

## Public Participation in Biotechnology Decisions: The Role of Institutional Biosafety Committees

**SUMMARY:** Many companies and research institutes have Institutional Biosafety Committees (IBCs) that help them manage complex decisions about research and development activities involving biotechnology, or genetic engineering. The membership of IBCs usually includes people from outside of the organisation conducting the research in order to provide independent review and assessment of their plans. In Australia, IBCs play a particularly active and participatory role in biotechnology research and development.

Most regulations governing biotechnology research and development focus primarily on what researchers must do to police themselves. Regulatory agencies require that research institutes apply for permission before undertaking certain activities and see that their staff carries out those activities safely. However, in some countries, research institutes are required to have people from outside of their organisation serve as members of their Institutional Biosafety Committees (IBCs) and play an active role in directing their research and development activities.

### What IBCs do

In general, an Institutional Biosafety Committee is a group that oversees biotechnology research undertaken within a particular organisation, and all IBCs have significant technical responsibilities. These may include reviewing research programmes and evaluating facilities, procedures and personnel within the organisation to ensure that biosafety guidelines are met.

In some countries, an IBC may also play a strategic role for the institution it serves. Before biotech research is initiated, the committee might be asked to confirm that the work will be in the best interest of the public, functioning similarly to an ethics committee or an institutional review board.

Some IBCs have the power to impact the progress of projects. In India and Australia, IBC endorsement is required before applications can be submitted by the research institute to the regulatory agency. In other countries, such as the Philippines, the IBC submits some applications directly to the regulator on behalf of the research institution. The IBC may also be required to investigate any accidents or incidents of non-compliance with regulations and report them to the regulator.

### The importance of IBC membership

Because the roles of IBCs can be so wide-ranging and have such a great impact on research, membership is important. Specific requirements for membership in IBCs vary but in all cases, the members are expected to have expertise in the full range of issues that the research may affect. For example, if an organisation's research involves a herbicide-tolerant biotechnology trait, then one of its IBC members must have expertise in weed science.



Research institutions may have much of this expertise inside their organisation's staff, but IBCs are generally required to have external experts among their membership to bring in additional perspectives on the issues. In India, a medical expert must sit on every IBC, as well as a nominee of the authorities (from the Department of Biotechnology).

In many countries, regulations go even further and require that there is at least one lay 'citizen' or 'independent' member on each IBC. This lay member should not have any business, research or previous personal interest in the work of the research institute. The lay member may literally be a community representative, as is the case in the Philippines, where research institutions must have IBCs for each province where field trials are taking place.

### IBC in Australia

Australia is one country where biosafety legislation and regulations require that IBCs actively participate in the review and decision making of all research, bringing valuable perspectives to the companies, universities and other organisations working in biotechnology.

IBC members in Australia must provide input at every stage of an organisation's R&D programme. For example, the IBC signs off on proposals for the initial genetic transformation work that is done at the beginning of a new project. Later they evaluate applications for work in the greenhouse, then field trial research, and finally broad commercial release, which in Australia includes stewardship and crop management plans.

Research institutes often give members access to very detailed and sometimes confidential information about their work. The IBC members review documents independently and then share comments with each other and the institute. Sometimes the issues are addressed with explanations from the institute and other times submissions or plans are changed based on feedback from the committee. In the end, each IBC member must give their endorsement of each submission before it is sent to the regulator.

As is the case elsewhere, IBCs in Australia must have all relevant scientific expertise adequately represented on the committee. To ensure appropriate scientific expertise, IBC members in Australia frequently include scientists from universities or other research institutes outside the institution to complement the knowledge of internal staff. In addition, each IBC in Australia must also have an independent lay member who does not have any personal, financial or research interest in biotechnology. The lay



member might have some familiarity with agriculture and science but is expected to have a perspective no different from a typical member of the public.

Working with IBC members who are employees of the research institute, the external members add value to the research and development process in several ways. The scientists may challenge expected results based on their own work, and the lay member may raise broad concerns that the committee wouldn't have considered otherwise. For example, the scientific and lay members of an IBC might work together on changes to field trial protocols that reduce the chances of breaches by reducing the number of trials and giving clearer instructions to the farmers carrying them out.

### IBC and public participation

An Institutional Biosafety Committee which includes members from outside the organisation conducting the research can contribute independent expertise and new perspectives into what would otherwise be purely internally-driven work. In a sense, this is a form of public participation in biotechnology decision-making that can have real impact on the way biotechnology research is carried out, from initial research programmes through to commercialisation plans.