OECD Documents on Biosafety Aspects:

Experiences and Lessons

KEN-ICHI HAYASHI, Ph.D.

Advisory Council Member,
Center for Environmental Risk Assessment (CERA)

ILSI Research Foundation

< Summary >

In accordance with development of genetically modified organisms (GMOs), Importance of science-based considerations on biosafety aspects has also been increasing in a wide range of areas. Dr. Hayashi has been engaging in various domestic and international works on biosafety of GMOs, particularly GM plants. One area of his activities concludes continuous works as a Japanese government expert to OECD which includes two frameworks, Group of National Experts in early 1990's and Working Group (WG) on Harmonization of Regulatory Oversight in Biotechnology after 1995. One of the major outcomes from these OECD's framework is the publication of a large number of scientific official documents on biosafety.

In a short article of "ILSI" published from ILSI Japan, Dr. Hayashi described about some of his works on selected subjects of the OECD documents in which he has been involved for their initiation, development and completion.

The descriptions are consisted of three parts. The first part traced back to early 1990's and "Scale-Up" document has been detailed with introduction of the concept of "familiarity" which is by now well-accepted globally. The second part presents selected cases of "Consensus Documents" both on introduced traits and biology of host species. The subjects include: herbicide tolerance, insect resistance, Points to Consider, rice, Brassica spp. and Eucalyptus spp. The third part includes WG's recent activities on facilitating harmonization for emerging issues. Brief descriptions are made for on-going two Projects, "Low Level Presence (LLP)" and "Environmental Considerations".

Through the articles Dr. Hayashi is wishing to convey to the readers the real stories on the basis of his experiences and lessons, with a hope to contribute for promoting better understanding of biosafety aspects for the benefit of all the parties concerned.