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"The objective is to identify and manage the risk"

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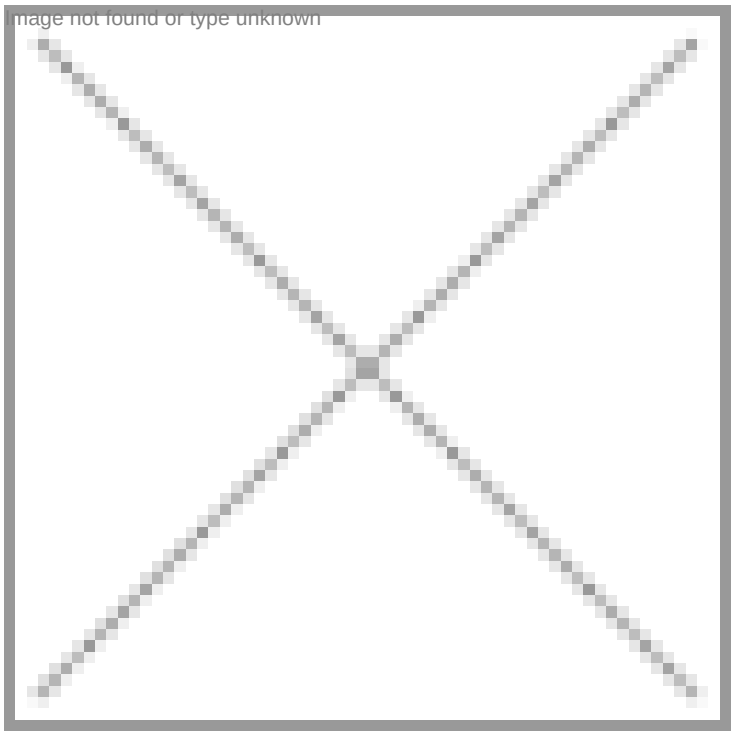

"The objective is to identify and manage the risk"

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-Dr Sue Meek, gene technology regulator, Australia

Australia is a trendsetter in setting up the unified regulatory structure for GMOs with its Gene Technology Act 2000, which is in force since June 2001. Managing the complexity of enforcing the regulation is the Office of Gene Technology Regulator (OGTR) headed by Dr Sue Meek, who is an independent statutory office holder responsible for administering and enforcing the national regulatory system for the development and use of gene technology. With 25 years of experience behind her, Australia's scientist-turned gene technology regulator is in charge since December 2001. Holding the office of the country's first gene regulator is a complex, tough task. Dr Meek shares with BioSpectrum how OGTR handles the complexity of the task.

Can you give a brief outline of the background of the Gene Technology Act 2000? What factors let to the formation of this Act and how has this helped the industry and public health initiative in Australia?

The use of gene technology in Australia was previously governed by a voluntary system overseen by the Genetic Manipulation Advisory Committee. It was decided that a national scheme for regulating gene technology was necessary as the range of applications for gene technology was changing very rapidly and legally enforceable ways to audit or monitor the use of gene technology and penalise breaches were needed.

The development of the Gene Technology Bill 2000 (the Bill) involved extensive consultation with all Australian jurisdictions and was conducted in four stages:

In 1998, a paper entitled "Regulation of Gene Technology" was circulated for limited public consultation, after which, a set of policy principles was agreed by the Commonwealth State Consultative Group on Gene Technology.

In 1999, the discussion paper "Proposed national regulatory scheme for genetically modified organisms â€“ How should it work?" was released for public consultation and invitations to attend targeted consultations were sent to approximately 1,000 individuals and organizations across Australia.

A consultation draft of the Bill was prepared by the Commonwealth Office of Parliamentary Counsel.

The draft Bill was released for public comment. Calls for submissions and invitations to public forums were published in newspapers in all jurisdictions and mailed directly to over 2,500 interested stakeholders.

In 2000, the Bill was referred to a Senate Committee Inquiry and subjected to extensive debate in the Australian Parliament. It was passed into law in December 2000 and commenced operation on June 21, 2001.

The Gene Technology Act 2000 (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology. Under the Gene Technology Agreement 2001, all States and Territories have committed to maintaining corresponding legislation.

The object of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs). The Act regulates both intentional release of GMOs into the environment and research in contained laboratory facilities.

In drafting the gene technology legislation, Australian governments decided to confine the Regulator's powers to the consideration of risks to human health, safety and the environment. This was due in part to feedback received during the consultation process which identified strong community concerns that a requirement to consider economic issues, such as the marketability of GM crops, could compromise the regulatory system's focus upon the protection of people and the environment.

How often do the various committees meet? And what is the coordination process you follow while liaising with other agencies such as TGA?

The Act established three advisory Committees: the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC). From January 1, 2008, GTEC and GTCCC will be replaced by the Gene Technology Ethics and Community Consultative Committee (GTECCC). The establishment of GTECCC was among a number of changes to the Act made by the Gene Technology Amendment Act 2007 that was passed in June 2007.

GTTAC meets three-to-four times a year on average, and is also consulted out-of-session. It is anticipated that GTECCC will meet two-to-three times per year.

The Act requires extensive consultation with key stakeholders and the public on applications to release GMOs into the Australian environment. The methods of communication used by the Regulator include sending letters or emails directly to relevant stakeholders and posting advertisements on the OGTR website and in national, state and regional newspapers.

The Regulator is required to seek advice and comment on the Risk Assessment and Risk Management Plans (RARMPs) prepared for each of these applications from a wide range of experts, agencies and authorities. Those consulted include the State and Territory Governments, the Australian Government Environment Minister, other Australian Government regulators prescribed in the legislation (Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration, the National Industrial Chemical Notification and Assessment Scheme and the Australian Quarantine and Inspection Service), GTTAC, and relevant local councils. The Act also requires the Regulator to invite submissions on the RARMP from members of the public.

The Act forms part of the integrated regulatory framework for the development and use of GMOs in Australia. All Australian Government regulators, mentioned above are also required to consult the Gene Technology Regulator when considering GM products (i.e., not live and viable). The regulation of GM (and non-GM) food is the responsibility of FSANZ. The regulation of

agricultural chemicals, including the use of herbicides on herbicide tolerant (GM or non-GM) crops, is principally the responsibility of the APVMA.

How many applications come to your office every year and how many get cleared? What is the time frame that an application takes from filing to clearing?

In 2006â€“07 the OGTR received 1474 applications and notifications as defined under the Act. Fluctuations in the timing and volume of application lodgement can be influenced by factors such as research grant funding cycles and seasonal agricultural factors.

Licences for DIRs issued in 2006â€“07 ranged from limited and controlled releases (field trials) to Australia-wide commercial releases of GMOs. Ten decisions on applications for DIR licences were made during the reporting period. All were made within the statutory 170 working day timeframe. Approvals do not necessarily occur in the same year as applications are received.

India is planning to emulate Australia's unified regulatory structure. What would be your advice to India and other Asian countries that are looking at outlining a similar regulatory structure and implementing it?

The object of the Act, which underpins the regulatory system, is to protect the health and safety of people and the environment. This is achieved by focusing on risk and ensuring that any risks to the health and safety of people and the environment posed by, or as a result of, gene technology are identified and managed.

The recent Review of the Act found that this object is being achieved and that Australia's regulatory framework is appropriate and being applied effectively.

Learning from the Australian experience, what are the implementation bottlenecks of putting in place such as structure that other countries can be forewarned about and thus be better prepared to handle it?

The most time consuming aspect of developing the national regulatory framework for GMOs was the extensive public consultation conducted. However, this process was necessary to ensure a clear understanding of the differing positions of all interested parties, and to provide information to interested parties to improve understanding of the issues involved.

The development and implementation of the Act included transitional arrangements for approvals made under the former voluntary system.

Nandita Singh