

The Japanese experience with the Blue Book and subsequent activities in environmental biosafety of GM crops

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The Blue Book made a big contribution to the development of the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) guidelines established in 1991 for almost all of the basic issues. However, the MAFF guidelines could not sufficiently cover some important areas that the Blue Book addressed well, such as potential consequences. This gap has been recovered substantially by a new law established in 2003. Japan still faces several important issues, including assessment of stacked products, potential consequences, comparative assessment, assessment of imported GM commodities and movement of concerned groups.

HISTORICAL DEVELOPMENT OF THE REGULATORY FRAMEWORK IN JAPAN

In accordance with the development of research on biotechnology, the first guidelines on recombinant DNA experiments were established for universities by the Ministry of Education, and for non-university institutions by the Science and Technology Agency, both in 1979. In 1983, Japan started to participate continuously in the meetings of the Group of National Expert (GNE) of the OECD, which achieved publication of the Blue Book in 1986. Thereafter, similar to many other OECD countries, a series of guidelines and a related regulatory framework were established in Japan. These include guidelines on industrial use of rDNA technology by the Ministry of Industry and Commerce in 1986. That for application in agriculture, forestry and fisheries by MAFF was established in 1989, and has been in effect with some interim revisions until 2003. That for feed was set up in 1992. All of these Japanese guidelines on environmental biosafety were terminated with the adoption of the Cartagena Protocol in 2003. Thereafter, a completely new law “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms” has been enforced. Also, agricultural-related Committees on Impact Assessment have been functioning as authorized by both the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Environment (MOE).

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IMPACT OF THE BLUE BOOK ON PROGRESS IN ASSESSMENT ACTIVITIES OF JAPAN

The Blue Book clearly stated in its “Recommendation Specific for Environmental and Agricultural Applications” that it is important to evaluate rDNA organisms for potential risk on a case-by-case basis in a stepwise fashion. Related further research was also encouraged. These conceptual principles were fully reflected in the MAFF guidelines set up originally in 1991.

Further, the MAFF guidelines made a good follow-up to the Blue Book in “Information required for a safety evaluation” that include host species, donor DNA, vector and rDNA plants, *etc.* However, it was noted that the MAFF guidelines did not sufficiently address those issues which were well-addressed in Appendix D of the Blue Book, particularly “Item D. Interactions of Engineered Organism(s) with Biological Systems” which includes “Target and non-target populations”, and “Item E. Potential Environmental Impacts”, which involves “Potential effects on target and non-target organisms”. Probably, these will be the major distinguishable differences between the Blue Book and MAFF Guidelines.

In short, the Blue Book made quite a big contribution to the development of the Japanese MAFF guidelines for almost all of the basic issues, both in conceptual principles and in scientific information. However, the MAFF guidelines could not sufficiently cover some important areas of potential consequences, such as interactions with target and non-target organisms that were well addressed in the Blue Book.

This gap has been recovered substantially in the context of conservation and sustainable use of biological diversity by the new law established in 2004.

SEQUENCE OF APPROVED PRODUCTS IN JAPAN

Under the old MAFF guidelines, a total of 114 events of 16 crops were approved for cultivation in Japan. Of these, 26 events were of Japanese origin including the following: low allergen rice, low protein rice, virus resistant rice, tomato and melon, disease resistant cucumber, insect resistant azuki bean, blue carnation, *etc.*

With the onset of the new law, most of the events previously approved by the old guidelines have either been approved or are in a process of re-assessment for final approval by the new law. Data and experiences accumulated in the old system have been utilized very efficiently through these procedures. The total number of approvals including new and re-applications is 75, involving 25 of Japanese origin as of July 2006. The majority of these approvals have been developed by foreign developers.

CURRENT TECHNICAL AND SCIENTIFIC ISSUES

1. Safety assessment of stacked GM plants:
 - need for further data or analysis will be on a case-by-case basis;
 - basically, additional new field tests for stacked plants may not be required unless potential interaction between the stacked traits is likely.
2. Safety assessment of potential consequences:
 - recognizing a shift of emphases more on potential consequences which involve extensive subjects;
 - need for a practical approach in selection of measurable targets and attainable goals.
3. Comparative assessment:
 - it is essential at every stage of assessment to estimate the magnitude of comparable risk;
 - need for developing methods for comparative assessment when relevant controls are lacking, such as for abiotic stress tolerant GM crops.
4. Assessment of imported GM commodities:
 - heavy dependency on huge imports of approved GM products for direct use in food, feed or processing (FFP);
 - need for possible simplification of data requirements as compared to assessment of GM seeds for cultivation.
5. Movement of concerned groups:
 - currently biggest problem in Japan, which prevents commercialization and even experimental field test of GM crops;
 - need for information of good monitoring results, such as the five years of results of no negative impact of *Bt* maize in Spain and other safe results of cultivation of GM crops acknowledged worldwide.