EVALUATION OF THE PROJECT BIOSAFETY MANAGEMENT OF GENETICALLY MODIFIED CROPS – CHINA (IDRC GRANT NUMBER: 103783-001)

IFPRI

FINAL EVALUATION REPORT

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Biosafety Management of Genetically Modified Crops in China (#103783-001)

2. Executive Summary

China pursued an aggressive investment path on biotechnology staring early 1980s. Investments in human, financial and technical resources yielded an impressive innovative environment that created multiple agricultural, medical and industrial applications. In agriculture only a few technologies from the public sector have been approved for commercialization. A smaller amount has achieved commercial success. Biosafety procedures were established to ensure the proper risk assessment of genetically modified crops and animals as a result from internal regulations as well as a result of China signing and ratifying the Cartagena Protocol on Biosafety. China's biosafety system is one of the most advanced in Asia, yet significant regulatory and decision making challenges remain to ensure a protective and efficient biosafety system. China rapid progress in biotechnology started to decelerate around 2001-2003 and by 2004-2006, its biosafety system was enduring criticism from external and some internal sources. In this policy milieu, IDRC provided a grant to the Chinese Center for Chinese Agricultural Policy (CCAP) to examine biosafety and biotechnology management issues. IDRC in turn requested Dr. Jose Falck Zepeda from IFPRI in 2009 to conduct an assessment of the CCAP biosafety management project in China.

Results from the assessment show that the research quality can be considered world class. The main focus of the project was to develop conceptual models and to apply state of the art methods in field studies as well as to perform regulatory impact assessments. The project's contribution to the field in terms of methodological development, field applications and connecting policy and practice, as well as policy outreach are exemplary and receive an excellent mark. The outputs from the research have been published in international peer reviewed, national and regional journals, book chapters and other types of policy outreach publications. The quality of CCAP publications derived from the IDRC project is excellent in technical, and although a literature search does not show many citations to the studies covered by the search, the expectations is that this situation will change over time based on the history of other CCAP publications on biotechnology and biosafety.

The project has had a significant impact on several stakeholders including the national and international scientific community, and policy and decision makers in China. An example of the quality and impact of CCAP policy outreach efforts is that China's government decided to fund a major grant through the Chinese Academy of Sciences to fund biosafety and biotechnology assessment and management efforts to CCAP. In addition to the publication record, CCAP also implemented substantial communication and dissemination strategy including seminars, workshops and presentations to decision makers in order to influence public policy as related to biosafety and biotechnology issues. Although CCAP has done an outstanding effort in disseminating its outputs, in fact has an exemplary track record in doing this effort, it can benefit from a more slightly more structured process for dissemination. The target audiences for the communication and outreach outputs were policy and decision makers, the scientific communities, research scientists, biosafety regulators and other relevant stakeholders.

In conclusion, the overall assessment is of an excellent project, outputs and policy outreach efforts that has an influence on policy making in China. This constitutes an excellent investment on the part of IDRC and certainly has contributed to advancing science in terms of contributions to methods and empirical approaches to biotechnology assessment. Furthermore, based on the list of pending publications much more publications and impact from the project is expected. Finally the assessment document provides a detailed list of potential research and policy outreach that IDRC may pursue in terms of biosafety and biotechnology management in China, sub-regions in Asia and at the global level. These recommendations are based on the assessor experience with biotechnology and biosafety issues but also from the exchanges with a small but resourceful set of stakeholders and experts.

3. Evaluation Report

i. Background of the Study

China has made significant investments in human and financial resources focused on biotechnology R&D for medical and agricultural applications starting in the early 1980s (Huang et al. 2003). Up to 2003, China pursued an aggressive investment policy with the intention of positioning itself in a leadership position for biotechnology development (Huang et al. 2001). The Chinese government viewed its biotechnology investments as a way to develop tools for ensuring food security, raise agricultural productivity, increase farm income foster sustainable development and improve its competitive position in international agricultural markets (MOA, 1990).

Chinese investment in agricultural biotechnology yielded significant capacity to innovate in biotechnology and has created a respectable pipeline for products to be commercialized in the near future (Huang et al. 2001; Rodriguez-Cerezo and Stein, 2009). Indeed China was the first country releasing commercially a GM crop and is one of two developing or transition economies who have released a public sector GM crop globally. Furthermore, the area planted to insect protected (Bt) cotton has increased steadily since its initial deployment (James 2008).

Up to 2009, however, only Bt cotton has been widely planted commercially of the 48 or more events who have received commercialization approval by the relevant regulatory authority, the National Biosafety Committee, to 2009[1]. Around 2004-2006 there seems to be a significant pace reduction in terms of investments and movement within the regulatory pipeline, commercialization approvals by the NBC and final political approval for commercial release in China. If we consider the significant investments in agricultural biotechnology by the public sector in China, then relevant questions are Why the holdup? Why more commercial releases by the public sector in China have not occurred?

There may be several answers to these questions. Issues such as intellectual property, limited capacity or experience with technology transfer, weak institutional frameworks and partnerships, and biosafety; may play a role in explaining the limited diffusion of public sector technologies to farmers. One additional explanatory factor is that during the period of 2004-2006, the Chinese government endured criticisms by non-governmental organizations, pressure groups and other

[1] China signed the Cartagena Protocol on Biosafety on August 8 2000, ratifying the Protocol on June 8 2005, entering into force September 6, 2005.

stakeholders in the international policy arena over its biosafety and biotechnology policies and its ability for implementation, as well as, questions about the potential impact of GM technology adoption on Chinese exports and trade.

Nevertheless, a small but significant component of China's investment portfolio in biotechnology included ensuring compliance with its own biosafety regulations and the Cartagena Protocol on Biosafety (See Box 1). China's biosafety regulatory development efforts ensured that Chinese biosafety laws and regulations cover most of the issues covered by other countries with advanced regulatory experience. To date China has accumulated knowledge and experience with risk assessments for experimentation, confined field trials and commercialization approvals to the point that its biosafety legislation has been modified over the last decade to improve efficiency and reduce implementation costs.

The later assessment does not mean that the biosafety management in China cannot be improved. By definition, biosafety regulatory systems learn and adapt over time when addressing increasingly more complex technologies and/or while the scope of decision making systems expand to include broader considerations beyond strict biosafety issues. In this policy milieu the need arose for an evaluation and examination of China's biosafety system procedures to improve its efficacy, efficiency, and transparency that would build a protective and enabling system (Jaffe 2006). At this juncture of China's biosafety regulatory system, The Center for Chinese Agricultural Policy (CCAP)[2] a premier research organization in China (See Box 2) obtained a grant from IDRC to examine a portfolio of biosafety regulatory implementation and management questions in China.

Major activities developed during the implementation of the IDRC project included policy, laws and regulations reviews, workshops, stakeholder interviews, development Bt cotton production practices database, analysis on the potential economic impacts of the Biosafety Protocol on trade, implementation Bt cotton production and seed market surveys. In addition the project collected cotton seeds and leaves for Bt gene expression tests, data cleaning and compilation, analysis and publication preparations. Important to note that the objectives and activities included in CCAP's Final Technical Report submitted to IDRC (See Box 2) are slightly different than in the original proposal submitted to IDRC. All adjustments and changes were approved by IDRC after annual or periodical reports during the course of implementing the project.

[2] For a complete list of acronyms please see Annex 1.

Box 1. China Policy on Biosafety

According to the National Biosafety Framework of China, the policy for biosafety of China contains the following elements:

(1) The overall objective for national biosafety management is to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected in a maximum way, while promoting research, development and commercialization of modern biotechnology through formulation of policies, regulations and relevant technical guidelines.

(2) The overall principles for national biosafety management consist of the principle of encouraging the research and development of biotechnology, combined with the precautionary approach, prevention as priority, coordination and cooperation between government departments, science-based management, public participation and strengthening the international cooperation on biosafety affairs.

(3) According to different risk levels, different measures such as encouraging, limiting and forbidding the commercialization, sales and use of different types of LMOs and their products, are adopted. The production, sales and consumption of LMOs and their products with low risks are encouraged, while the production of LMOs and their products with high risks are prohibited, to minimize the adverse impacts to biodiversity, human health and environment which likely caused in the process of production, transportation, sales and utilization of LMOs.

Source: China Biosafety Clearinghouse http://english.biosafety.gov.cn/swaqxxjhs/zc/200401/t20040113_87989.htm

Description of the methodology employed

I performed the assessment of the CCAP project funded by IDRC, through the examination of CCAPs Final Technical Report, CCAP Project Brief, and list of outputs (see Annex 1) submitted to me in the course of the evaluation. In addition I performed a literature search using the program “Publish or Perish” to examine biotechnology and biosafety publications cited in Google Scholar by team members participating in the project. Furthermore, I conducted several interviews with the project leader, Dr. Jikun Huang, team members and collaborators and potential beneficiaries of the project, as well as external experts familiar with the project and CCAP and its accomplishments. Annex 2 contains a full list of persons interviewed, consulted or with I discussed the CCAP project and biosafety and biotechnology issues in China. Parts of the draft report and potential future activities in China was discussed with a small group of experts and project personnel convened by the assessor during a visit by the assessor to China for the meeting of the International Agricultural Economics Association in Beijing, August 16 - 22, 2009.

Box 2 IDRC Project Biosafety Management of Genetically Modified Crops after Their Commercialization

Overall Goal
The overall goal of the project is to improve farmers' income, food security, and the health of rural people through the development of a biosafety regulatory system, a healthy input market and an efficient public service sector that will ensure farmers better access to new technology, knowledge and information.

Major Objectives:
1) To have a better understanding of the policy making process and the institutions and biosafety regulations governing GM technology
2) To have a better understanding of long-run benefits of GM technology (Bt cotton) to small farmers in rural China
3) To have better understanding of the performance of seed market, farmers' practical choices of seeds available in the market, including approved or unapproved Bt cotton seed by biosafety committee, and their impacts on the productivity of Bt cotton technology
4) To have a better understanding of the performance of insecticide market and pest-control behaviors of farmers in Bt cotton production
5) To evaluate the effectiveness of recent policies on seed subsidies, IPR enforcement and other regulations on the productivity of Bt cotton at farm level; and
6) To generate policy implications for future GM technology development that will contribute China's food and nutritional security and lend valuable lessons to other developing countries in Asia and beyond.

Cooperating units: Stanford University; Rutgers University; Chinese Academy of Agricultural Sciences

Project methods strengths and weaknesses

Undertaking an evaluation of policy, decision making and stakeholder impacts from a research project has many limitations including impact attribution, tracing and determination of indirect impact, identification of the impact pathway. The best practice approach is to use several methodological approaches as is done in this evaluation. Interviews with experts, literature review, examination of research outputs, tracing of impacts and the familiarity of the assessor with the research program, are a major strength of the current assessment.

Due to time and resources limitations, I only managed to interview a relatively small number of stakeholders and/or persons familiar with the IDRC project. The window of opportunity for contacting relevant persons was too small as many of the policy makers were also involved in the International Agricultural Economics Conference in Beijing, as the Ministry of Agriculture and other relevant Ministries co-sponsored the event. Time and resource limitations were not the only two issues limiting access to personal interviews. As biosafety and biotechnology remain a sensitive topic in China, attempts made to contact independently other policy and decision makers involved with the biosafety review process and GM crop approval process were not successful. Several attempts were made independently to contact relevant persons familiar with CCAP and the IDRC project, which were not successful or were re-directed to public relations or information officers who provided standard information material or politely refused to respond questions about biosafety and biotechnology policy beyond what was contained in the information provided. The information collected was therefore heavily supplemented with the submitted outputs, literature reviews, literature searches and examination of other materials relevant to the assessment. Certainly literature searches and reviews have limitations and weaknesses of their own as they are an excellent indication of contributions to the field and methods, but may not be a good indicator of policy and decision making intake and use of project results, thus the need for consultations with experts and persons familiar with the project.

ii. Activities and Achievements

Evaluation Findings

Outputs submitted by IDRC and by Dr. Jikun Huang (Project Leader) include the final IDRC technical report, one M. Sc. thesis, three Ph.D. dissertation, six journal articles, one book chapter, one policy brief and several presentations in addition to a list of expected outputs to be delivered shortly after the formal end of the project. The later include one book, and additional journal articles.

The outputs produced during the project are numerous and of an excellent quality. The assessor does not have any doubt that the outputs produced by the project which have not been published yet in reputable peer reviewed journals, will be published, given sufficient time. Although the citation statistics do not show that the biosafety articles have been cited much in the literature in Google Scholar yet (See Annex 6 Table A.6.1) this fact is not surprising there has been a very limited time lag between publication and the literature search performed by the assessor. Based on the track record, including publication history and professional relevance shown by the members of the CCAP team members for biotechnology economic assessments, the assessor expects that citations will indeed pick up.

Table A.6.1 in Annex 6 also shows the quality of outputs produced by CCAP in the biotechnology and biosafety arena. More than 63 publications have been published in peer reviewed publications as documented by the software "Publish or Perish."[3] As seen in Table A.6.2 the impact of such publications, as measure by citations, is excellent. Some of the publications presented here have one of the highest citation scores I have seen for the agricultural economics literature, especially for developing and transition economies literature.

Research quality

[3] This software searches in Google Scholar and therefore will yield a different count than the social index aggregators. The advantage of using this software is that it is easy to use allowing calculating impact coefficients in a rapid manner.

The quality of the research outputs produced by CCAP in the IDRC project is simply outstanding. The focus of the research was not the development of theory or conceptual models, rather the innovative application of methods for field work in areas not addressed by researchers in the past. Certainly the CCAP project provided ample applications for policy research analysis and practice which I can assess as being world class in quality.

The practical applications in the CCAP project addressing refuge management, insect damage and control, secondary pest damage, pesticide use and economic performance are excellent, and are state of the art in terms of methodology applications. The work on consumer issues is quite advanced in terms of methods and is one of the first studies done for China and Asia[4]. The specific biosafety applications to IPR and biosafety regulatory design and decision making still need some development. However, this is a reflection of the existing narrow foundation in terms of theory and conceptual models in the literature. Several issues remain to be examined in order to address the multiple questions regarding biosafety and those that may be limiting the transfer of GM biotechnologies to farmers in China. Reviewing specific results from the CCAP study illustrates the quality of its research.

Biosafety regulations

Strict application of biosafety regulations raises productivity slightly but induces a delay in the release of a technology to farmers. Implementation of the basic mandates of the Cartagena Protocol induces moderate impacts for China agriculture, simply because the country already has a functional biosafety system. The system indeed needs support in terms of redesign and improvements in efficiency and efficacy, but these are minor compared to the needs of other countries in Southeast Asia. In fact, one of the potential recommendations that will arise from this study evaluation is that future investments by IDRC may consider projects that use China's experience in supporting capacity building and strengthening efforts for selected countries in the continent and elsewhere.

Cotton productivity and insect damage abatement/control

Results from this study show that the impact of Bt cotton on secondary pest's damage is small. This is reflected in the lack of insecticide use increase for controlling secondary pests. Results show a robust decline in pest applications over time. However, farmers' pesticide applications

[4] In the consumer assessments, there needs to be much more developments in terms of methods and approaches (Smale et al. 2008).

are influenced by information and knowledge about the technology and risk preferences. Two thirds of the variation in the expression of the Bt protein in the field can be explained by farm practices, although there are large variations spatially.

Consumer and Other Institutional Issues

Improvements in the IPR environment in China and in the seed sector can increase the level of benefits from cotton technologies. In average, seed subsidies are ineffective in raising productivity, although this varies spatially. Seed markets in China are quite complex, so much that farmers have a difficult time distinguishing superior varieties. As a consequence farmers in some instances prefer to save seed which they can expect have a good performance.

iii. Result: Impact(s) on decision-makers, public or private sector, or in related activities

My assessment of the outstanding quality of CCAP outputs is robust. Where the IDRC project really shines, however, is in the built relationship between research, and the policy and decision making processes, achieved by CCAP during the IDRC project and beyond. As described previously the CCAP project has examined quite comprehensively important cotton productivity issues and biosafety regulatory issues and questions. Due to the complex nature of the biosafety process, especially as it relates to stakeholder interests and questions, more remains to be done.

Impacts on decision makers

Based on conversations with Dr. Dafang Huang (Senior Scientist, Former Director Biotechnology Research Institute, Beijing) the outputs produced by CCAP and with the CCAP team during the lifetime of the IDRC project, were instrumental in the decision by the Chinese government to continue supporting biotechnology and biosafety in China. Outputs from the IDRC funded project produced by CCAP were also instrumental in the decision by the Chinese Government in investing in biosafety and biotechnology innovation and deployment efforts to farmers. In fact, the Chinese government provided a grant of approximately US$ 13 million to CCAP within the Chinese Academy of Sciences to fund biosafety research and other regulatory issues. Furthermore, the project contributed to improving China’s cotton subsidy program by proposing and government adopting, more transparent government seed procurement processes and bidding mechanisms.

Impacts on farmers and other stakeholders

My analysis of CCAP's impact on farmers and other stakeholders show that the project has had significant impact in China by providing knowledge and information to relevant stakeholders especially decision and policy makers. The case where IDRC provided evidence for reforming the seed sector and the agricultural extension system made a robust case for further discussion in the policy making circles. As China needs to meet its obligations under the CPB, CCAPs work in biosafety and its likely impact makes the case for biosafety support in China, mainly to refine and improve its existing systems in order to improve efficiency and efficacy, but also to lay the groundwork for second and third generation GM crops which will bring more and more sophisticated regulatory issues and problems for their risk assessment.

iv. Dissemination

The original project proposal contemplated a distinct policy outreach strategy for the project. The policy outreach strategy followed the track used by CCAP over the last decade that has proven to be quite successful with decision makers in China, although there are opportunities for improvement, especially once research projects are directed towards ensuring impact on the main target groups including producers, consumers and other relevant stakeholders.

The main targets of the communication and dissemination strategy in the CCAP/IDRC project were policy makers and the scientific community in China and abroad. The primary purpose was to identify and analyze ongoing biosafety regulatory issues that may be slowing biotechnology product deployment in China. In order to be effective, CCAP identified the need to publish in international high quality peer reviewed journals that brings credibility to its work, which in turn supports dissemination of its research findings to appropriate decision makers. Research outputs were presented to decision makers through well thought seminars and other events, as well as targeted publications including policy briefs. CCAP are regularly consulted by high-level policy makers in China. Therefore, CCAP research conducted during the IDRC project also had the objective of influencing policy.

Project output dissemination, in my opinion, has been to date excellent and indeed has reached their intended targets. CCAP has planned additional outputs to be completed after the project concluded; these have been trickling over time. Of especial merit, has the emphasis that CCAP has put on developing human resources for regulatory impact assessment and other areas of biotechnology evaluation. This will prove to yield long-run impact for policy development and implementation in China.

In the future dissemination and communication can be improved by increasing the sophistication of the policy outreach approach within CCAP projects and within other IDRC research programs. Here, I define policy outreach as the deliberate communication of sound and solid research results to policy makers in order to offer them policy instruments and policy analysis alternatives for their consideration and potential use. In fact, I propose including an explicit communication and policy outreach component that drives output dissemination via appropriate media.

Any policy outreach strategy, however, has to address critical needs for research results to enter the policy domain. To resolve this need and for policy outreach to be successful, any research project needs to identify the appropriate decision makers and the most opportune time to approach them. Timing and appropriateness of the information conveyed thus become critical to maximize research project effectiveness in the field. Furthermore, communication of policy messages needs to be targeted carefully to the different and relevant stakeholders and needs to be a long-run process that should continue beyond the lifetime of a research project, so that its research findings become incorporated into the decision making process as much as possible. The implication of this is of course that implementing organizations and ideally the donor, must be prepared to fund the suggested policy outreach activities, beyond the life of the project using own funds or through additional grants to fund such activities.

v. Audiences

In this specific project, the main beneficiaries of the project's research results where the target groups within the decision making community including the Ministry of Agriculture, Ministry of Science and Technology, the National Biosafety Committee, and those agencies that set plans and budgets within China.

In the long run, IDRC's main concern is supporting projects with a positive impact on poverty and livelihoods. Implication from the donor's mission is that policy changes directly impacted by a project implemented by CCAP - or other policy groups- need to induce changes that will benefit farmers. Demonstrating impact from policy interventions is an important issue for most research policy organizations in agriculture. Research policy organizations therefore need to develop roadmaps or pathways for policy impact that document positive impacts on farmers.

A potential pathway for impact is that if the work done by CCAP does indeed improve the effectiveness and efficiency of biosafety systems in China, the improved system ensures the proper risk assessment and management of potential technologies. An improved system leads to an eventual release of safe and appropriate technologies that have the potential to benefit resource poor farmers. We can show that the policy research has indeed yielded impact on its ultimate users. The impact pathway then is indirect and predicated on the changes that policy options induce in the decision making arena.

vi. Conclusions and recommendations:

Overall project assessment

My overall assessment of CCAP project funded by IDRC is that this was an excellent investment on the part of IDRC. Outputs quality complies with the highest international standard. The CCAP project managed to produce not only outputs of the highest quality but also manage to disseminate its products amongst relevant policy and decision making clients. One of the consequences of this effective intervention was that the government of China invested significant resources funding biosafety management efforts.

The IDRC project achievements are multiple and of high impact. However, the project can be highly commended for managing to influence policy and decision making in China, but also in accomplishing its objective of building internal capacity by investing in human resources for biosafety regulatory impact assessment.

Potential research and policy outreach avenues

Based on my interactions with the CCAP team, consulted officials and experts, literature review and my own experience with biotechnology, biosafety, technology decision making processes, it is my opinion that there are several areas that may be worthwhile pursuing for future funding, not only in China and Southeast Asia, but in other parts of the world.

Potential avenues for research and policy outreach take advantage of countries with advanced technical skills in biosafety and biotechnology for building capacity in other countries. Furthermore, the proposed avenues respond to the need for increased sophistication of regulatory systems, as they become exposed to a more diversified portfolio of technologies. Certainly, there is an opportunity to improve the efficiency and efficacy of China's biosafety system, which is common to other countries with advanced regulatory systems.

Proposed avenues require exploiting comparative advantage in the region in order to develop or augment capacity to address policy issues relevant to national, regional and international biosafety systems and countries stemming from excellence-driven research and analysis using advanced research methodologies and skills. Policy research can help advance knowledge and contribute to sound policy making by augmenting the scope of short term technical regulatory assistance by elevating the level of analysis to a systematic, comprehensive and long run view. The proposed policy research needs to incorporate the mandate of delivering international public goods, as these outputs can benefit not only lead countries but other countries developing or implementing biosafety systems, therefore multiplying the possible impacts both across countries and overtime. Potential avenues for research and policy outreach projects include:

Using China's existing biosafety system to build capacity in the region

a) Strategically use China's accumulated expertise with biosafety assessments and decision making. Draw experience and that of other countries in Asia (Philippines, Japan, and Thailand) to transfer regulatory capacity to lower income countries such as Myanmar, Laos, and Vietnam. Even in the case where a country declares itself "GM-free" it still needs some regulatory capacity to deal with imports.
b) Note that it is not necessary to develop huge capacity that will go unused, implies rather building capacity as needed. This is especially important as donors need to avoid the temptation of building up complex capacity to regulate biosafety issues when it is not needed or where a simpler system may suffice.

Improving China's biosafety system

a) China needs to improve transparency and knowledge flows on decisions. Increase participation in biosafety decision making by other than biotechnology scientists
b) Financing biosafety assessments – Identify who should pay for biosafety assessments. This area o research needs to define the political economics and power relations that may affect or be affected by regulations.

c) Develop capacity at the provincial /local level for facilitating compliance to biosafety regulations by research institutions but also for monitoring and enforcement purposes.
d) Implementation regulations in countries with a federal type system. Needs arises for addressing the dichotomy between the center and state/provincial/local laws and regulations which may enter into a conflict. This includes compliance with biosafety regulations and decisions made at the Center with enforcement at the local level

Biosafety supporting biotechnology decision making

a) Understanding institutional and legal issues that shape biosafety implementation and biotechnology deployment including political economies of biosafety decision making, power relationships and regulatory outcomes. Issues such as biotechnology deployment, impacts and outcomes, and gender, health and overall poverty alleviation efforts are a must.
b) Understanding the pillars of biosafety functional capacity and biotechnology decision making is a must for designing capacity building and strengthening efforts that will empower countries with lesser capacity to build their own functional and enabling systems

Global policy studies on biosafety issues

a) Conduct a comprehensive analysis of gene escape events (e.g., illegal or unwanted introduction of GM crops) and identify policy options for developing countries focusing on the economic considerations of liability and redress, risk evaluation and policy instruments to manage such issues.
b) Reconnect biosafety with the broader context of technology, agriculture and economic development. The purpose is to robustly situate biosafety regulatory processes within a balanced, well thought and rational decision making processes.
c) Cross comparative studies on specific biosafety regulatory decision making issues including determining the need of insect resistant management strategies, defining appropriate environmental impact or risk assessment methodologies, incorporation and timing of socio-economic considerations and impact assessment procedures, and support in estimating the cost and benefits of regulatory efforts.

4. Annexes

Annex 1. List of Acronyms

CCAP……….The Center for Chinese Agricultural Policy
IFPRI………..International Food Policy Research Institute
MOA……….Ministry of Agriculture
CBD…………Convention on Biological Diversity
CPB……………Cartagena Protocol on Biosafety

Annex 2. List of people

The following is a list of people interviewed, contacted, or with whom I discussed (formally or informally) IDRC project, CCAP activities, or potential work in biosafety and biotechnology policy in China.

Jikun Huang, Director and Project Leader, The Center for Chinese Agricultural Policy

Dafang Huang Senior Scientist, Former Director Biotechnology Research Institute, Beijing, China

Ruifa Hu, Senior Scientist, The Center for Chinese Agricultural Policy

Melinda Smale, Senior Scientist, OXFAM America.

Guillaume Gruere, Research Fellow, International Food Policy Research Institute

Carl Pray, Professor, Rutgers University

Annex 3. Bibliography of all documents reviewed

<u>Main Evaluation Review Bibliography</u>

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Annex 4. TORs for the evaluation and/or evaluator

TERMS OF REFERENCE (ToR) FOR THE EVALUATION OF THE PROJECT BIOSAFETY MANAGEMENT OF GENETICALLY MODIFIED CROPS –CHINA (IDRC GRANT NUMBER: 103783-001)

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1. **Project Title**:

Biosafety Management of Genetically Modified Crops in China (#103783-001)

2. **Project Leader**:

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3. **Person responsible for Evaluation**:

Dr. Jose Falck-Zepeda,
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4. **Background and Purpose of the Evaluation**:

5. **Period of Evaluation**:

July 15, 2009 – October 31, 2009

6. **Methodology**:

The assessment will be largely done through the examination of final technical report, project briefs, list of outputs, and examination of final outputs available. Furthermore, the assessor will sustain several interviews with the project leader, Dr. Jikun Huang, collaborators and potential beneficiaries of the project, as well as external experts familiar with the project and its accomplishments. The evaluator will further discuss evaluation issues and potential avenues for research with a small panel of experts convened by the assessor during a visit by the assessor to

China for the meeting of the International Agricultural Economics Association in Beijing, August 16 - 22, 2009.

7. **<u>End of Project Evaluation Structure</u>**:

i. Activities and Achievements:

Research Quality: Examine and comment upon the quality of analysis of the research undertaken.

In terms of contributions to the field, how has this project contributed to (a) theory (b) conceptual models (c) methodological development in this field of study and (d) policy and practice.

ii. Results:
What impact(s) has the made on decision-makers in the public or private sector, or in related activities?

iii. Dissemination:

- Was a communications/dissemination strategy developed for the project?
- Who were the main target audience or user of the research? What plans did the researchers make to disseminate research findings? For what primary purpose? (e.g. to influence public policy? Contribution to emerging literature? etc.)
- Has dissemination been to date satisfactory and have the researchers made adequate plans for dissemination further results of the research?
- How might dissemination and communication be improved in the future?

iv. Audiences:

- Specific audiences who have benefited or may benefit from dissemination of this research.

v. Conclusions and recommendations:
What is the overall assessment of the achievements of this project?

What are the potential research avenues that may benefit from additional efforts for funding in the future in China and other countries in the region?

7. **<u>Deliverables and Due Dates</u>**:

Deliverable	Due Date
5-7 page draft report answering items ii to iv under "End of Project Structure Assessment"	August 1, 2009
10 page final report with the inclusion of item v "End of Project Structure Assessment"	October 30, 2009

Annex 5. Biography of the evaluator

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Sex:	Male

Annex 6. Citation Analysis

Table A.6.1 Citations using "Publish or Perish" software

Cites	Authors	Title	Year	Source
283	J Huang, S Rozelle, C Pray, Q Wang	Plant biotechnology in China	2002	Science
261	C Pray, D Ma, J Huang, F Qiao	Impact of Bt cotton in China	2001	World Development
256	CE Pray, J Huang, R Hu, S …	Five years of Bt cotton in China- the benefits continue	2002	The Plant …
141	J Huang, R Hu, S Rozelle, C Pray	Insect-resistant GM rice in farmers' fields: assessing productivity and health effects …	2005	Science
121	J Huang, S Rozelle	Environmental stress and grain yields in China	1995	American Journal of Agricultural Economics
114	J Huang, R Hu, C Pray, F Qiao, S Rozelle	Biotechnology as an alternative to chemical pesticides: a case study of Bt …	2003	Agricultural Economics
109	J Huang, C Pray, S Rozelle	Enhancing the crops to feed the poor	2002	Nature
103	J Huang, R Hu, S Rozelle, F Qiao, CE …	Transgenic varieties and productivity of smallholder cotton farmers in China	2002	Australian Journal of …
73	J Huang, R Hu, H van Meijl, F van Tongeren	Biotechnology boosts to crop productivity in China: trade and welfare implications	2004	Journal of Development …
48	J Huang, R Hu, Q Wang, J Keeley, JF …	Agricultural biotechnology development, policy and impact in China	2002	Economic and Political …
42	F Hossain, CE Pray, Y Lu, J Huang, C Fan, R …	Genetically modified cotton and farmers' health in China	2004	International Journal of …
41	J Huang, S Rozelle, C Pray, Q Wang	Plant biotechnology in the developing world: the case of China	2002	Science
24	J Huang, Q Wang, Y Zhang, JB Falck-Zepeta	Agricultural biotechnology development and research capacity in …	2001	Report to ISNAR and CAS, Beijing,
22	J Huang, Q Wang	Biotechnology policy and regulation in China	2003	
21	K Anderson, J Huang, E …	Impact of China's WTO accession on rural-urban income inequality	2004	China's Economic …
20	CE Pray, B Ramaswami, J Huang, R Hu, P …	Costs and enforcement of biosafety regulations in India and China	2006	International Journal of …
20	… Lin, A Somwaru, F Tuan, J Huang …	Consumer attitudes toward biotech foods in China	2006	Journal of International …
18	J Huang, R Hu, S Rozelle, F Qiao, CE …	Small holders, transgenic varieties, and production efficiency: the case of cotton …	2002	… biotechnology
16	J Huang, H Qiu, J Bai, C Pray	… , acceptance of and willingness to buy genetically modified foods in Urban …	2006	Appetite
12	J Huang, R Hu, H van Meijl, F van Tongeren	Biotechnology boosts to crop productivity in China and Its Impact on …	2002	Fifth Annual Conference on Global …
12	J Huang, Q Wang, J Keeley	Agricultural biotechnology policy processes in China	2001	unpublished paper, Beijing: Center for

10	H Jikun, S Rozelle, C Pray, W Qinfang	Plant biotechnology in China	2002	Science
10	J Huang, Q Wang, Y Zhang, J falck Zepeda	Agricultural Biotechnology Research Indicators: China	0	Science
9	J Huang, R Hu, H van Meijl, F van …	Economic impacts of genetically modified crops in China	2003	… Durban, South Africa
7	J Huang, R Hu, S Rozelle, C Pray	Genetically modified rice, yields, and pesticides: Assessing farm-level productivity …	2008	Economic Development and …
7	J Huang, R Hu, C Pray, S Rozelle	Plant biotechnology in China: public investments and impacts on farmers	2006	4 th International Crop Science …
7	S Rozelle, J Huang, K Otsuka	… of a viable agriculture: advances in biotechnology, market accessibility and land …	2005	The China Journal
7	… , M Smale, SD Rozelle, R Hu, J Huang	Wheat genetic diversity in China: measurement and cost	2003	Agricultural trade and …
6	W Lin, A Somwaru, F Tuan, J Huang, J Bai	Consumers' willingness to pay for biotech foods in China: A contingent	2007	
5	JHSRC PRAY, W QINFANG	Plant biotechnology in China	2002	Pestology
4	J Huang, R Hu, S Rozelle, C Pray	China: Emerging public sector model for GM crop development	2007	Gene Revolution: GM Crops and Unequal …
4	R Hu, J Huang, H Lin, S Rozelle, C …	Bt cotton in China: Are secondary insect infestations offsetting the benefits in farmer …	2006	… Biotechnology …
4	C Zhang, J Bai, J Huang, WK Hallman, C Pray, HL …	Consumer acceptance of genetically modified foods: a comparison …	2004	… Annual Meeting, Denver …
4	J Huang, CE Pray	Economic impacts of Bt cotton in China	2002	… on the Biosafety of Genetically Modified …
3	J Huang, K Otsuka, S Rozelle	The Role of Agriculture in China's Development: Past Failures; Present …	2008	China's Economic Transition: Origins, …
3	CE Pray, J Huang, R Hu, Q Wang, B …	Benefits and Costs of Biosafety Regulation in India and China	2006	… Biotechnology: …
3	J Huang, S Rozelle, C Pray	Development, policy and impacts of genetically modified crops in China	2005	… to Honor the 75th …
3	J Huang, S Rozelle	China aggressively pursuing horticulture and plant biotechnology	2004	California Agriculture
2	H Qiu, J Huang	… and Their Attitudes Towards Genetically Modified Food: Empirical Evidence from …	2006	2006 Annual Meeting, August 12-18, 2006, …
2	J Huang, R Hu, H Zhang, C Pray, J Falck-Zepeda	GMO Biosafety Management and Regulatory Costs: A Case Study in …	2005	
2	J Huang, R Hu, S Rozelle, C Pray	Development, policy and impacts of genetically modified crops in China: A …	2005	Paper for the Belfer Center for …
2	J Huang, R Hu, S Rozelle, C Pray	Genetically Modified Rice, Yields and Pesticides: Assessing Farm-level	2004	Beijing: Center for Chinese Agricultural Policy, …
2	J Huang, Q Wang, Y Zhang, JF Zepeda	Agricultural Biotechnology Research Indicators	0	CCAP Working Paper 01-E3, CCAP,
1	C Pray, J Huang	Biofortification for China: Political Responses to Food Fortification and GM …	2008	

1	F Qiao, J Huang, S Rozelle, J Wilen, P Dialogue	Managing pest resistance in fragmented farms: an analysis of the risk of Bt …	2006	
1	J Huang, H Lin, R Hu, S Rozelle, C Pray	Eight years of Bt cotton in farmer fields in China: Is the reduction of …	2006	
1	K Teng, J Huang	… environment and product development for agricultural biotechnology	2004	
1	J Huang, S Rozelle, H Ni, N Li	Impacts of Agricultural Trade and Related Reforms on Domestic Food	2003	A Report Submitted to FAO, …
1	F Cunhui, H Jikun, H Ruifa, Z Caiping	The Impacts of Bt Cotton on Pesticide Use in China	2002	China Rural Survey
0	F Qiao, J Wilen, J Huang, S …	Dynamically optimal strategies for managing the joint resistance of pests to Bt toxin …	2009	European Review of …
0	J Huang	Biosafety management of generically modifed crops (China): final …	2009	
0	J Yang, J Huang, S Rozelle, W Martin	Implications of Adopting Special Products and Sensitive Products in Doha …	2009	
0	R Hu, C Pray, J Huang, S Rozelle, C Fan, C Zhang	Reforming intellectual property rights and the Bt cotton seed industry in China: Who …	2009	Research Policy
0	J Huang, R Hu, J Cao, S Rozelle, A …	Training programs and in-the-field guidance to reduce China's overuse of fertilizer …	2008	jOurnal Of SOil and water …
0	J Huang, D Zhang, J Yang, S Rozelle, N …	Will the Biosafety Protocol hinder or protect the developing world: Learning from …	2007	Food Policy
0	W Lin, A Somwaru, F Tuan, J Huang, J …	Are Urban Consumers in China Ready to Accept Biotech Foods?	2006	2006 Annual Meeting, …
0	… Somwaru, F Tuan, J Huang, J Bai, C …	Consumers' Willingness to Pay for Biotech Foods in China	2005	… Annual meeting, July …
0	B Lohmar, J Wang, S Rozelle, J Huang, D Dawe	Investment, Conflicts and Incentives: The Role of Institutions and Policiesin …	0	faculty.washington.edu
0	J Huang	… CHINA'S PUSH TO MODERNIZATION: ADVANCES IN BIOTECHNOLOGY, …	0	agecon.purdue.edu
0	J Huang, H Qiu, J Bai, C Pray	Awareness and Acceptance of Genetically Modified Foods in Urban China	0	fed.ccer.edu.cn
0	J Huang, R Hu, S Rozelle, C Pray	Genetically Modified Rice, Yields and Pesticides: Assessing Farm-level	0	iis-db.stanford.edu
0	LIN William, A SOMWARU, T Francis, J HUANG, BAI …	Are Urban Consumers in China Ready to Accept Biotech Foods?	0	absfafrica.org
0	R Hu, C Pray, J Huang, S Rozelle, C Fan, C Zhang	Reforming Intellectual Property Rights, Bio-safety Management and the Bt …	0	iis-db.stanford.edu

Table A.6.2 Citation Analysis using "Publish or Perish"

Papers	63		h-index:	18
Cites/paper:	29.67		g-index:	43
Cites/author:	499.73		hc-index:	14
Papers/author:	18.52		hI-index:	
Authors/paper:	3.97		hI,norm:	10
Citations	1,869		AWCR:	222.9
Hirsch	a=5.77 m=1.13		AW-index:	14.9
Contemporary	ac=4.55		AWCRpA:	57.8
Cites/paper	29.67/4.0/0 (mean/median/mode)		e-index:	37.3
Authors/paper	3.97/4.0/4 (mean/median/mode)		hm-index:	7
2 paper(s) with 1 author(s)				
8 paper(s) with 2 author(s)				
6 paper(s) with 3 author(s)				
25 paper(s) with 4 author(s)				
18 paper(s) with 5 author(s)				
4 paper(s) with 6 author(s)				

Annex 7. Relevant Biosafety Regulations in the P.R. China

Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (1996)

The regulation is aimed at promoting research and development in the area of agricultural genetic engineering in China, strengthening safety administration, preventing possible hazards caused by GMOs and their products to human health and environment on which human beings rely for existence and agricultural ecological equilibrium.

The genetic engineering items covered in the Implementation Regulation include rDNA technology using vector systems, and introduction of rDNA into an organism by using physical, chemical and biological means. The "Implementation Regulation" is applicable to agricultural organisms whose genome constitution has been changed by using genetic engineering technologies. The agricultural organism includes plants and animals related to agricultural production, plant-related microorganisms, veterinary microorganisms, aquatic animals and plants.

The organisms that are not included are:

(a) Plants obtained by spontaneous generation, and by using artificial selection and hybridization technologies; from mutagenesis via chemical or physical means; and by using organ culture, tissue culture and cell culture as well as protoplast fusion technology and chromosome ploidy manipulation;

(b) Animals obtained via spontaneous generation and by using artificial selection, artificial insemination (excluding rDNA), superovulation, embryo chimera, embryo partition, and nucleus transfer or ploidy manipulation technology;

(c) GM microorganisms (excluding virus and subvirus) obtained by using chemical and physical mutagenesis; transfer of non-recombinant DNA via transduction, transformation or conjugation processes.

Regulation on the Administration of Agricultural Transgenic Biosafety (2001)

The regulation covers the activities of research, testing, production, processing, marketing, import or export of agricultural GMOs within the territories of the People's Republic of China. These have been formulated for the purpose of strengthening safety administration of GMOs, safeguarding human health and safety of animals, plants and microorganisms, protecting the environment, and promoting research on agricultural GMOs.

Procedure for the Administration of Assessing Agricultural Transgenic Biosafety (2002)

Procedure for the Administration of the Safe Import of Agricultural Genetically Modified Organisms (2002)

Procedure for the Examination and Certification of the Labels of Genetically Modified Organisms (2002)

The procedures focus on the report management and approval, the administration procedures applied to the GMOs imported for different purposes and on application, reviewing, cancellation and other procedures of agricultural GMOs labeling.

Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations cover the activities of research, testing, production, processing, marketing, import or export with respect to agricultural GMOs within the territories of the People's Republic of China that are required for safety evaluation. These Implementation Regulations are formulated in accordance with the "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purposes of strengthening the safety assessment administration of agricultural GMOs, safeguarding human health and safety of animals, plants and microorganisms, and protecting the environment.

Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations are formulated in accordance with the "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purpose of strengthening the labeling administration of agricultural GMOs, standardizing the marketing activities of agricultural GMOs, guiding the production and consumption of agricultural GMOs, and protecting consumers' right of full access to the information about the products.

The marketing of any agricultural GMOs listed in the labeling catalogue needs to comply with these implementation regulations. All agricultural GMOs listed in this catalogue and intended for marketing need to be labeled. As per the regulation, any agricultural GMO without a label or whose label is not in conformity with the requirements of these implementation regulations would be banned for import or marketing.

Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations are formulated in accordance with "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purposes of strengthening the safety administration on imported agricultural GMOs, and applies to the safety administration of any activity of importing agricultural GMOs and their products into the territories of the People's Republic of China. It covers the import of the agricultural GMOs for research and testing; commercial production and as raw material for processing.

Regulation on Inspection and Quarantine of Import and Export of Genetically Modified Commodities (2004)

This Regulation is applicable for the inspection and quarantine of GM commodities imported and exported in all ways including, but not limited to, trading, raw material processing, mail, carrying, production, entrusted reproduction, research, exchange, exhibition, aid and grant. It has been formulated to strengthen the inspection and quarantine of import and export of GM commodities, safeguarding the human health, ensuring the safety of animals, plants and microorganism and protecting the ecological environment, based on the Law of The People's Republic of China on Import and Export Commodity Inspection, the Law of The People's Republic of China on Food Hygiene, the Law of The People's Republic of China on Quarantine of Import and Export Animal and Plants and respective administrative rules as well as the Regulation on the Safety Management of Agricultural GMOs.

Measures on Approval of Agricultural Genetically Modified Organisms Processing (2006)

The Measures have been formulated in accordance with "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purpose of strengthening the safety administration on approval of agricultural GMOs processing. It stipulates the qualifications of those who process agricultural GMOs, the procedures of applying the processing permit, the permit administration, etc.

Decree 10 (CH7053) Labeling Regulation (2007)

Decree 10 states that the reason for the regulation is “to strengthen the administration of GMO labeling, standardize the selling activities of agricultural GMOs, guide the production and consumption of GMOs and protect consumers’ right to be informed.” The regulation spells out the type of labeling required as well as the specific language that is required on the individual labels.

Source

Gupta, Karihaloo, and Khetarpal (2008) based on information by Yu Wenxuan, China University of Political Science and Law, China, email: wenxuan_yu@sohu.com, ywenxuan@clapv.org (Personal communication) and USDA Foreign Agricultural Service, GAIN Report CH7055: China, Peoples Republic of BiotechnologyAnnual 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291718.doc; accessed on 16 October 2007).