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ENSURING BIOSAFETY AT THE NATIONAL LEVEL

SUGGESTIONS TO IMPROVE THE OPERATION OF THE SOUTH AFRICAN BIOSAFETY REGULATORY SYSTEM

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South Africa has the only fully functioning biosafety regulatory system in Africa. Farmers plant approved varieties of genetically engineered corn, cotton, and soybeans, and research is being conducted to apply genetic engineering to numerous other crops. While the South African system is functioning and has issued authorizations for activities with genetically modified organisms (GMOs) for 10 years, many stakeholders believe it could be improved. As a result, the South African biosafety regulatory system has undergone an evaluation, which included a review of operating procedures and authorizing legislation as well as a series of stakeholder interviews. The evaluation has resulted in several recommendations to improve the operations of the South African system and allow it to become more efficient and effective.

Biosafety in South Africa

In 1997, South Africa enacted the "Genetically Modified Organisms Act" (GMO Act) to regulate transgenic crops. The law requires that an application with a risk assessment be submitted to obtain a permit from the Agriculture Minister. An Executive Council (EC), comprised of eight members from different national departments, reviews and approves the applications with the help of a Registrar, who administers the GMO Act. The law also provides for a Scientific Advisory Committee (SAC) to advise the EC on scientific and technical issues.

Improving Transparency of the Regulatory System

If a biosafety regulatory system is transparent, it will be more understandable to a variety of stakeholders (applicants, government officials, and the public at large), it will be more efficient, and it may result in decisions that garner more public confidence. A transparent biosafety regulatory system provides the public with information about the regulatory process, the applications that are being reviewed, and a clearly written decision with the basis for the government's decision. Clear criteria also allow applicants to submit complete and thorough applications.

1. Providing Applications to the Public in a Timely Manner. Under the current regulatory system, the applicant is required to publish a notice of the application and the public is given 30 days to submit comments. However, anyone who wants to see the nonconfidential portions of the application before making comments must formally request that information under the public information law and must wait for the government's response. Sometimes the response takes time, requiring the comment period to be extended and delaying government action on the application.

One solution to this problem would be for the applicant to submit a nonconfidential copy of the application when the public notice is published. The Registrar could then make the copy available online. This would increase transparency, enhance public participation, eliminate extending the public comment period, and expedite the decisionmaking process.

2. Providing a Written Decision. Under the current system, the EC makes decisions on permit applications by consensus, informs the applicant of a favorable decision through the issuance of the permit, and places a public notice regarding the issued permit on its website. However, the EC does not provide the reasoning behind its decision in any official government

document that could be made available to the public. To improve transparency and make the regulatory system more efficient and effective, the regulatory system should issue a written decision document to applicants and the public.

First, the release of such a document would help *all* applicants understand what is needed in an application (not just the applicant for that particular permit) and would identify the issues that are most relevant to the decisionmakers' decision. This information would help future applicants to properly tailor their applications to address any previous concerns the EC may have had, to focus on appropriate issues, and to submit correct data.

Second, creating a decision document can help the EC make good permit decisions. Decision documents provide a written record of each decision, allowing the current EC to review old decisions and compare them to new permit applications. This might result in more consistent and uniform decisions over time and reassure current EC members that their decisions are consistent with what the EC has previously done. Third, a decision document can force EC members to critically consider their decision and to limit their decision *only* to legitimate issues within their mandate.

3. Guidance on Socioeconomic Considerations. South Africa allows socioeconomic considerations to be factored into the permit decision process. In order for the biosafety regulatory system to be transparent and clear, and to allow applicants to understand how their applications will be judged, guidance on the inclusion of socioeconomic considerations should be issued. That guidance should describe the categories of socioeconomic considerations that can be considered, who is responsible for assessing them, how they will be assessed, and how the resulting assessment will be factored into the decisionmaking process. Such information would allow stakeholders to understand how socioeconomic considerations fit into the approval process and would allow applicants to assess the merits of their applications before they submit them.

Ensuring the Best Science-Based Decisions

Biosafety decisionmaking involves a risk assessment for potential issues that might be raised by the GMO and the specific activities requested by the applicant. In South Africa, the risk assessment and application are reviewed by the EC and they receive expert advice from the SAC. However, several enhancements could improve the system's current operations:

1. Building Biosafety Capacity at the EC. EC members are asked to make scientific and technical decisions about the safety of proposed biotechnology activities and products, yet many EC members know little about agriculture, the biology of different crops, or the potential risk issues for GMOs. Building the capacity of EC members would allow them to better understand the issues involving permit applications and would lessen the number of basic follow-up questions they pose to the applicant or the SAC. With knowledge of the issues that come before them, EC members would be more capable and confident to assess applications, address all relevant issues, and make correct decisions.

2. Providing Procedures for "Real Time" Answers to Technical Issues. As the EC reviews applications and the expert reports from its SAC, scientific and technical questions are often raised. Under current procedures, those questions are transcribed by the Registrar and then sent to either the applicant or the SAC for a response, delaying the application decision until the answers are received at a future EC meeting. Many of the questions raised by the EC members, however, could be answered immediately by the applicant or the SAC experts, if they were present at the EC meeting. By allowing the applicant and/or the SAC experts to attend the meeting and answer any outstanding scientific or technical questions, the EC would obtain "real time" answers. The EC could then make an immediate application decision and improve the overall efficiency of the application decision process. When the applicant is present, a recording or transcript of the question-and-answer period could be made available to ensure the public that there has been no improper communication.

Conclusion

Biosafety regulatory systems should be dynamic and able to change as they acquire experience in reviewing and approving GMOs. After years of successful regulation, the South African system could incorporate further improvements to make it more efficient and effective. Other countries designing regulatory systems can also learn from South Africa's experiences and integrate similar policies and procedures into their national systems.

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FOR MORE INFORMATION: Jaffe, Gregory. 2007. Analysis of South Africa's Biosafety Regulatory System. PBS report; available upon request (ifpri-pbs@cgiar.org).

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