, focused and optimises the use of available resources. Identifying critical time points where communication should be provided helps to streamline outreach and ensure efficient use of available communication resources. For example, stakeholders who are interested in the testing of new transgenic organisms might want to be alerted when applications for confined field trials are received. Stakeholders who are interested in food safety might want to know when approvals are given for import of commodities that may contain transgenic organisms and when applications are received for general use of transgenic food crops.

#### 3.2.3. Best outreach tools for stakeholder groups

Determining the best mechanism to reach specific stakeholder groups and to get their feedback, where needed, will have an impact on the cost effectiveness of biosafety communication activities. E-mail is a popular communication tool, being both cost effective and quick. Where email is inaccessible, then other mechanisms will need to be considered such as radio, newspaper and even NGOs and extension workers. Politicians and high ranking civil servants may not screen their own email and reaching them on specific issues may require innovative mechanisms for delivering information. These tools are discussed in more detail in Section 4.

#### 3.2.4. Best communicators for stakeholder groups

Finding credible communicators has a positive impact on the effectiveness of communication. Leaders and decision makers prefer to hear from people with status in the community or country. Scientists relate well to information from peers and credible deliverers of information to the public may vary depending on topic. Food safety messages may be best received from people with standing in the human health field, or from nutritionists and clinics. Farmers may prefer to hear from extension officers and agriculturalists that they know and trust. Industry will want to hear from the regulators and be able to ask probing questions about what impact the issues will have on their business practices, *etc*.

Effective risk communicators should be identified for each stakeholder group. There may be some communicators who are well suited to interaction with more than one stakeholder group and others who are chosen to deal specifically with one group. These communicators may be staff members in the biosafety office or other people, like scientists and academics, who are invited to help with outreach to specific groups of stakeholders. Generating a list of potential communicators for specific stakeholder groups allows the biosafety office to work with this group in training and to have a pool of trained resources to access as needed.

In general, the effective communicators need to have credibility with the stakeholder group, to be trusted and sincere, have good language skills and have good listening skills. Biotechnology surveys in some countries (SAASTA, 2004; Eurobarometer, 2005) have investigated and identified communicators that the public considers credible sources of information on biosafety. These vary from country to country and depend on the cultural norms and social context.

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#### 3.2.5. A communication work plan

The final output of an effective communication strategy should be a work plan that will detail the how, when, who and why of implementing the biosafety communication activities. The types of communication activities, the timeframes and the responsibilities should be clearly set out. This form of planning helps to ensure that good communication will be implemented within the time and resources constraints of the biosafety office. The work plan should ensure that communication activities are planned to focus on biosafety processes and milestones, such as the implementation of new regulations, the approval of new transgenic activities and opportunities for public participation.

#### 3.3. Messages

Biosafety offices need to develop skills and tools to deal with risk communication, which, by its very nature, can be urgent and emotive. Experience has shown that challenges to biosafety systems can be driven by misinformation, so an immediate response needs to provide quick, clear and accurate information to counter any inaccuracies. Achieving speed, clarity and accuracy requires pre-planning and careful consideration. These resulting messages should be officially approved to be delivered at any time without further approval. Message planning can be undertaken in several ways and these are detailed below.

#### 3.3.1. Key messages

A central feature of any communication strategy is the development of key messages about the biosafety office and the biosafety process. Key messages are the information the biosafety office wants people to know about its activities and the regulatory process. They are different to message maps (discussed in the next section), which address questions from stakeholders. Key messages are distilled by the biosafety staff and reflect the most important facts that should be known about biosafety in the country. Once established and circulated to all staff, the key messages can be expanded to include sub-messages and message priorities for specific stakeholder groups.

For example, the key messages for a national biosafety office may cover one or more of the following:

- The authority under which the national biosafety office is established and operates;
- The relevance of biosafety to citizens and stakeholders;
- The activities that trigger biosafety;
- The importance of risk assessment;
- The way biosafety decisions are made; and
- The opportunities for public participation.

Each key message should be short, concise, and completely free of jargon. Sub-messages can be developed to expand on aspects of the key message. For example, the message on the authority given to the biosafety office may state: "Biosafety is authorised by national laws". A sub-message would add the details to be used only when needed, *e.g.*, "National Biosafety Act No. 21, 2007; National Environmental Protection Act No. 56, 2006, Section 13. An example of the layout of key messages for a national biosafety office is shown in Figure 1.

Once the biosafety office has identified the key messages about national biosafety, and has expanded these to sub-messages containing additional facts, this key message diagram forms the basis of all communication from the office. These are messages that are approved for all staff members to use at any time. They are also the key points that communicators from the biosafety office should try to deliver at every opportunity. As communication is developed for specific stakeholder groups, it may be valuable to identify which of the key messages are most relevant to each group. This will help to ensure that all communication with these groups

contains the most important messages that meet their communication needs. Once these key messages have been delivered in any new communication, it is okay to add additional information that addresses specific concerns or needs which are not addressed by the key messages. These secondary messages may be of particular interest to a specific group of stakeholders. The wording on these will need to be reviewed and approved, and once approved, these additional messages may become sub-messages under specific key messages for that group.

The value of working with key messages is that these approved texts can be used at anytime by anyone authorised to talk about the work of the biosafety office. This helps to streamline communication, making rapid responses possible and ensuring that important information is delivered at each communication opportunity. Key messages also help to keep communication consistent, no matter who is being interviewed or who in the office is preparing a statement.

Communication trainers encourage communicators who attend interviews, or workshops or speaking opportunities to arrive with three key messages already identified. The communicator needs to work all three of these into the communication opportunity regardless of the questions asked. This is a proven mechanism for ensuring that no matter how difficult an interview is the biosafety office will always have put important information into the hands of the public, and interested and affected stakeholders.

Vincent Covello, a well known risk communicator, (<u>http://info.med.yale.edu/eph/ycphp/messagemapping.pdf</u>) suggests the following guidelines for establishing key messages:

- Limit the number of key messages to about three;
- Supplement these with about three sub-messages that address underlying, related concerns or specific questions;
- Keep each key message to about 9 words maximum (be concise);
- Aim to present all the key messages in a maximum of 30 seconds (be brief);
- Prepare messages that are understandable for 12 year olds (be clear);
- Order the messages so that the first and last ones are the most important;
- Cite credible third parties, when appropriate;
- Use visual aids to enhance key messages, where appropriate; and
- Balance negative key messages with positive or constructive solution messages.

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Figure 1. Example of the layout of key messages and sub-messages for a national biosafety office.

#### 3.3.2. Message maps

Message mapping is a valuable concept refined by Vincent Covello (*viz.*) for use in risk communication. This tool is used to prepare proactive responses to questions and challenges from key stakeholder groups. Having identified the stakeholder groups relevant to national biosafety, the communication team should spend some time developing message maps that can be used to respond to these sectors. The team needs to identify the questions and challenges that will most likely be raised by each stakeholder group, and then identify a set of supporting facts that will provide a reasoned and accurate response. It is suggested that the planning team considers the following aspects in relation to each stakeholder group during the planning of message maps (adapted from Covello: <u>http://info.med.yale.edu/eph/ycphp/messagemapping.pdf</u>):

- Health and safety;
- Ecological impacts;
- Economic impacts;
- Quality of life;
- Equity, access and fairness;
- Cultural and symbolic norms;
- Legal and regulatory issues;
- Basic information (Who, What, Where, When, Why);
- Openness, transparency and access to information;
- Accountability;
- Options and alternatives;

- Control (economic, political, etc.);
- Benefits; and
- Trust.

When message maps are established to deal with questions and challenges from key stakeholder groups, these message maps need to be approved and made available to all staff members for immediate use. Depending on the urgency of the request or challenge, any communication in response to this should take these messages into consideration and the message maps should be reviewed to identify approved wording and to be sure that all the important messages are relayed at the time of the response.

Covello's suggested format for the biosafety message maps is provided in Table 1, and an example of a message map for one biosafety stakeholder group is provided in Table 2.

 Table 1. Message map template adapted from Covello (<a href="http://info.med.yale.edu/eph/ycphp/messagemapping.pdf">http://info.med.yale.edu/eph/ycphp/messagemapping.pdf</a>).

Stakeholder group:		
Question / Concern:		
Response Message 1	Response Message 2	Response Message 3
Supporting Fact 1.1	Supporting Fact 2.1	Supporting Fact 3.1
Supporting Fact 1.2	Supporting Fact 2.2	Supporting Fact 3.2
Supporting Fact 1.3	Supporting Fact 2.3	Supporting Fact 3.3

#### Table 2. Example of a message map developed to respond to a challenge about the national biosafety system

#### Stakeholder group: Activists Question / Concern: The biosafety system in [country] is unable to assess the safety of imported transgenic food. **Response Message 1 Response Message 2 Response Message 3** All transgenic foods imported into Approvals are based on scientific Transgenic foods approved and [country] require biosafety approval. evidence of safety consumed in other countries are considered safe for local consumption. Supporting Fact 1.1 Supporting Fact 2.1 Supporting Fact 3.1 The Biosafety Act (#44, 2009) Foods derived from transgenic Transgenic food approvals are based stipulates that imported transgenic organisms are assessed for safety with on international standards for food commodities must be approved before respect to allergenicity, composition, safety assessment. entry into [country]. toxicity, nutrition and changes to intended use. Supporting Fact 1.2 Supporting Fact 3.2 Supporting Fact 2.2 **Biosafety Regulations (2010, Section** International standards for food safety If specific use or vulnerability is 10) require importers to declare the assessment are applied to foods identified in local populations then additional food safety testing may be presence of transgenic imports and derived from transgenic organisms. apply for biosafety approval. required.

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Supporting Fact 1.3	Supporting Fact 2.3	Supporting Fact 3.3
The process for approval of imported transgenic food is functioning in [country] and is implemented by the [biosafety agency].	[Country] reviews the safety of imported transgenic food products taking into consideration aspects that are specific to its citizens and communities.	[Country] food safety labelling laws require any safety aspects of foods to be clearly labelled on the food items.

With these message maps at hand, authorised staff at the biosafety office will be able to respond to questions and challenges immediately with consistency, clarity, and accuracy. The prior approval of the message wording allows the biosafety office to respond quickly and openly to questions which helps to raise their credibility and transparency in the eyes of the stakeholders. These message maps can be used to devise "frequently asked questions" (FAQs) documents that can be accessed from the biosafety website.

#### 3.3.4. Quick messages

How does a biosafety officer respond to a stakeholder or community leader when asked 'What do you do?' Biosafety is a complex service that is not easily explained to a lay person. However, if biosafety officers wish to appear open and frank and to use these opportunities to raise awareness of national biosafety, then a quick response to this and other questions should be prepared and memorised for easy use.

The quick messages are used in situations that allow only a short, uncomplicated answer, such as meeting someone at tea break during a conference, or at a government / stakeholder networking function. While the opportunity may seem small the response will form an opinion in the listener's mind that could last a long time. Thus, taking time to brainstorm wording for quick messages is well worth the effort, because of the impact this could have on raising awareness of biosafety and the role of the biosafety agency.

# Questions that require quick responses include:

#### What do you do? / What is your job?

Possible answer: I am a scientist / administrator / manager in the [county] biosafety agency. We regulate the safety of genetically modified organisms.

#### What is biosafety?

Possible answer: Biosafety is a process that reviews the safety of new transgenic organisms before they are approved for testing or use in [country].

#### Are transgenic organisms safe?

Possible answer: Any approved transgenic organism has been assessed for its safety and has been found to be as safe as or safer than conventional organisms.

#### What is transgenic in [country]?

Possible answer: [Country] has approved the use of a number of transgenic medicines, food ingredients and crops. Details are published on the agency website.

#### What is a transgenic organism?

A transgenic organism is a plant, microbe or animal that has been genetically changed to improve it in some way. An example is maize that can protect itself against insect attack or drought.

# 4. Channels and tools for communication

When planning the dissemination of information, a biosafety communicator must consider how the information is presented and how it will be delivered. This is necessary to find the most effective means of communicating with each target group of stakeholders. The methods of delivering information and obtaining feedback may vary considerably from group to group. For example, a twelve page scientific report is unlikely to be read by members of parliament who are too busy to plough through volumes of technical information and who might be frustrated by the technical nature of the writing. When determining how to reach specific stakeholder groups it is good to first review how they already receive information. These existing channels

may be the preferred and best means of information delivery to a target group. Consider, too, how the stakeholder groups already interact with regulatory departments, and whether existing channels can be used to obtain input and feedback.

In addition to finding the best routes for information sharing, it is also necessary to consider the packaging of the information. Choices between long, detailed reports and short, snappy facts can be critical in ensuring that the communication is read and makes an impact. Appropriate packaging and delivery systems help to ensure that the information is accessible and of interest to the target group. **Consider existing communication routes** 

For example, when communicating with consumers about the presence of approved transgenic ingredients in the food supply, it may be useful to review how consumers were informed of other changes in the food supply, such as vitamin-enriched bread and fortified maize. This may identify existing, functioning mechanisms of mass communication regarding foods.

The choice of language is also an important consideration. While it is desirable to provide communication in many languages, this is seldom feasible and may be less effective than concentrating on one or two languages with the widest outreach. These decisions need to be made in terms of the available resources and the mechanism for greatest impact. In some countries, information provided in the primary language is picked up and translated into additional languages by existing public and private sector operators in various parts of the country, including extension officers, NGOs and the media.

Special delivery considerations are needed for illiterate or semi-literate audiences.

# 4.1. Electronic communication

Rapidly the Internet is becoming the preferred mechanism for information sharing, for engagement, and for obtaining feedback from a wide group of stakeholders and interested people. This is true for both developed and developing countries, as increased computer availability and the expanded mobile phone service improve Internet access. While it should be remembered that not all stakeholders have access to electronic communication in rural Africa (see §4.2, §4.3, §4.4), electronic communication is the most efficient and most cost effective means of information sharing. As such, building good tools in the biosafety office for electronic communication is essential.

#### 4.1.1. Website

A website is the primary tool for electronic communication. One should be established for the biosafety office and its set up should be easy to manage and also easily accessed by viewers. Easy access means avoiding memory rich aspects that will slow down the time it takes for stakeholders to access the site and find information. A simple, clear layout is most professional. Flashy, gaudy eye-catchers are best avoided, after all, the people who visit the site are already interested in the biosafety information; they do not need to be lured.

Professional assistance with the set up of the site will ensure that optimised search words help stakeholders

and interested people to find the site easily and navigate through the information that is provided. People will be looking for:

- contact details for the office;
- information about the processes needed to obtain permission for transgenic activities;
- access to the biosafety regulations;
- forms for applications;
- composition of the committees and decision making bodies that oversee the safety and socioeconomic reviews and decision making;
- details on decisions; and
- transgenic organisms and products that are approved and are being used in the country.

Links can be used to direct readers to the legal instruments and to background information on biotechnology and specific transgenic organisms. Using links allows the biosafety website to focus on safety and not on promotion of biotechnology.

Highlighting opportunities for public and stakeholder participation will be popular with interested and affected parties. Many biosafety offices develop a contact list of stakeholders and interested parties, and offer regular readers access to automatic delivery of updates, opportunities and summaries of activities using tools such as listservs.

#### 4.1.2. Listservs

Listservs are used to keep interested stakeholders updated on new information that is posted on the website, or is issued by the biosafety office. Stakeholders are invited to join listservs. If they accept this option, they are notified through their email service of all new additions and updates to the site.

It is important to use this option judiciously as numerous unimportant messages can be tedious and will cause stakeholders to remove their names from the listserv option. However, posting of revisions to regulations, meeting dates and venues for consultation, new applications, and decisions are all interesting updates that are useful for stakeholders to get notification of through the listserv.

#### 4.1.3. Social media

The expanding use of smart phone technology makes the growing social media options a valuable tool for aspects of biosafety communication. Social media options are popular with the younger generation, leaders and the media. They provide useful tools for rapid response to misinformation and for monitoring public sentiment. Social media tools stimulate discussion of topical issues which may be initiated or followed by the biosafety office.

Until a biosafety office is functional and is receiving applications regularly there may be few opportunities to use services such as Twitter or Facebook. However, as activity increases the biosafety communicators should assess whether these, or other social media tools, might be valuable for mass communication with interested parties in a country.

### 4.2. Print communication

Print communication has been the stalwart of outreach for decades. However, the value of this form of communication has decreased in the wake of electronic communication tools. While print communication was valued as a more permanent information source, people with access to electronic media are storing less and less paper in their offices and homes. Nevertheless, there is still a place for printed communication in

biosafety offices. Much of this will be developed as an electronic resource and posted on the website, rather than printed and distributed by the office. Interested stakeholders will print copies of the materials they need.

Some stakeholders may still need printed communication. This will be determined by cultural norms and specific stakeholder requirements. While it was normal practice to hand out printed information at workshops and public consultations, much of this information is now placed on DVDs for delegates to take home and access as needed. Some of the more commonly used printed materials are listed below.

**Brochures**. A short brochure, one page folded, about the structure and functioning of the national biosafety process is a valuable asset for communication. It can be published on the website in full colour and printed in one colour for handouts at meetings and workshops.

**Flyers**. These are usually inexpensive publications for a specific purpose, such as informing the public about information meetings. They can be printed on low quality paper and the cost of distribution needs to be taken into consideration. For example, if the approval of a confined field trial site requires notification and consultation with communities in the area, then a flyer could be distributed at a local market informing people of the date, time, venue and purpose of the meeting.

**Newsletters**. Newsletters are best used with an established group of interested people and when there is enough new activity and decision making to fill the pages regularly through the year. This is seldom the case with biosafety, but has been used successfully with biotechnology awareness where the new developments in genetics and the development and testing of transgenic applications keep the content flowing.

**News bulletins**. These are published when there is something of interest to report. They are distributed to interested and affected parties. Now, this distribution is primarily through a website.

**Policy briefs**. These are useful to improve understanding of the purpose and scope of the many pieces of policy that impact on biosafety in any country. Once drafted, they provide a communication resource that will be accessed by new users of the biosafety services and by others who are comparing policies or looking for guidance in their own policy development. Providing this information will reduce the number of questions that the biosafety office receives on aspects of policy, applications and timing with respect to specific transgenic activities.

# 4.3. Public meetings

Public meetings on the biosafety system are generally aimed at information sharing and consultation. Information is shared in public meetings when new policies or activities are likely to impact on local communities. These meetings can be combined with existing community meetings, shows and exhibitions. They are a valuable mechanism for reaching illiterate and semi-literate stakeholders.

Public meetings enable regulators to ensure that stakeholders and affected parties are adequately informed about the activities and their potential impact, and to obtain feedback on the acceptability of the proposed policy or planned activities. This information is assessed after the meeting and used to inform policy development and decision making. As such, these meetings are generally held before policy is finalised or before a decision with potential impact is taken.

However, some risk management conditions may require public meetings to inform local affected parties of activities that have already received approval.

# 4.4. Broadcasts

In countries where governments and citizens regularly deliver and receive information via radio or television, these may provide viable routes for sending information to specific stakeholders. However, the use of radio and TV for general communication appears to be decreasing with the increased use of the Internet and

websites. One possible exception is the use of radio programs directed at the farming community in many countries. Where these are still popular, they provide an affordable mechanism for reaching growers and farmers.

Information to be shared on broadcast sites is supplied to the broadcaster in the form of a typed information release, or may be part of an interview where a member of the biosafety office is interviewed to provide more in depth information and enable feedback through phone-in or e-mail opportunities. Radio and television messages and interviews are a valuable mechanism for reaching illiterate and semi-literate stakeholders.

# 4.5. Labelling

Labelling is sometimes proposed by consumer groups as an information source for consumers, but regulators are cautioned to consider just how much information can be delivered in this way. There is very little information that can be presented on a food label. Currently food labelling is focused on safety issues, such as the possible presence of allergens or ingredients that may be responsible for food intolerances. The need for these labels is automatically triggered when transgenic food has these risks and no additional labelling requirements are needed to ensure this.

As food labels expand to present information on their agricultural production method (e.g., organic, free trade) and source (e.g., locally produced or country of origin), there has been considerable pressure to indicate whether the ingredients are derived from transgenic organisms. This pressure is aimed at providing choice, but can be mistaken as a safety warning label. As such, regulators have to consider how effective labelling will be at raising public awareness without also raising unwarranted safety concerns. Assessing the effectiveness of food labelling needs to take in to account the following issues:

- The practicality of labelling: whether all foods that contain transgenic ingredients can be labelled and how fresh produce will be labelled at informal food stalls;
- The amount, quality and value of information on a label;
- The cost of labelling and how this cost will impact on food prices;
- The number of people who read labels; and
- The government's ability to monitor compliance in formal and informal markets.

In many countries assessments of the value of food labelling for general awareness and choice have indicated that alternative mechanisms for mass information are more effective for enabling choice than individual food labels. If the reason to label is to share information, then the communicators need to determine how effective this will be and how it will impact on food costs.

# 5. Information for applicants

The most essential communication is with the stakeholders who will use the biosafety process. This information will help them to assess what is required from them with respect to regulatory approval for activities they plan to undertake with transgenic organisms.

# 5.1. General

There are a number of websites available that deal with general information about biosafety, what it is, why it is necessary and how it is implemented. Links to these sites provide a quick resource for new stakeholders without requiring any development resources from the biosafety office.

These sites explain:

- The principles and the implementation of biosafety assessment and risk management;
- The role of the Cartagena Protocol on Biosafety;
- Databases of regulatory decisions in countries and in regions;
- Biosafety information on transgenic organisms that have been approved for planting and as food and feed;
- Databases of biosafety legal instruments that are in effect in various countries and regions; and
- How transgenic organisms are made and how they are used to supplement existing technology in various sectors.

The rest of the biosafety information is country-specific, thus must be developed and made available by the biosafety office. Preparing this information should be a priority because it provides the guidance needed by the stakeholders to access the biosafety process. Ensuring the quality and accessibility of this information will play a large role in reducing the workload of the biosafety office with respect to day-to-day

# Some examples of sites offering general information about biosafety

The principles and the implementation of biosafety assessment and risk management:

- Center for Environmental Risk Assessment <u>http://cera-gmc.org/</u>
- Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management http://bch.cbd.int/onlineconferences/ahteg\_ra.shtml

The role of the Cartagena Protocol on Biosafety:

http://bch.cbd.int/protocol/

Databases of regulatory decisions in countries and in regions:

- Biosafety Clearing House
   <u>http://bch.cbd.int/database/decisions/</u>
- Center for Environmental Risk Assessment <u>http://cera-gmc.org/index.php?action=gm\_crop\_database</u>
- GMO Compass <u>http://www.gmo-compass.org/eng/gmo/db/</u>

Biosafety information on transgenic organisms that have been approved for planting and as food and feed:

• Center for Environmental Risk Assessment <u>http://cera-gmc.org/index.php?action=gm\_crop\_database</u>

Databases of biosafety legal instruments that are in effect in various countries and regions:

• Biosafety Clearing House <u>http://bch.cbd.int/database/laws/</u>

How transgenic organisms are made and how they are used to supplement existing technology in various sectors:

 South African Agency for Science and Technology Advancement <u>http://www.pub.ac.za/index.php?option=com\_content&view=</u> <u>article&id=29&Itemid=90</u>

enquiries for direction on how to carry out various aspects of the biosafety regulatory requirements. These

guidance documents need to grow with the system and should be easy to revise. They should be routinely reviewed and kept up-to-date, reflecting the very latest information on the biosafety requirements for each of the activities.

# 5.2. Scope of the national requirements

This communication informs developers and users about what activities are covered by the national biosafety regulations. The information is paraphrased from the legal instruments in non-technical language. It clearly lays out what organisms are considered transgenic under national law, and what activities with these organisms require some regulatory action on the part of the developers or importers of transgenic organisms. This information provides contact information for stakeholders to discuss their products with the regulatory office and get clarity on how they will be regulated. In general, the scope of a biosafety process will cover plants, animals and microbes that have been genetically altered in a laboratory. Most biosafety systems exclude genetic modifications introduced through breeding or mutagenesis. The activities with transgenic organisms typically include research; development and testing; general use (marketing); import; export; and in some cases, transit through a territory.

From a biosafety viewpoint the amount of exposure to the environment impacts on the risk associated with an activity. As such, biosafety regulators describe three levels of exposure:

**Contained**, which is use within a facility that includes research in laboratories, greenhouses and screenhouses. It also includes the many fermentation processes with microbes that make medicines and food ingredients;

**Confined**, which is controlled release with specific measures to keep the new organisms within a defined area and removal of the organisms at the end of the activity. This is used to test new crops, as well as to test new vaccines in clinical trails;

**Unconfined**, which is the general release of a transgenic organisms for use by the public, such as the sale of seed and planting material and the release of living vaccines or organisms that are used in soil and water remediation.

Products derived from approved transgenic organisms are assessed for safety at the same time as the biosafety assessment of the transgenic organism. For the most part the products are non-living, such as processed foods, enzymes and fibres. Planting materials such as seed, stalks and tubers are living products from the transgenic organisms and will have restrictions with respect to transfer into countries where the transgenic organism has not been approved for general use. Once obtained, regulatory approvals for general use include the approval of the proposed use of any products from the transgenic organism. As such, products from transgenic organisms are given approval at the same time that the organism itself is approved and are not reviewed separately.

### 5.3. Process

Once developers, users and traders have established that there will be regulatory requirements for their activities with transgenic organisms, they want to understand clearly the regulatory process that they need to follow at each stage of the development, testing and release of a transgenic organism. These details will include when to submit applications for approval. This information will identify the points at which applications are required and how long to apply before the proposed start of the activity to ensure that there is a timely decision. This will also indicate whether there is a set timetable for sittings of decision making committees and what the cut-off date for submission is, if the aim is to have the application considered at a specific meeting.

Information should be provided on the format of the applications, whether set application forms are provided, what the quality of the information should be and the text formatting requirements. In addition, there should

be information regarding how the application is submitted; whether there needs to be a hardcopy or electronic copies, and the number of copies of each. Protocols need to be provided for dealing with confidential business information (CBI) and whether a copy of the application with CBI deleted is needed for public review in electronic and/or hard copy. It is important to state where the application should be submitted: a street and postal address for hard copies and an email address for electronic copies.

The process for acceptance, review and decision making should be described so that applicants know what to expect regarding requests for additional information and when a decision can be expected. All process information should be reviewed and updated regularly to be sure that applicants have access to the latest requirements. When updates are loaded onto the website or made available at the office, it is good practice to notify interested and affected parties of the new requirements through email.

# **5.4. Timelines**

Information on timelines for biosafety regulatory reviews and decisions is important to help applicants understand the time it will take to obtain a decision on specific activities. In general, a review process involves an acknowledgement of receipt of an application; a review for completeness of administrative information; a deficiency letter requesting missing information; a scientific review for safety which may result in a request for further technical information; and a decision. For activities that impact directly on citizens there may be need for a public notice requesting public response to the application; a time to respond to issues raised during the public participation; a socioeconomic review to request additional socioeconomic information, *etc*.

# 5.5. Forms

Application forms provide a useful tool for standardising the content of applications and ensuring that adequate information is received. These are stylised forms that are filled in by the applicant and may or may not allow attached files with additional information. Not all activities are suited to the use of an application form, but, where this is possible, it can greatly reduce the time needed for biosafety review and decision making by eliminating unwanted information and helping to ensure that all the required information is provided. Providing an accompanying guideline for each form helps applicants to understand the specific requirements of application sections and is a valuable tool to help ensure that completed application forms are adequate and efficient for the task of biosafety review and approval.

# 5.6. Activity-specific information

Each different type of activity with transgenic organisms is likely to have different application requirements and different review processing. These differences are easily explained by developing separate guidelines that outline the specific requirements for each of the activities, such as: import, export, research / contained use; testing / confined use; and general release / unconfined use.

### 5.6.1. Facility registration

For the most part facility registration requires the submission of a completed application form that clearly states the location of the facility, the person in charge of the facility; the person in charge of biosafety compliance at the facility; the type of transgenic organisms to be developed; the volumes of transgenic organisms to be contained within the facility; a description of biosafety measures at the facility; how biosafety compliance will be monitored and documented; protocols for emergency containment; and who is responsible for communication with the national biosafety office. The review process is likely to include an inspection of the contained facility and an agreement on the biosafety risk level that is approved for the facility, which will determine which activities and organisms can be worked on at the site.

There is usually an indication of how follow up inspections will be undertaken and any reporting requirements

that will be audited during these inspections. Information should be provided on how long registrations are active and directions on how to maintain, extend, or discontinue registrations should be outlined. Any fees for facility registration should be clearly laid out. Communication about the facility registration process should be included in any information about the working of the national biosafety system, and there should be access to information on previous and current facility registration applications under review in the country.

#### 5.6.2. Contained use

Generally contained use applications are submitted for facilities that are already registered, but some biosafety offices process facility registration at the same time as an application for contained use. Communicating the requirements for contained use applications can be provided in guidelines and can be facilitated by creating an application form to be completed and submitted by the applicant. The guidelines and the form should be concise and clear. Communication about the contained use application process should be included in any information about the working of the national biosafety system and there should be access to information on previous and current contained use applications under review in the country.

#### 5.6.3. Confined use

Communication for confined use can include links to international best practices that define the basic requirements for running field trials and clinical trials. The biosafety office can supplement these existing guidelines with country-specific requirements that are needed to ensure compliance with the national laws.

Communication for confined use may, in some countries, require additional communication activities, such as consultations with stakeholders and communities in the trial area. Some biosafety offices use confined use applications to generate public awareness of the biosafety system by publicising the receipt of the applications, any calls for public input and the decisions. Communication about the confined use application process should be included in information about how the national biosafety system works, and information on previous and current confined use applications under review in the country should be easily accessible.

#### 5.6.4. General use

Communication requirements for general use applications can range from non-existent to quite extensive depending on the national regulations. Transgenic organisms submitted for general release approval are likely to be approved for use in the everyday market place with no restrictions or very few conditions. In some countries, decisions on general use applications require some level of public consultation or awareness prior to approval, in order to get feedback from interested and affected parties on the potential concerns and/or benefits of the new products.

These communication opportunities need to be carefully thought out to guarantee that the requirements for both outreach and data collection are met. The development of a standard template for communication on general use applications is a good way to ensure that this communication is consistent and complete across all applications. An approved template can be used by staff members to draft information that will be issued by the biosafety office, and templates can be used to guide applicants in how to merge their communication responsibilities with those of the regulators. Importantly, a clear distinction between regulatory communication and developer communication must be established to maintain the credibility of the regulatory process and to make sure that stakeholders clearly understand the different roles and responsibilities of the regulators about the general use application process should be included in any information about the working of the national biosafety system. In addition, stakeholders will want to know about general use applications that have been previously reviewed and those that are currently under review in the country.

#### 5.6.5. Food and feed imports

Approvals for food and feed imports will have regulatory requirements for communication based on the national biosafety regulations. These may or may not require some public awareness information, in addition to communicating decisions. The extent of the communication will also depend on the resources available to the national biosafety office and careful planning can help to ensure that communication is effective within these constraints. Communication about the food and feed import process should be included in any information about the working of the national biosafety system. In addition, there should be access to information on previously reviewed food and feed applications and applications that are currently under review in the country.

#### 5.6.6. Transit

Transit refers to transgenic material that crosses through a country to get to the country of import. This happens, for example, when shipments of transgenic grain are off loaded at ports and trucked inland to a neighbouring country that has ordered them. Countries that have specific regulatory requirements for the transit of transgenic organisms across sovereign land may have requirements for public communication in this regard. Certainly, it will be necessary to devise clear guidelines for how transit is regulated in the country and what the responsibilities of the applicants are in this respect. Communication about the transit application process should be included in any information about the working of the national biosafety system. Also, there should be access to information on previous transit applications and those currently under review in the country.

#### 5.6.7. Appeals

Where the regulatory process allows applicants to appeal against biosafety decisions, there needs to be clear guidance on how appeals are activated and what the responsibilities of the applicants are in this regard. Once again, an application form with associated guidance helps to simply and standardise the appeal process. Communication about the appeal process should be included in any information about the working of the national biosafety system. There also should be access to information on previous appeals and appeals that are currently under review in the country.

### 5.7. Confidential business information

Confidential business information (CBI) is present in some biosafety applications. This information is confidential mainly because it protects the business interests and competitiveness of the applicant. As the product is developed, more and more technical information is published and/or becomes part of patent applications, putting it into the public domain. As such, the most CBI generally occurs early in the development process when the transgenic organisms are still contained or confined. As the product approaches general release, much of the initial CBI is made public and no longer needs protection. Many general release applications no longer have a CBI component.

National regulatory systems need to have a mechanism to protect CBI so that biosafety regulators can have access to all relevant safety information for their risk assessments. These systems require staff and reviewers to sign confidentiality agreements. They also require the biosafety offices to keep two copies of the applications: one with the CBI present and one with the CBI deleted, but marked, so that its presence is known. The former copy is used for risk assessment reviews and decision making and is only made available to people who have signed confidentiality agreements. The latter copy is available for public access.

Biosafety communication must clarify why CBI is needed in biotech applications, how this is handled by the regulatory office and how this process enables the regulators to have access to all the relevant biosafety data for decision making.

# 6. Communicating biosafety decisions

Neutrality is a key requirement for all regulatory communication, but this is especially important when drafting decision documents that record regulatory responses to specific applications for activities with transgenic organisms. Various types of decision documents are issued from biosafety offices and all aim to be informative without showing any bias towards the technology itself. Decision documents from functioning biosafety agencies illustrate the wide range of formats used for these documents. Some agencies simply record the decision as an entry in a table that lists all biosafety decisions, while others provide some information about the transgenic organisms, and even the process used to reach the decision. There are different types of biosafety decision documents. Some provide scientific risk assessment (biosafety) recommendations or socioeconomic risk assessment recommendations. The main decision document combines components of any review recommendation documents to support the decision on an application to carry out a specific activity with transgenic organisms.

Decision documents function to record the outcome of an application, but also as a communication tool to publicise the working of the national biosafety authority. The content of a decision document depends on the mandate of the decision making committee. Most decision documents accurately summarise the decision, including any conditions that may be associated with a decision that approves an activity. Decision documents may include information on the process used to reach the decision and on the people who participated in the reviews and the decision making.

The content of the decision document is rarely detailed in legislation, but maybe outlined in guidelines that provide the policy for these documents in the biosafety office. Once the format is decided it is useful to create a template for all decisions to ensure that these are consistent and complete. Since regulatory decisions are legal documents, the input of legal advice is essential in developing templates so that the content meets the requirements of the law and is unambiguous. All decision documents need to be signed by the person authorised to issue decisions. In some countries the names and/or signatures of all members of the decision making committee are required. Where the decisions are recommendations from scientific and economic review panels, it is common for these to be signed by all members of the review committee, or by the chairperson of the review committee on behalf of the committee members.

Communication pointers for drafting decision documents:

#### **Contents of a Decision Document**

- Name of the regulation empowering the decision;
- Final decision and any conditions appended to an approval
- Short synopsis of the application:
  - The identity of the transgenic organism(s);
  - An outline of the proposed activity;
- The purpose of the activity;
- The risk assessment process:
  - Summary of the identified risks and the assessment of each of these;
  - Summary of viable risk management options (Terms & Conditions of approval);
- A summary of concerns raised by scientists, government, the public, and stakeholders;
- A list of those involved on the various review committees and in decision making;
- Signature of the responsible regulator; and
- Contact details for more detailed information on the transgenic organism and its regulatory review.
- A decision document that simply states that the proposed activity is "approved" rarely provides sufficient information for interested and affected stakeholders, or for researchers reviewing the

regulatory activities of biosafety offices.

- The decision document should be written in non-technical, layman's language without jargon to ensure that it is widely understood.
- The tone must not support or denounce biotechnology, but must remain neutral, reporting only the facts of the decision.
- Biosafety issues should be clearly stated and, where these have the potential to result in undesirable impact, the approved risk management options should be carefully laid out with an explanation of how these will help to mitigate any risk.
- The decision document is the key guidance for drafting the permit or other form of approval, so it must contain all the risk management conditions required for safe implementation of the activity.

National biosafety decision documents are generally issued for each biosafety decision, but may cover many transgenic organisms depending on the type of activity.

Importantly, decision documents are legal documents and may become the focus of legal challenges or appeals. For this reason, care should be taken in drafting and reviewing decision documents before they are made public, and legal advice should be used in developing templates that can help ensure the clarity and consistency of the content.

Countries that are Parties to the Cartagena Protocol on Biosafety have an obligation to submit certain biosafety information to the Biosafety Clearing House<sup>1</sup> (BCH). This includes the submission of biosafety decisions. Regulatory offices of countries that are Parties to this Protocol have received extensive training and support in what information to submit and in how this should be submitted. The BCH website provides access to guidance and training on how to meet these communication requirements<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup> <u>http://bch.cbd.int/about/</u>

<sup>&</sup>lt;sup>2</sup> https://bch.cbd.int/user/signin.shtml?returnurl=%2fmanagementcentre%2fdefault.shtml http://bch.cbd.int/help/topics/en/webframe.html?Training\_Materials.html

# Communication Guideline

April 2012

# 7. Public participation

Involving the public in biosafety issues is seen as an important communication activity that helps to increase the transparency of the regulatory process. The level of participation is generally dependent on the level of interest the public has in the subject. People who are actively involved in biotechnology will have heightened interest, while those who are not involved may have a passing interest when they perceive some impact on their lives. It is impractical to expect all members of the public to be as involved and as interested as stakeholders. For this reason, the information needs of stakeholders are quite different from those of the general public. The national biosafety office should aim to raise awareness of biosafety in the general public and engage biosafety stakeholders more fully in biosafety processes. Both communication objectives, awareness raising (§7.1) and consultation (§ 7.2), include the need for engagement and feedback. Feedback from the general public is useful for establishing the information needs of this group and for assessing whether the biosafety process is meeting their requirements with respect to protection of the environment, and food and feed safety. Feedback from stakeholders can be general or very specific, depending on how they are consulted.

### 7.1. Raising awareness

Raising public awareness is a challenge for any regulatory office. Many people find regulation unexciting and only distantly relevant to their everyday life. However, if the public are to accept approved products of biotechnology, at least the interested parties need to be well informed about how safety is assessed and how decisions are made.

The communication strategies for raising public awareness closely follow the strategies established for biosafety communication in Section 4. The size of this group, known as the 'general public', makes it important to use tactics that enable the spread of information through existing channels, such as the Internet, the media, teachers, extension officers, health workers, nutritionists and NGOs. Impact of public awareness communication is hampered by limited resources and the diverse needs of a large number of people. These limits outreach are an important consideration when planning public awareness communication. The impact of these communication efforts can be expanded by providing information to those who can further disseminate it. These disseminators of information include teachers, opinion leaders, community health workers, nutritionists, journalists and extension officers.

The information needs of the general public are very different from

# A tip for effective public awareness meetings

It is important to focus public awareness meetings on the large majority of stakeholders who are looking for balanced information to make informed decisions. While it is essential to present the positions of the anti-GM groups and the pro-GM groups, this is best done by the facilitators, not the groups themselves. Experience has shown that when these two opposing groups are at a meeting the focus is always on their disagreements and not on the large body of information that is not contested and that will help inform the general public.

those of interested and affected stakeholders. The biosafety office needs to determine the level and content of information that should be disseminated to raise public awareness on biosafety. This can be done informally by speaking to members of the public to find out what they know and what they would like to know about biosafety. Add to this what the biosafety office would like the public to know about the national process, *i.e.*, the key messages discussed in Section 3.3.1.

The website remains the primary communication tool for raising general public awareness. It is important that the format of this site is appealing to the general public, as well as to stakeholders. Is should be easy to access and provide background information for awareness raising, in addition to the specific information required by stakeholders. Where funding is available for raising public awareness there may be opportunities for other targeted communication, such as media outreach, newspaper and magazine articles, and information stalls at

relevant meetings and conferences.

Responding to misinformation in the general media helps to raise the profile of biosafety, while ensuring that the public have accurate information. Letters to the editor provide a useful mechanism for this, but they need to be delivered as soon as possible after a published challenge. There may be letters from individuals that require a direct response, thus there needs to be a process for quick and clear responses - a rapid response strategy.

Providing teaching materials for the education system raises the awareness of biosafety in younger generations. These school modules can be short and made available to teachers wishing to expand aspects of life skills and orientation courses. A possibility is giving teachers who run these modules access to handouts, such as rulers printed with key messages about biosafety. Distribution of these materials can be very costly, which should be carefully considered before these tools are used.

#### 7.1.1. Media Interaction

Although interaction with the media can be challenging, it is beneficial for ensuring that the public receive balanced and accurate messages about biosafety. It is important for biosafety offices to understand the pros and cons of media interaction, as well as the benefits of establishing a good working relationship with this integral group of communication stakeholders. Most public and private institutions have policy on how to interact with the media and, if no policy exists then the biosafety office should establish an institutional policy with respect to media interaction. This is needed in order to create an effective flow of information. Establishing this policy requires knowledge of how the media works and how to get the most out of media interaction.

Regulators need media coverage because information about the safety of transgenic products must reach the public. Biosafety is also an interesting and complex topic that can be controversial, making it of interest to the media.

**Training.** All biosafety staff should receive training in dealing with media. This training should include developing an effective working relationship with the media. This should encourage the media to use the expertise at the national biosafety office, thereby ensuring that accurate information about biosafety is disseminated to the public. Proactive outreach to the media helps ensure that the public are well informed about developments in national biosafety and about current issues. It is better, and easier, to distribute topical information proactively than to respond to challenges. This proactive information can cover the current status of biosafety, plans for the future, and specific issues that are likely to arise as a result of published decisions and activities. Outreach to the media can be useful for correcting misinformation and dispelling myths.

There are pros and cons to media interaction. Wire services, newspapers, magazines, television, and radio have the distribution power to carry important information directly to the general public. However, the media can misinterpret or misuse biosafety information, which can damage the public acceptance of biosafety and biotechnology. This has resulted in most institutions developing specific policy for media interaction that includes the need to obtain approval to speak to the media and approval for any information distributed to them. Obtaining approvals can be laborious and, if delayed, can result in the information not reaching journalists in time for publication deadlines. This may appear as if the biosafety office is not transparent and is trying to conceal certain information. These perceptions decrease the credibility of the regulatory process.

**Spokespeople**. If the government communication policy allows only specific spokespeople to speak to the media, then the biosafety office must work within this process. It is important to ensure that official spokespeople have pre-approved messages and are kept up to date on the key messages and supporting messages used by the biosafety office. There should also be a number of contact people in the biosafety office that official spokespeople have direct access to, so that responses to media

enquires are not delayed when people are out of the office. All staff members should be aware of the urgency in assisting official spokespeople with responses to media enquiries.

If there is no institutional policy for interacting with the media, then a planned biosafety communication strategy should include the authorisation of a number of staff members to speak to the media using pre-approved messages. This should include a procedure to ensure that specific answers are developed and approved quickly in response to specific questions in media enquiries.

Accessing the media. When delivering messages to the media it is important to know who to speak to in the media organisations. Contacting the right person will ensure that the messages are sent out quickly and accurately. These contact people are gatekeepers who know where biosafety information will be of interest and which journalists are most likely to use the information to create news stories. Gatekeepers in television, radio and newspaper newsrooms screen news releases and monitor incoming calls. Identifying gatekeepers that are competent with dissemination of biosafety information will greatly increase the effectiveness of outreach efforts. Regardless of the types of media used, it remains important to establish good media contacts.

The media need access to subject experts who can provide comment on current issues, clarify complex subject matter, and provide context for current issues and concerns. Journalists keep records of subject experts and use these contacts to answer questions, provide clarification and supply additional information that will add depth to their articles. It is important that the biosafety office is the first contact on issues related to national biosafety, thus the biosafety office needs to be accessible to journalists. Accessibility can be improved by having approved key messages that can be given to a journalist without additional approval. These are used to keep the communication channels open with the media while the biosafety office investigates specific questions and develops accurate and informative responses. These additional responses may need approval and the approval process for such messages needs to be efficient. If the biosafety office does not meet the needs of the media, then other groups will fill this gap and use the opportunity to forward their own goals, sometimes to the disadvantage of national biosafety.

**Media needs.** An important part of working effectively with the media is to understand and meet their needs. Information sent to them should have audience appeal and state the relevance to readers. Stories that stimulate debate or are controversial are also well received. Stories that generate high

ratings or increased readership will be particularly appealing and, if this happens, the journalist is likely to follow up with additional interviews and articles. Always provide new information with fresh angles to sustain public interest. Also, content should be short and concise.

The press release will be used to initiate a story that will be more than just the information sent by the biosafety office. The journalist will expand the basic content with additional information and interviews. Usually the story will include related information and interviews with stakeholders and affected people. To capture the interest of a journalist a press release Tips to establish and maintain media relations:

- Use any established institutional policy and procedures for media interaction;
- Identify one relevant news contact at each media organization;
- Build rapport by nurturing positive relations with the media;
- Be a good resource for biosafety by sending new information or items of interest;
- Stay in touch to maintain the relationship;
- Compliment the media on accurate well researched stories;
- When a reporter quotes the biosafety office, send a note of appreciation, or, if necessary, a correction;
- Ensure that journalists receive consistent messages; and
- Designate one person as spokesperson for the media with a backup in case of absence.

must indicate clearly the relevance to the public along with the contact details of people who can be interviewed. It is helpful to attach relevant, high resolution photographs.

Understanding the needs of the media helps establish a professional working relationship. Importantly, journalists have very tight delivery deadlines and generally need a response within hours. Supplying contact details for other experts, or even for those who oppose biotechnology, helps journalists to balance the content of their story. A journalist will appreciate being advised of a new issue or an event that could make an interesting story, and they should honour any restriction (embargo) established for when the information can first be released. This early notification gives them a chance to have a story prepared for release when the embargo is lifted. In press releases, the embargo is printed at the top of the page and says "Embargoed until [date], [time]". However, an embargo does not guarantee the media will hold the information, therefore it is necessary to be selective and use this only with journalists who have a good track record with the biosafety office.

Helping journalists do a good job is one way of building a good working relationship. They need good story ideas, timely information and access to interviews under tight deadlines. Helping them achieve this requires preparation and the biosafety office should be ready to offer more information than is originally requested and offer a full range of background materials, such as statistics, websites, photographs and contact lists for experts who could be interviewed. This information should be organised, edited and approved for dissemination so that is it is available to send at any time. Journalists will also value suggestions of potential interview questions and angles that would expand the story. When the biosafety office is helpful and accessible to journalists they are more likely to pay attention to suggestions and information.

Do's	Don'ts
Be brief: Use concise, succinct messages, sound-bites, short quotes	Don't offer stale news: Avoid suggesting flimsy or old information
Be accurate: Check facts, edit, identify the right reporter / contact / publication	Don't say something you do not want to see in print or hear on the air. Assume nothing is "Off the record", even when chatting informally
Be accessible: Respond quickly to requests - within an hour	Don't persist if a story is rejected: No amount of encouragement will change their minds. Instead, ask the journalists what type of information they would want to pursue
Be honest: Admit if you don't know an answer - offer to find out. If you cannot find out, say so	Don't miss deadlines. Always call if you are delayed.
Be prepared: Have information ready, organised and edited.	

#### Guidelines for working with the Media

#### 7.1.2. Activists and Misinformation

Among other purposes, activism is used to challenge and change poor policy or stop unwanted activities. For the most part activism provides an option for citizens that they use constructively when government is slow to respond to voiced concerns that appear to have been ignored. However, activism is not always used for these purposes and has been employed to forward the needs and agendas of groups funded by supporters and commercial competitors. This form of activism is not aimed at addressing wrongs, but at disrupting commercial activities and slowing down the progress of targeted activities. Its aim is mostly disruptive and non-constructive. Such activists will commonly keep out dissenting voices and contrive to have the first and last word in interviews or debates. The communication machinery of these activists is rarely fettered by ethics or accuracy.

Few areas of biosafety fall outside the scope and interest of activists, making it useful to understand these organisations and the way they work. Activists who are funded to oppose and stall activities, earn their services by not conceding, no matter how shaky their opposition base. These activists use misinformation when there are few facts to support their cause. This misinformation is designed to instil mistrust and fear in the undiscerning public. Unchallenged misinformation can become urban legend, acquiring a sense of truth and value far beyond its worth. Biosafety activists target their misinformation to NGOs, decision makers, politicians, vulnerable commercial entities and the general public.

The best tools to dismantle activism against the biosafety process and the national biosafety system is an understanding of how activists operate; have a strong knowledge of biosafety and the national biosafety system; and have a rapid and confident response mechanism. It is important that misinformation about the biosafety system and the process is responded to quickly and forcefully. This should be possible with the key messages, message maps (Section 3), and with additional responses to more focused questions and personal attacks.

Biosafety regulators should avoid being drawn into defending biotechnology or the biotechnology industry, as this should be done by scientists working for public and private institutions and business spokespeople. However, it is important that regulators respond to misinformation about the *safety* of transgenic organisms. This response should be rapid to ensure that the public does not associate harm with activities that are well managed, organisms that are contained and confined, or organisms that have been assessed and found to be as safe as conventional organisms used for the same or similar purposes. Addressing safety claims from activists requires accurate technical information. Biosafety administrators should work with local scientists to prepare these messages proactively and to prepare responses to new challenges as quickly as possible. Delays in responding will be interpreted by the activists as uncertainty and concern within the biosafety office. This negative image will be forwarded to the public.

Commonly, activists will quote a study they say supports the potential hazards of an activity with a transgenic organism or transgenic organisms in general. The response needs to be quick and confident. Where the study is new, the biosafety office needs to request the information from the activists with the promise to review it and come to a decision about the relevance of the study to local activities. From experience, activists will rarely provide the information requested, but the biosafety office should search for the study or the article and review the information while they wait.

In many previous cases, the studies quoted by activists have proved to be poor, or not to have concluded the harm claimed by the activists. These facts can be quickly determined by scientists and an appropriate response can be issued. Consistently rebutting activist claims with sound science considerably weakens their position in the eyes of the public. Where claims appear to be valid, the biosafety scientific advisors should prepare recommendations on how this information will be used by the regulators to ensure the safety of the country's citizens and environment. This statement can be used by the biosafety decision making body to respond to the activist claims.

Activists will attack the efficacy of the national biosafety framework with challenges of weak capacity, collusion with the developers, conflict of interest on the biosafety regulatory bodies, and even personal attacks on some of the staff and decision makers. Preparing for this and having established policy on how it will be addressed is essential if the biosafety office wishes to provide rapid, firm responses to misinformation about the process and people responsible for national biosafety.

In all responses to activism it is valuable for the biosafety office to provide a contact point for concerned consumers, where they can get responses to their own questions and concerns. This could be a telephone

number with times when the telephone will be answered, or a website with an email contact option, or an email address for the biosafety office. All submissions to this contact point should be addressed quickly with accurate responses.

When debating with activists it is important to stay calm, to prepare three points you wish the audience to hear and to repeat them as often as you can. Activists tend to focus on extremes, so it is valuable to point out the middle ground and to reiterate the safety process and its success over the last three decades. In many instances there will be opportunities to challenge their knowledge of the key benefits of new technology in their own fields of interest, *e.g.*, food safety, environmental protection, conservation. Reiterate each concern they raise, to show that you have heard it, and then give your reply. If challenged with new 'scientific evidence' ask for a chance to verify it before commenting as so many previous activist claims have proved misleading, *e.g.*, brazil nut, tryptophan, monarch butterflies, Mexican maize, terminator genes, *etc.* It is important to acknowledge that there are safety issues (*e.g.*, the potential for unwanted impact on the environment or human health) and this is why there is a biosafety framework and process. Always include that the biosafety systems have worked well and have enabled access to safe new products around the world, none of which have caused harm to the environment or human health.

#### 7.1.3. Advocacy Groups

Advocacy groups are formed to influence public policy and decision making. They have a specific agenda and this determines where they stand on issues and policies. As such, advocacy groups that are involved in biosafety of biotechnology products can represent of those strongly supporting the use of the technology, those with no specific bias towards the technology, or those strongly contesting the use of biotechnology. They could be advocates for consumer choice, organic agriculture, environmental protection, sustainable living, food security, agricultural development, poverty alleviation or some other cause that is important to their constituents. The needs and concerns of all of the advocacy groups must be taken into equal consideration. Their response is often reasoned and fact based. However, the national biosafety regulators must be careful not to associate with some of these groups to the exclusion of others. This partisan approach will undermine the credibility of the regulators, especially with respect to their bias and any undue influences on their decision making. Regulators should have a clear understanding of the goals of each of these groups when taking into consideration their inputs on policy and decision making.

# 7.2. Consultation

Biosafety communication strategies ensure that there are channels for stakeholders and interested and affected citizens to provide input into policy development and decisions that will impact on their lives. Some countries engage stakeholders widely during the development of policy. Once the policy is representative of the needs of the citizens the government departments implement it with minimal additional public engagement. Further public engagement is undertaken only when there is an identified need for this and not for every decision taken under the approved policy. Other countries consult on new policy *and* consult on each decision taken in the implementation of the policy. This can be costly, time consuming and repetitive.

#### 7.2.1. Public consultations

Public consultations provide a valuable tool in policy development and, in some countries, are used to assist decision making and raise public awareness. The 'public', in terms of biosafety consultations, is a gathering of stakeholders that includes interested and affected parties. As such, these are better described as stakeholder consultations and are different to public awareness outreach.

Consultations provide an opportunity for a two-way movement of information and enable biosafety regulators to identify key areas that need attention. Consultations also encourage ownership of biosafety regulations and the regulatory process.

Regulators use public consultation to understand the needs of the stakeholders with respect to biosafety policy and its implementation. Ultimately, the value of biosafety will only be accepted if society sees biosafety processes as effective and protective of local communities. This acceptance in not guaranteed - it must be earned.

Because many people have limited knowledge and interest in science and agriculture and decisions are driven more by politics and economics than by science or humanitarian needs, it is challenging to gain acceptance of biosafety. This challenge increases when activism disrupts the biosafety process and instils a mistrust of the regulators and the developers of transgenic products. In addition, animal and human biotechnology can raise complex ethical and social questions, which need to be recognised and addressed. Plants and microbes are less controversial, but even so, the regulatory process for these organisms has not always gained acceptance easily.

Regulators use consultations to highlight how the biosafety process works and how decisions are reached. They provide information that will raise awareness and understanding of biosafety and that confirms the safety of products that are approved for introduction into the environment and food supply. To do this, they must ensure that society has sufficient information to make informed decisions. While consultation is mostly aimed at stakeholders with an interest in the technology, public consultation broadens its outreach to potential users of the transgenic products.

When planning a consultation it is important to identify and invite key stakeholders and other interested and affected parties. Where possible, using existing structures for public consultation considerably reduces the work and increases the chance of meeting the consultation goals by attracting sufficient people from the targeted stakeholder groups. Before talking about biosafety issues it may by necessary to ensure that the delegates have a clear understanding of the technology and what a transgenic organism is. Once the attendees have this background it will be possible to focus on the purpose of the consultations, such as obtaining feedback on the practical implementation of proposed new biosafety guidelines. Scientists and regulators should be present to provide factual information in layman's language and should be trained not to delve too deeply into the science, but to keep the subject light and accessible for non-specialists.

#### Tips for interaction with the public

Have printed information available with contact details for a reputable website (preferably the national biosafety site) that addresses public concerns about biotechnology.

Be aware of your gestures and body language when addressing a public meeting as these inform perceptions.

Treat all concerns as relevant and important and address them simply and completely.

Be prepared to admit when you do not know an answer and offer to follow up.

Use jokes carefully as cultural norms are very different.

Be aware of cultural protocols and acceptable actions.

Where biosafety regulation requires public participation in policy development, mechanisms to involve stakeholders in consultation meetings on proposed policy changes should be implemented in a timely manner. This will ensure that the stakeholder input is captured in the policy development documentation. Where biosafety regulations have a requirement for public consultation on decision making regarding specific applications, these should be limited to those activities that have potential socioeconomic impact, such as imports for food and feed use and applications for growing or releasing transgenic organisms in the country. Activities such as research, field testing and clinical trials are temporary and may not result in any useable product or social impact. Standard consultation practices for research and testing should be sufficient for these activities without the need for additional public input into biosafety decision making. When planning consultations for input into decision making for general use applications, the biosafety office should consider how consultations are undertaken for

other technology introductions and apply these processes to the transgenic approvals where this is feasible.

The outputs from consultations should be a clear understanding of the major concerns and needs of affected stakeholders and specific input on regulatory issues or decisions. To achieve this, regulators need to prepare

specific questions for the consultation. Information from these consultations will be fed into the policy development process and could lead to development of new policy or policy amendments. Ultimately the results should be more efficient regulations that meet the needs of the stakeholders and most of the general public. Prioritising issues and needs is an essential task as the biosafety process will rarely be able to meet everyone's needs, especially is there are fringe groups with interests that favour their own activities, but do not meet the national development priorities or acceptable safety standards. A well-planned consultation that allows for information sharing, information gathering and clear mechanisms for how the information will be used, can increase the credibility of the biosafety regulatory process.

It is important to keep official records of the discussion and the issues raised at public consultation meetings, and to have a mechanism of feeding this information into the policy development process and to biosafety administrators and decision makers.

#### 7.2.2. Addressing challenges and concerns

It is rare that everything undertaken by a regulatory office satisfies all stakeholders, so biosafety offices need to prepare to address questions, concerns and challenges. Common biosafety challenges and areas of concern include concerns about the regulations and concerns about whether risk assessment is able to ensure a high enough level of safety. Regarding regulations, both the policy and the decisions can be controversial. As mentioned earlier, it is common for new technology to raise concerns in communities and these will need to be addressed by the biosafety office.

Examples of concerns about the regulatory system include questions about transparency, conflict of interest, partiality, inclusive decision making, the scope of regulatory oversight, the effectiveness of the biosafety process, and bureaucratic delays caused by inefficient processing of applications. Regional regulatory concerns include questions about national sovereignty, costs of regional biosafety bodies, unintended transboundary movement and mechanisms to deal with concerns that are specific to some countries in the region.

Anticipating concerns about the regulatory process enables biosafety offices to address these using the message mapping process (Section 3). In this way, these questions can be answered quickly, helping to build the credibility and transparency of the biosafety office. Making these answers available on the website as "frequently asked questions" (FAQs) provides easy access to this information.

Concerns about the application of biotechnology fall into four categories:

- Environmental safety;
- Food and feed safety;

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- Economic impact; and
- Social impact.

Most of these concerns are not specific to transgenic organisms, but apply to other activities as well, *e.g.*, fuel supply, forestry, agriculture, industrial waste management, development in sensitive ecosystems, expanding urban sprawl, etc. However, it is the impact of transgenic organisms that is the focus of this manual. Most of these concerns can be addressed in FAOs, but concerns about the impact of specific transgenic organisms need to include specific safety and socioeconomic information directly related to the application of the new organisms and their products. The regulatory office needs to address concerns about both the intended improvements in transgenic organisms and concerns about unintended impact that might result from the insertion of new genetic material, or the adoption of the new products.

Many of these concerns (see text boxes) can be addressed proactively by considering their relevance and, where necessary, assessing measures to manage the concerns. Anticipation of controversial issues and areas of concern, and preparation of comprehensive responses will help to address them effectively. These prepared responses can be posted on the

#### The concerns raised about environmental impact include:

- Negative impact on local microorganisms, plants and animals that might displace existing species in the release environment or decrease biodiversity at the genetic, species or ecosystem levels;
- Improvements that may cause increasing weediness or invasiveness of the transgenic organisms, or of sexually compatible organisms that receive the new traits following release of the approved events;
- Insertion of new genes requiring farmers to use more chemical treatments in their management of transgenic organisms;
- Loss of environmental resilience present in local land races;
- Farmer preference for transgenic crop events will lead to the loss of other agricultural planting material, which will lower the biodiversity of crops and reduce the genetic material available to help address future constraints;
- The insertion of pest control genetics into certain organisms will impact on non-target organisms by direct interaction in the release environment or by indirect interaction as a result of the active ingredient remaining active in the environment after the transgenic organism has been removed; and
- Successful transgenic organisms will out-compete other organisms and cause these to decline in number and diversity in the release environment.

#### Concerns about food and feed safety focus on:

- Toxins that might be introduced into transgenic organisms or existing toxins that might be increased in the transgenic organism as a result of changes in gene regulation introduced by the insertion of new DNA;
- Allergens that might be introduced into transgenic organisms or existing allergens that might be increased in the transgenic organism as a result of changes in gene regulation introduced by the insertion of new DNA;
- Nutritional changes in staple foods that might impact on the health of people who rely on these foods for subsistence;
- The use of antibiotic resistance marker genes in some transgenic organisms that might lead to a decrease in the effectiveness of clinical antibiotics, even though scientific studies have shown this is very unlikely to occur;
- Unexpected effects that decrease food safety as result of an unknown change in the food and feed derived from the transgenic food organisms; and
- The feasibility of segregating different organisms and their products if segregation is recommended as a risk management measure to reduce the change of harm or to increase choice options for consumers.

biosafety website, *e.g.*, as FAQs, and used at public consultation meetings. The responses should be reviewed regularly to ensure that the information is up to date and accurate, and to ensure that new concerns are added and addressed as they are anticipated. Alerts about new concerns come from stakeholder interaction and from information from other biosafety agencies.

It is important for biosafety offices to keep abreast of media output with respect to the biosafety system and to

be quick to respond to inaccurate information. It is not necessary to have all responses published, as editors will notify journalists if their articles are questioned, and they will require more diligent fact-checking if there are frequent letters identifying poor content.

# Concerns about negative economic impact focus on: The impact of outcrossing (when the new genes move from the transgenic crops to other non-transgenic crops of

- the same species) on other farmers' harvests;
  The impact of adoption of transgenic crops on other farming systems that do not use these crop improvements, such as complex harvest handling, segregation and labelling systems; and
- The costs of stewardship requirements to manage the movement of regulated materials in international trade.

#### **Concerns about social impact:**

- Changes in traditional ways of doing things;
- Loss of traditional knowledge;
- Preference for landrace crops as a family food source;
- Loss of control over own planting material and the ability to save seed;
- Loss of traditional trading of planting material between rural farmers;
- Ethical and religious issues related to food and food preferences; and
- Labelling as a mechanism to chose what foods are purchased or planted.

# 8. Emergency communication protocols

Biosafety offices need to anticipate and plan for emergency communication. Emergencies may be in the form of notification of an accidental release of regulated organisms from contained or confined facilities, or of import of unapproved transgenic organisms for food and feed use. It may happen that unapproved planting material is found in the hands of local farmers, or that a shipment of transgenic grain is dispatched to a country where it has not yet been approved.

This emergency protocol should contain the stepby-step procedures for staff to take when communicating about a biosafety emergency. The protocols should state clearly who is authorised to speak to the media in the event of an emergency; who in the regulatory management should be notified; and who should have prior access to any press release or statement before its release. Importantly, there should be a number of alternative staff members identified for communication content approvals in case key people are away. The emergency protocols should contain the office, mobile and home telephone numbers of the key staff members and their e-mail addresses.

# Components of an emergency communication protocol:

- Who should be contacted immediately, with contact details and alternatives;
- Who will work on response messages, with contact details and alternatives;
- Who is authorised to speak to the media, with contact details and alternatives;
- What procedures will be used to approve new biosafety messages not already in the messaging system;
- Who will maintain a page on the website to keep stakeholders informed of the emergency and the actions taken;
- Provision of contact details for enquires about the emergency from the general public and who will receive and respond to these enquiries;
- Who will maintain an update of the emergency communication, actions taken and input received;
- Who will receive the updates on the emergency and how frequently these will be dispatched;
- Who will issue the final report on the emergency communication when the situation has returned to normal; and
- Who will organise a review of the emergency communication and changes to the protocol as a result of this experience.

# 9. Agency-specific communication

Aspects of communication will vary between the biosafety regulatory offices in the different government departments and different countries. As such, it may be necessary to have components of the communication strategy that are specific to certain agencies and activities. Alternatively, the different government departments or agencies may choose to have their own communication strategy. If this is the case, it will be important to include links to this material in the national biosafety website, so that stakeholders can access specific information and requirements as quickly and as easily as possible.

# 9.1. National Biosafety Committee (Authority)

The national biosafety committee that is responsible for the implementation of biosafety, the coordination of activities carried out by different government departments, and the issuing of decisions on all applications for transgenic work, will need to have standard operating procedures of all of these activities, including the implementation of a biosafety communication strategy. Communication materials will need to include information on biosafety policy and procedures; international relations; and a template for decision documents for the different types of approvals issued by the decision makers. Where national biosafety committees play a primary role in emergency communication it is important to set up a process for this that details who is responsible and the procedures that must be followed when communicating with other regulatory bodies, and with the media

# 9.2. Advisory Committees

Advisory committee will need to provide communication materials that include information on how risks are assessed, the role of risk management measures, explanations about the presence of risk, and templates for their recommendations to the decision making committee on aspects of each application reviewed. Where advisory committees play a primary role in emergency communication it is important to set up a process for this, that details who is responsible and the procedure that must be followed when communicating with other regulatory bodies and with the media.

#### 9.2.1. Scientific

The scientific advisory committee provides input into technical communication materials and provides recommendations to the decision makers on the safety aspects of specific applications, including safety concerns raised by stakeholders and the public. Templates for these recommendations may or may not include a summary of the technical aspects of the transgenic work; a summary of the risk assessment; a final recommendation on the safety of the activity; and any risk management conditions that should be included as part of the approval to help ensure a higher level of safety.

Where scientific experts are needed for emergency communication, a protocol should be established to guide how this input will be received, and how scientists will communicate with other regulatory bodies and with the media.

#### 9.2.2. Socioeconomic

The socioeconomic advisory committee provides input into socioeconomic communication materials and provides recommendations to the decision makers on the socioeconomic aspects of specific applications, including socioeconomic concerns raised by stakeholders and the public. Templates for these recommendations may or may not include a summary of the socioeconomic aspects of the transgenic work; a summary of the assessment of socioeconomic impact specific to a planned activity; and any conditions that should be included in the approval to help ensure acceptance of the activity, and any approved product.

Where socioeconomic experts are needed for emergency communication, a protocol should be established to guide how this input will be received, and how they will communicate with other regulatory bodies and with the media.

# 9.2. Institutional Biosafety Committee

The role of an institutional biosafety committee is outlined in the regulations and will determine the communication responsibilities of these institutions. In some instances institutional biosafety committees undertake a risk assessment review of the planned activities and prepare a report for the biosafety regulators indicating whether the work can be carried out safety at the institution. This report may detail the containment and confinement conditions that will be applied to specific activities to increase the level of safety. Some institutional biosafety committees are responsible for reporting on the process of approved activities and templates for these reports should be developed to help ensure consistency and completeness of information. Institutional biosafety committees that are responsible for monitoring the compliance of approved activities at their institutions will need to have an emergency communication protocol that is activation should accidental release occur at the site.

Where institutional biosafety committees play a primary role on emergency communication, it is important to set up a process for this that details who is responsible, and the procedures that must be followed when communicating with regulators and with the media.

# 9.3. Plant Quarantine

Plant quarantine agencies must establish communication that informs the public and stakeholders of their role in biosafety, and informs stakeholders of procedures that need to be followed when importing, or exporting, living transgenic organisms from the country. The plant quarantine agencies need to establish templates for the information on applications that have been received; concerns assessed; and the final decisions.

Where plant quarantine offices play a primary role in emergency communication, it is important to set up guidelines for this, that detail who is responsible, and the procedure that must be followed when communicating with other regulatory bodies and with the media

## 9.4. Inter-agency communication

The biosafety office needs to establish a procedure for keeping interested and affected government and public agencies informed of transgenic applications, risk assessment information, and decisions reached in regard to specific applications. This information must be timely and must reach the identified gatekeepers, who will ensure that it is correctly distributed within collaborating agencies and departments. Mechanisms to inform affected agencies of emergencies related to biosafety need to be clearly laid out in a manner that details the procedure to follow, and the specific people to contact, including contact details and alternatives should the contact person be away at the time of the communication.

# 10. Monitoring and evaluation

It is important to monitor the implementation of the biosafety communication strategy and to evaluate its effectiveness. Monitoring the implementation will check that the timelines and proposed activities are being met, and that the procedures for communication are up to date and are being followed. Assessing the effectiveness of the communication is more difficult and may require specific measures to determine whether stakeholders are benefiting from the biosafety communication activities, and whether the information and outreach is meeting their needs.

# 10.1. Indicators to measure implementation

The implementation of communication can be measured against the communication strategy that is devised by the biosafety office. This will include a timeline against which planned activities can be tracked and recorded as completed. This list of planned activities and the outputs from the communication strategy can be compiled into a check list to facilitate the assessment of implementation. Regular reviews of the timeline and the proposed activities are important as this helps to identify implementation problems early on, so they can be discussed and addressed.

# 10.2. Indicators to measure effectiveness and impact

The effectiveness of the communication strategy is more difficult to monitor. Stakeholder awareness of the procedures and requirements for applications could be measured by monitoring the number of enquiries received in relation to the number the applications processed. If many applications are being processed from new applicants and relatively few enquiries are received about the process, then the information available on the website may be sufficient. It is also useful to survey website users and applicants directly to get an assessment of the effectiveness of the communication from the biosafety office.

# 10.3. Tools for assessment

Recording and monitoring enquires received in the office by mail, telephone, e-mail, website enquiries and social media interaction is one mechanism of identifying where the information on the website is adequate, and where it is inadequate for the general users of the biosafety process. A policy and system to gather this information from all staff members will be needed, in order to capture and process the data. Bearing in mind that it is important to have tools to assess communication impact from all mechanisms of outreach, some of these may need to be developed for specific outreach activities. Tools to monitor electronic communication are relatively easy to apply.

Numerous enquiries for information already on the website will indicate that the information is not easy to find. Enquiries for information that is not already packaged for easy dissemination will indicate that this needs to be added to existing communication materials, or new communication needs to be developed. Someone in the biosafety office should be appointed to monitor enquiries and to report regularly on what areas of communication are most effective and which areas need to be improved.

In addition, it is useful to request users of the website to complete very short surveys on how successful their visit to the site has been. This can be set up to target new users and irregular users. People who are regular users of the site could be targeted with a more detailed survey to identify whether their information needs are being met. Importantly, to get a good response from these surveys they should not occur more than once a year and should be set up so that a regular user only receives the survey request on one visit to the site. Provision of a permanent mechanism to provide feedback on the website enables users to respond when they find communication areas that work well, or that do not work for them.

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#### 10.4. Mechanisms to improve effectiveness

Responding to the information received in the monitoring exercises should help to improve the effectiveness of the biosafety communication strategy. These responses may be modifications to existing communication materials, changes to how they are disseminated to specific stakeholders, changes to who communicates to a specific sector, and the development of new materials for specific stakeholder needs. The monitoring and responding to information needs is an important responsibility for the biosafety office and should be accorded adequate human resources and priority by the management.

#### 10.4.1. Continuous assessment

The use of surveys and permanent response options on the website provide ongoing assessment of the biosafety communication strategy. Applicants can be sent short surveys on an annual basis to obtain feedback on how well the biosafety communication is meeting the needs of those who use the system regularly. Someone in the biosafety office needs to review all the feedback received; to summarise the content; distribute it at biosafety staff meetings; and ensure that problematic areas are addressed quickly.

#### 10.4.2. Using feedback

Amassing a lot of feedback is a pointless exercise if someone is not tasked to use these data to recommend changes and modifications to the communication strategy. These recommendations should make biosafety communication more effective at meeting the needs of the stakeholders. A procedure to respond to feedback should be developed and implemented with specific responsibilities detailed and timelines identified. This will help ensure that feedback is processed regularly and that changes are made to improve the way the biosafety office communicates about biosafety in the country and in the region.

# **11.** Communication capacity strengthening strategy

All staff members should receive updates of key messages, message maps and quick messages. They should be encouraged to provide feedback on these messages so that messaging is kept relevant and up to date.

While communication may be the responsibility of one or more biosafety staff members, all staff at the biosafety office should be trained in the importance of communication; the procedures that must be followed; and the role that they may need to play in the case of activism or emergencies. This training can be offered annually to new members of staff and more regularly to those biosafety officers directly responsible for communication. The content of the training for general staff and for communication staff will vary, but organising a joint one-day of training per year will help to keep the process consistent and updated.

The communication staff members can run the training for the general biosafety staff members. Professional communication training should be provided for the communication staff. Also, there will be need for product-specific biosafety training related to specific organisms, activities or approvals, and this can be provided to the communication staff by members of the scientific and socioeconomic advisory committees.

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