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**“Good regulatory practices for developing countries – lessons  
learned in South Africa from an Appeal under the GMO Act”**

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**ABSTRACT**

In South Africa, activities involving genetically modified organisms (GMOs) are regulated in terms of the Genetically Modified Organisms Act 15 of 1997 (the GMO Act). This Act has been operational since the end of 1999, and South Africa has gained considerable experience in the contained use and release of GMOs during this time.

In June 2003 the Executive Council appointed in terms of the GMO Act approved an application by Syngenta for the general release of GM Maize event Bt11. In October 2003 an NGO, Biowatch Trust, lodged an appeal against this decision, and, as provided for in the Act, an Appeal Board was appointed by the Minister of Agriculture to consider the appeal.

The Appeal Board reached a decision in September 2004 to dismiss the appeal, but specified some amendments to the conditional general release permit issued to Syngenta. The experience gained from this appeal, which is the most comprehensive appeal that has been brought under the GMO Act thus far, provides important lessons not only for South Africa but particularly for other countries that are in the process of developing their own regulatory procedures.

The appeal process highlighted the need for clear legislation, to prevent differences of legal interpretation; and the need for well-functioning regulatory processes to avoid unintentional procedural irregularities. Documentation should record all the risks that were considered (even where the risk may be negligible) during the review of an application, and reasons should be given to justify any decision reached. Any gaps in the documentation have the potential to lead to later questions and concerns.

The risk assessment process normally involves an assessment of data and information provided by the applicant. In the majority of cases, particularly in developing countries, the application is likely to concern the use or release of a GMO originally developed and tested elsewhere. The applicability of the data to a different country should be carefully considered, and the need for any additional country-specific data should be defined. In South Africa, field trials in the country must precede any application for general release. Increasingly, data on potential secondary ecological effects arising from the introduction of the GMO are being required, but given the impossibility of addressing every ecological issue, the question that must finally be answered is “how much information is enough to reach a decision?”.

Where there is a lack of capacity or insufficient funding to adequately assess risk or to ensure that regulatory processes are strictly adhered to, developing countries in particular may find that any irregularities open the door for decisions to be challenged by individuals or organizations that are concerned about the introduction of GMOs. The appeal process is not only time consuming but costly for all concerned, and may unnecessarily tie up scarce resources.

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